

No. 82264-6

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

JULIE ANDERSON, individually and on behalf of the Estate of
DALTON ANDERSON, and DARWIN ANDERSON individually,

Appellants

v.

AKZO NOBEL COATINGS, INC., and KEITH CROCKETT,

Respondents

**RESPONDENTS' COMBINED ANSWER TO BRIEFS FILED BY
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JUSTICE FOUNDATION AND NATIONAL FIBROMYALGIA
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INTRODUCTION

Respondents and Defendants below Akzo Nobel Coatings, Inc. (“Akzo Nobel”) and Keith Crockett (collectively, “Respondents”) respectfully submit this brief in response to the briefs filed by amici curiae Washington State Association for Justice Foundation (“WSAJF”) and National Fibromyalgia Association (“NFA”). WSAJF and NFA address various issues under the *Frye* doctrine, and argue for substantial changes to the doctrine. Both would have the Court change *Frye* in ways that would effectively render it inapplicable to expert medical causation testimony. The Court should decline to do so. It is the trial court’s duty, under *Frye*, to ensure that expert testimony on medical causation, no less than other types of scientific evidence, is reliable before such evidence is presented to the jury. If trial courts are stripped of this gatekeeping role, novel medical causation testimony will become admissible based merely on the *ipse dixit* of the expert. The result would almost certainly be injustice, as juries are poorly served by being asked to evaluate the reliability of novel scientific evidence, and expert witnesses are granted wide latitude to offer opinions, including opinions on the ultimate issue to be decided by the jury.

The briefs filed by WSAJF and NAF also each show only a passing familiarity with, or interest in, the facts of this case. Both

misconstrue the Superior Court's ruling below in order to fit the particular axes they wish to grind. NAF's central argument is that the Superior Court erred by testing Appellants' medical expert's "conclusion" under *Frye*, rather than his "methodology." In fact, the court's ruling required that the theory or principle underlying the expert's opinion, not his conclusion, pass muster fully, in keeping with the *Frye* standard as enunciated by this Court on multiple occasions. WSAJF asserts that the Superior Court would only be satisfied with proof of "statistical studies" to show general acceptance of the expert's underlying theory of causation. Again, this is incorrect. The Superior Court did not insist that statistical studies were required to prove causation; rather, the court considered all of the evidence put forward by Appellants, and found it insufficient to meet their burden of proof under *Frye*.

Respondents' also address herein WSAJF's brief argument concerning Appellants' wrongful discharge claim. Regardless of this Court's resolution of the central issue in *Cudney v. ALSCO, Inc.*, S.C. No. 83124-6, the Court should not reverse on this assignment of error. Appellant Julie Anderson failed to make out a prima facie case of wrongful discharge in this case because she chose not to take advantage of the statutory scheme provided by RCW 49.17.160.

ARGUMENT

A. **WSAJF and NFA Identify *Frye* Issues that Have No Bearing on This Case.**

The arguments set forth by amici curiae WSAJF and NFA address discreet issues under *Frye*. Both friends of the court, however, identify the wrong issues, and thus misapply the doctrine to the facts of this case. NFA identifies the relevant issue as whether the *Frye* test requires proof that an expert's "conclusions" are generally accepted in the relevant scientific community, or whether only the "methodology" employed by an expert must be generally accepted. NFA Br., pp. 3-13. WSAJF argues that asserting a distinction between conclusions and methodologies assumes the wrong question, and that the issue in this case is actually whether expert medical causation testimony must be founded on supporting statistical studies. WSAJF Br., pp. 7-18. Both are wrong. The issue before the Court is whether a scientific expert may rely upon an unproven *general* theory of causation that lacks acceptance in the relevant scientific community, to reach an opinion as to *specific* causation in a particular case. That is the issue that was addressed, and properly resolved, by the Superior Court below.

1. **NFA Asserts an Illusory Distinction Between “Methodology” and “Conclusions”.**

This Court has held on multiple occasions that the theory or principle underlying an expert’s opinion, and not only the methodology or technique used by the expert, must be generally accepted in the relevant scientific community under *Frye*. E.g., *State v. Gregory*, 158 Wn.2d 759, 829, 147 P.3d 1201 (2006); *State v. Copeland*, 130 Wn.2d 244, 255, 922 P.2d 1304 (1996); *State v. Gentry*, 125 Wn.2d 570, 585, 888 P.2d 1105 (1995); *State v. Riker*, 123 Wn.2d 351, 359, 869 P.2d 43 (1994); *State v. Cauthron*, 120 Wn.2d 879, 889, 846 P.2d 502 (1993), *overruled in part by State v. Buckner*, 133 Wn.2d 63, 941 P.2d 667 (1997). See also discussion in Resp. Br., pp. 20-26. The fallacy in NFA’s reasoning is that it mistakes “theory” for “conclusion.” NFA’s quotes the *Frye* decision itself as follows:

[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

NFA Br., p. 6, (quoting *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923) (emphasis added)). NFA correctly interprets this statement to mean that “[t]he theory underlying the test, not the conclusion, required general acceptance,” *id.*, but then goes on to claim that “[a] causation

opinion is a conclusion arising from applying a methodology to facts to deduce the conclusion.” *Id.*, p. 8.

That assertion completely bypasses the distinction between general and specific causation, a distinction that is essential to understanding how *Frye* works, and is intended to work, in a case such as this. In order to prove their case, Appellants must show that the diagnosed brain malformations of Dalton Anderson were caused by prenatal exposure to the organic solvents manufactured by Respondent Akzo Nobel, i.e., they must carry their burden to show *specific* causation. Appellants’ expert Sohail Khattak, M.D. was retained to offer precisely that opinion. In order to reach that opinion, however, Dr. Khattak must presuppose that such causation is possible as a general matter. In other words, his opinion necessarily relies upon a theory of *general* causation that prenatal exposure to the organic solvents in question is capable of causing developmental malformations of the type suffered by Dalton in the first place. That general theory of causation is the theory or principle upon which his opinion concerning specific causation is based. In the words of *Frye*, it is “the thing from which the deduction is made.” 293 F. at 1014.¹

¹ The Ninth Circuit has explained the distinction between general, or “generic”, and specific, or “individual” causation in the toxic tort context as follows:

Respondents' *Frye* challenge was never directed towards Dr. Khattak's opinion concerning specific causation; rather, it was directed towards the theory underlying that opinion.² As this Court has held many times, the theory underlying an opinion must have general acceptance in the relevant scientific discipline, and it is the plaintiff's burden to show such general acceptance. The Superior Court below properly required Appellants to make such a showing, and properly found that they failed to do so. NFA's

Causation in toxic tort cases is typically discussed in terms of generic and specific causation. General, or "generic" causation has been defined by courts to mean whether the substance at issue had the capacity to cause the harm alleged, while "individual causation" refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance [W]e believe the appropriate understanding of generic causation is the one plaintiffs assert: whether exposure to a substance for which a defendant is responsible, such as radiation at the level of exposure alleged by plaintiffs, is capable of causing a particular injury or condition in the general population. *In order to prevail on their claims, however, plaintiffs must establish both generic and individual causation.* This means that they must establish not only that the toxic substances released from Hanford are capable of causing the conditions complained of, but in addition, that Hanford emissions were the cause-in-fact of their specific conditions.

In re Hanford Nuclear Reservation Litigation, 292 F.3d 1124, 1133-34 (9th Cir. 2002) (internal citations omitted) (emphasis added).

² Respondents, of course, strongly maintain that Dr. Khattak's opinion concerning specific causation is wrong as a factual matter, and that Dalton's malformations are, in fact, attributable to genetic causation. See Superior Court's discussion of testimony offered by Respondents' expert William Dobyns, M.D. CP 788-89.

distinction between “methodology” and “conclusions” thus has no application to this case.³

2. **WSAJF Mischaracterizes Respondents’ Argument and the Superior Court’s Ruling Below as Requiring “Statistical Studies” to Prove Medical Causation.**

WSAJF also misconstrues the basis of Respondents’ challenge below and the Superior Court’s application of *Frye* to this case. WSAJF characterizes Respondents’ argument as “advocating that Dr. Khattak’s opinion, otherwise based on a reasonable degree of medical certainty, nonetheless lacks general acceptance because it is not supported by precise epidemiological studies showing statistically that organic solvents are capable of causing the particular birth defects suffered by Dalton Anderson.” WSAJF Br., pp. 8-9. This summary is erroneous and ignores the arguments actually made by Respondents.

As an initial matter, Respondents, both below and on appeal, have strenuously asserted that Dr. Khattak’s opinion is not “otherwise based on a reasonable degree of medical certainty.” In fact, there are very good

³ Nor does it have any application to the holdings in *Grant v. Boccia*, 133 Wn. App. 176, 137 P.3d 20 (2006) and *Ruff v. Dept. of Labor and Indus.*, 107 Wn. App. 289, 28 P.3d 1 (2001), both of which NAF requests be overruled. NAF Br., p. 3. Those decisions, like the Superior Court’s ruling in this case, properly required the plaintiffs to show that the *theory* underlying medical causation testimony was generally accepted, not that an expert’s *conclusions* were generally accepted. See Resp. Br., pp. 24-26.

reasons to exclude Dr. Khattak's opinion under *Frye* quite apart from his reliance on a theory of general causation that lacks general acceptance.

See Resp. Br., pp. 41-44.

More pertinent to the present question, however, WSAJF's argument concerning *Frye* and the presence or absence of statistical evidence is, like NFA's methods vs. conclusions argument, irrelevant to this case. WSAJF relies heavily on this Court's opinion in *Reese v. Stroh*, 128 Wn.2d 300, 907 P.2d 292 (1995), for the proposition that statistical studies are not required for admission of expert testimony under *Frye*. WSAJF Br., pp. 12-15. However, *Frye* was not applied in *Reese* because the defendant "did not argue that the theory or methodology involved . . . lacks acceptance in the scientific community." 128 Wn.2d at 307. Accordingly, the Court held that "[a]n expert opinion regarding application of an *accepted theory* or methodology to a particular medical condition does not implicate *Frye*." *Id.* (emphasis added). In other words, it was not disputed in *Reese* that the scientific basis for the medical expert's opinion had gained general acceptance in the relevant scientific community. The issue, therefore, was whether statistical support was required for the expert's opinion under ER 702 or ER 703, a question this Court answered in the negative. *Id.* at 309-10.

WSAJF's argument tries to stuff this case into the same box as *Reese* by asserting that the Superior Court's *Frye* ruling "was based on the lack of supporting studies." WSAJF Br., p. 14. This assertion misreads the Superior Court's decision, and ignores the crucial distinction that *Reese* did not present a *Frye* issue because general acceptance of the underlying theory was not disputed. WSAJF would have this Court believe that the Superior Court below found that the general causation theory underlying Dr. Khattak's opinion was generally accepted, yet excluded his opinion anyway because of a lack of statistical support. In fact, the Superior Court held that there was no evidence to support Dr. Khattak's general theory of causation, with the exception of one study, which the court found "alone does not demonstrate any general consensus in the scientific community that prenatal exposure to organic solvents specifically caused PMG or any other type of neuronal migration defect. Indeed, no medical expert in this case has opined that one study that contained one finding of a particular type of birth defect would be generally relied upon by scientists to establish a cause-and-effect relationship." CP 786-87.

In short, the Superior Court did not exclude Appellants' medical causation testimony because of a lack of statistical studies. Rather, Dr. Khattak's opinion was excluded because Appellants failed to carry their

burden to show general acceptance of the underlying theory, whether by statistical studies, or any other type of evidence. *Reese* did not address this issue, and, in fact, both *Grant*, 133 Wn. App. at 181, and *Ruff*, 107 Wn. App. at 301, distinguished *Reese* on precisely this point.

WSAJF also erroneously asserts that *Frye* should not apply at all in this case because “[t]he absence of supporting studies did not render the medical causation testimony in *Reese* novel or otherwise subject to *Frye*, let alone admissible.” WSAJF Br., p. 13. Again, this argument overlooks the fact that general acceptance of the underlying scientific principle was not disputed in *Reese*, which obviously would make a *Frye* inquiry inappropriate in that case.

Moreover, WSAJF’s argument concerning the applicability of *Frye* rests upon the same misreading of the Superior Court’s ruling described above, i.e., the claim that the court insisted on statistical studies to support the theory of general causation underlying Dr. Khattak’s opinion. *See* WSAJF, pp. 14-15 (“The superior court’s decision to exclude Dr. Khattak’s testimony was based on the lack of supporting studies. The superior court does not appear to have found any other fault with his testimony.”). This is simply untrue. In fact, the Superior Court carefully considered every bit of evidence Appellants’ put forward, finding that, other than the one study referenced above, none of the articles in the

medical literature cited by Appellants “showed even an association – let alone a causal relationship – between [prenatal exposure to organic solvents] and neuronal migration defects, PMG, or multicystic kidney disease.” CP 785 n 3. *See* discussion in Resp. Br., pp. 29-30. The court also noted that Dr. Khattak conceded that his theory “has not been fully tested” and stated that “we don’t have enough research,” finding these statements to be “an implicit acknowledgement” that his theory did not pass muster under *Frye*. CP 787. In short, the Superior Court did not insist on statistical studies. Rather, it looked at the totality of Appellants’ evidence, and, finding that it consisted of only one study that, standing alone, was insufficient to demonstrate general acceptance, ruled that Appellants had not carried their burden of proof under *Frye*. WSAJF’s mistaken argument concerning statistical studies should not lead to a reversal of that decision.

B. NAF’s Four Suggested “Approaches” Would Eviscerate the *Frye* Standard in Cases Requiring Expert Testimony on Medical Causation.

NAF asks the Court to adopt any or all “four fair approaches” to admissibility of expert medical causation testimony under *Frye*. NAF Br., p. 4. NAF’s suggestions are united in that each one would eviscerate *Frye* in this area, an outcome NAF obviously has a vested interest in seeing come to pass.

1. **NAF Asks the Court to Exempt Medical Causation Testimony from *Frye*.**

First, NAF suggests a rule that medical causation testimony simply be exempted from analysis under *Frye*, pointing to the Superior Court's discussion of decisions in jurisdictions outside Washington. NAF Br., pp., 13-14. However, the approaches adopted in those states do not exempt medical causation testimony from *Frye*; rather they exempt consideration of the theory underlying such testimony, requiring only that the techniques or methodology used to arrive at an opinion are generally accepted. See *People v. McDonald*, 37 Cal.3d 351, 372-73, 690 P.2d 709, 208 Cal. Rptr. 236 (1984) (*Frye* invoked primarily for evidence "produced by a machine").⁴ NAF cites to no authority in any *Frye* jurisdiction holding that medical causation testimony is not subject to *Frye*, nor is there any reason why such evidence should be exempted. Indeed, were this Court to adopt such a rule, medical causation experts would be permitted to base their opinions on literally any theory of causation they can imagine (not to

⁴ The California court's comment in *McDonald* that "[w]e have never applied the *Frye-Kelly* rule to expert medical testimony," 37 Cal.3d at 373, may be understood in the historical context within which the decision was made, i.e., in 1984, before the widespread application of *Frye* (and *Daubert*) in toxic tort cases, or in civil litigation generally. Indeed, *McDonald* was one of the principal cases discussed by the Court of Appeals in *Reese v. Stroh*, 74 Wn. App. 550, 557-58, 874 P.2d 200 (1994), in holding that *Frye* should not be applied in civil cases, a holding that was not upheld by this Court on review of that decision.

mention on completely untested scientific methodologies), without regard to consensus medical opinion. No jurisdiction has gone this far, nor should Washington become the first.

Moreover, nor should this Court narrow application of *Frye* solely to techniques or methodologies, and not also apply it to the underlying theory upon which an expert bases her or his opinion. Washington is hardly in the minority in requiring general acceptance under *Frye* of both the principle or theory underlying novel scientific expert testimony and the methodology or technique applied. To the contrary, it appears that the majority of *Frye* courts are in accordance. See *Ratner v. McNeil-PPC, Inc.*, 27 Misc.3d 322, 323, 898 N.Y.S.2d 772 (N.Y. Sup. 2010) (“It is well settled [under *Frye*] that expert testimony which involves novel scientific theories or techniques will be admissible at trial only upon a showing that such theories and such techniques are generally accepted within the scientific community.”); *McWilliams v. Dettore*, 387 Ill.App.3d 833, 851, 901 N.E.2d 1023, 327 Ill. Dec. 290 (2009) (“The circuit court ruled that Dr. Gomez’s causation theory – that [the plaintiff]’s ovarian cancer ‘could be’ the result of her treatment for stage IV lymphoma – was not generally accepted under *Frye* [.] On appeal, the plaintiffs do not contend this ruling was erroneous, which comes as no surprise given that Dr. Gomez cited no scientific support for his position.”); *Blackwell v. Wyeth*, 408 Md.

575, 608, 971 A.2d 235 (2009) (Holding with respect to expert testimony on medical causation that the expert's "conclusion is ethereal because the bases of the expert's opinion, including the theory of causation, and the methodologies are *not* generally accepted as reliable within the expert's particular scientific field.") (citation omitted) (emphasis in original); *State v. Johnson*, 186 Ariz. 329, 331, 922 P.2d 294 (Ariz. 1996) ("Under *Frye*, scientific evidence based on a newly postulated theory is admissible when that theory has been generally accepted in the relevant scientific community."); *State v. Vandebogart*, 136 N.H. 365, 375, 616 A.2d 483 (N.H. 1992) ("Generally, courts applying the *Frye* standard to determine the admissibility of DNA evidence have employed a two-prong test that requires both the theory and the techniques implementing the theory to be generally accepted in the relevant scientific community.") (and cases cited therein). It is also significant that the *Daubert* test continues to require examination of the theory or principle underlying scientific expert opinion. *See Reese*, 128 Wn.2d at 315 ("The determination of 'scientific knowledge' requires a two-prong inquiry: (1) whether it is more likely than not the expert's methodology and principles are reliable, and (2) whether those principles and methodology can properly be applied to the facts at issue.") (Johnson, J., concurring) (citing *Daubert v. Merrell Dow*

Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993)).⁵

In addition, the Courts of Appeals of this State have been consistently applying *Frye* in accordance with this Court's jurisprudence, developing a coherent body of case law, particularly in the toxic tort context, that sets forth clear standards for litigants. The *Grant* and *Ruff* decisions were discussed in Respondent's Brief. See Resp. Br., pp. 24-26. Since briefing by the parties was completed, another Court of Appeals decision has been issued that is perfectly consistent with those two cases. The plaintiff in *Eakins v. Huber*, 154 Wn. App. 592, 595, 225 P.3d 1041 (2010), alleged that coronary stents containing nickel caused a systemic allergic reaction. Citing this court's decisions in *Riker* and *Copeland*, the Court of Appeals identified the relevant standard under *Frye* as follows:

In examining evidence under this standard, courts look at whether the underlying theory is generally accepted in the appropriate scientific community and whether there are experiments or studies using that theory that are capable of producing reliable results and are generally accepted in the scientific community. We do not evaluate whether the scientific theory is correct, but whether it has achieved a general acceptance in the relevant scientific community.

⁵ Appellants' expert medical causation evidence would be inadmissible under *Daubert*, as well as under *Frye*, precisely because the principles relied upon by Dr. Khattak are not reliable. See discussion in Brief of Amicus Curiae Washington Defense Trial Lawyers, pp. 10-15. This is not a case where the evidence at issue would be admissible under one standard and not admissible under the other.

Id. at 599 (internal citations omitted). The court then carefully considered the evidence of general acceptance put forward by the plaintiff, finding it insufficient under *Frye*, as follows:

Given that medical studies do not establish a causal relationship between stainless steel stents and the types of reactions suffered by [the plaintiff] and the disagreement among medical experts in the pertinent fields of allergy and cardiology about the cause of [the plaintiff]'s symptoms, we conclude no scientific consensus exists as to Dr. Adams's causation theory. At most, the medical studies indicate that it is a possibility, not a probability, that the nickel in stainless steel stents cause allergic reactions in patients with nickel allergies. However, the record indicates that this theory needs further empirical testing and that the few anecdotal reports of hypersensitivity reactions to [stents] do not establish a causal relationship between placement of such stents and these reactions. More specifically, for our purposes, they do not establish that nickel, as opposed to other allergens, cause such responses. Therefore, [the plaintiff] fails to establish a genuine issue of material fact as to the causation component of her claim.

Id. at 608. *Eakins* thus is merely the latest example of this state's consistent and rational application of *Frye*. Nothing in that history calls out for change. On the contrary, the consistency of *Eakins* with prior decisions of the Courts of Appeals supports confirmation of *Frye*, and the principles upheld by the trial court in this case.

2. **NAF Asks the Court to Exempt Medical Causation Testimony Based on a "Three-Step" Process from *Frye*.**

Second, NFA suggests a three-step process for the evaluation of medical causation testimony based on epidemiology. The three steps

involved are: biological plausibility; temporality; and lack of alternate explanations. NFA Br., pp. 15-16. NFA relies for this argument upon the record in two Superior Court decisions, which the Court has determined it will not consider. (Letter to counsel dated May 28, 2010).

In any event, this approach should not be adopted by the Court. If adopted as NFA suggests, the opinion of any expert who bases her or his opinion on this three-step method would automatically be admissible, without regard to whether the underlying theory of causation was generally accepted. For all the reasons discussed in the previous section (and in the section following, concerning differential diagnosis), the Court should not permit experts on medical causation to testify based on underlying theories of causation that are not generally accepted.

3. **NAF Asks the Court to Exempt Medical Causation Testimony Based on Differential Diagnosis from *Frye*.**

Third, NFA suggests that “testimony based on differential diagnosis to form a basis of medical causation opinions” should be admitted “outside the ambit of *Frye*.” NAF Br., p. 4. In fact, maintaining consideration of the underlying principle or theory within the *Frye* test is particularly important for medical causation testimony precisely because such evidence typically relies upon the method of differential diagnosis, i.e., a process by which a medical practitioner starts with a list of known

causes of a condition, and then rules out causes until what remains is the most likely cause of the condition. The technique is reliable, however, only if the cause that is pinpointed is a known, i.e., generally accepted, cause to begin with. If opinions based on differential diagnosis were exempted from *Frye* analysis, an expert could offer an opinion under ER 702 and 703 that a condition was caused by something that is not a known cause of the condition. Such a result would introduce a dangerous element of unverifiable subjectivity, leaving juries as the arbiter of novel scientific theory, precisely what *Frye*, *Daubert*, ER 702 and every related principle of law is intended to prevent.

Multiple courts have recognized this issue and held that differential diagnosis does not render an expert medical opinion reliable in the absence of evidence that the underlying theory of general causation is itself reliable. For example, in *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 n. 5 (2nd Cir. 2005), the Second Circuit considered a district court's exclusion of expert testimony that the plaintiff's cirrhosis was caused by a particular drug, where the expert relied upon differential diagnosis, but had not offered "any reliable basis for concluding that [the drug] is capable of causing the cirrhosis In other words, he has offered no reliable ground upon which [the drug] may be 'ruled in' as a plausible cause of the cirrhosis." The circuit court affirmed as follows:

A differential diagnosis is “a patient-specific process of elimination that medical practitioners use to identify the ‘most likely’ cause of a set of signs and symptoms from a list of possible causes.” As the district court observed, this method does not (necessarily) support an opinion on general causation, because, like any process of elimination, it assumes that “the final, suspected ‘cause’ remaining after this process of elimination must actually be *capable* of causing the injury.” Where an expert employs differential diagnosis to “‘rule out’ other potential causes” for the injury at issue, he must also “‘rule in’ the suspected cause,” and do so using “scientifically valid methodology.” Here, Dr. Dietrich may have used a differential diagnosis to rule out competing causes of cirrhosis without establishing that [the drug] is among them.

Id. at 254 (internal citations omitted) (emphasis in original). *See also McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) (“A valid differential diagnosis . . . only satisfies a *Daubert* analysis if the expert can show the general toxicity of the drug by reliable methods Thus, 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.”); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 885-85 (10th Cir. 2005) (“We are unable to find a single case in which differential diagnosis that is flatly contrary to all of the available epidemiological evidence is both admissible and sufficient to defeat a defendant’s motion for summary judgment. Plaintiff’s experts’ differential diagnoses and case studies are scientifically unreliable because they assume what science has largely shown does not exist – a causal

connection between silicone breast implants and disease.”); *In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig.*, 2010 WL 1727807, *2 (D.S.C.) (“Even where differential diagnosis opinions are permitted regarding specific causation, such evidence satisfies the *Daubert* standard only if general causation has already been established. Thus, to allow plaintiffs to rely on differential diagnoses to establish causation would amount to allowing an impermissible end-run around the general causation requirement.”) (internal citations omitted).

A dissent filed in *Marsh v. Valyou*, 977 So.2d 543 (Fla. 2007), by Justice Cantaro (joined by three other justices of the Florida Supreme Court) illustrates the error of permitting expert medical testimony based on differential diagnosis under *Frye*, without requiring general acceptance in the relevant medical community of the “known cause” of a condition, as follows:

To illustrate with an extreme example: a patient suffering from depression sees a doctor because her arm hurts. She does not know why her arm hurts. The doctor diagnoses a broken arm. The patient cannot tell the doctor how she broke her arm. The doctor may, through performing tests and interviewing the patient, conclude that it could not have been a car accident (the patient was not involved in an accident) and it could not have been playing sports (the patient does not play sports), but the doctor cannot then conclude that it must have been the depression that caused the broken arm – unless, of course, the doctor can show that the theory that depression can cause a broken arm is generally accepted in the scientific community. Similarly,

only if it is generally accepted that trauma is a *potential* cause of fibromyalgia may an expert testify that, through differential diagnosis, she has concluded that trauma caused *this plaintiff's* fibromyalgia. Differential diagnosis is not a wild card that can be used to introduce novel scientific theories into the courtroom.

Id. at 565 (internal citations omitted) (emphasis in original).⁶

Jurors, relying on their own experience, presumably would not credit the testimony described in Justice Cantaro's "extreme example." The average juror lacks the experience, however, to disregard a similarly unsupported causation opinion that prenatal exposure to organic solvents caused congenital brain malformations. This is precisely why *Frye* is needed, and why it is particularly needed where an expert seeks to cloak a theory that lacks general acceptance with the accepted methodology of differential diagnosis.

4. **NAF Asks the Court to Exempt Medical Causation Testimony Based on "Extrapolation" from *Frye*.**

Finally, NFA suggests that this Court exempt "extrapolation" from *Frye* analysis. Extrapolation, explains NFA, "involves establishing a cause and effect relationship based on similar, yet not identical, scientific

⁶ Justice Cantaro's dissent has been cited with approval outside Florida. See *Warren v. Topolski*, 2009 WL 1231099, *2 (Del. Super. 2009) ("[I]n the *Marsh* decision under *Frye*, the dissent convincingly stated the impropriety of the majority's decision, noting the absence of general acceptance of the expert's opinion.").

studies and theories.” NFA Br., p. 19. Like NFA’s suggestion to take differential diagnosis outside the ambit of *Frye* analysis, this approach would essentially render *Frye* inapplicable to underlying theories of general causation, since a medical expert could always extrapolate from some other, accepted, theory.

This danger was recognized by the U.S. Supreme Court (applying *Daubert*) in *General Electric Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997), as follows:

Respondent points to *Daubert*’s language that the ‘focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.’ He claims that because the District Court’s disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error . . . But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

(Internal citation omitted).

Indeed, this is precisely the conclusion the Superior Court reached below in response to Appellants’ assertion on motion for reconsideration that they need only show that exposure to organic solvents may cause brain damage generally, or “encephalopathy.” The court correctly noted

that encephalopathy is an “extremely broad” term defined as “any degenerative brain disease,” and that it was not limited to developmental malformations of the brain. CP 827-28. Accordingly, the court found that there was a “fundamental difference” between “encephalopathy, i.e., generalized organic brain damage that occurs after birth, and developmental malformations of the brain that occur during fetal development,” analogizing to a hypothetical plaintiff who tried to establish general acceptance of the theory that a mal-formed lung in a child born to a mother who smoked during pregnancy was caused by prenatal exposure to cigarette smoke on the basis of evidence that cigarette smoking causes lung cancer. *See* discussion in Resp. Br., pp. 37-41.

Exempting medical causation opinions based on extrapolation from application of *Frye* would nullify the type of intelligent analysis engaged in by the Superior Court, and would replace it, as the U.S. Supreme Court recognized, with a requirement that courts in this state “admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Joiner*, 522 U.S. at 146.

C. WSAJF’s Policy Arguments Likewise Seek to Eviscerate the *Frye* Standard.

WSAJF argues that *Frye* “should not be allowed to undermine the purposes of tort law,” and that “if retrospective epidemiological studies

having the degree of specificity required by the superior court were required, then the first victims of any newly recognized toxic exposure would likely be left without a remedy.” WSAJF Br., p. 18. This statement assumes what it sets out to prove, however. The first victims of any “newly recognized” toxic exposure will have a remedy under *Frye* precisely because the exposure has been recognized in the relevant scientific community. The *Frye* test is the result of counter-balancing the goal of protecting innocent victims against the harm of holding innocent parties responsible for injuries they did not cause. Scientific reliability is the fulcrum this balancing pivots upon. *Frye* does not undermine the purposes tort law. Rather, it requires that plaintiffs who allege an injury comply with one of the most basic principles of tort law – that they prove a defendant caused their injury by a preponderance of the evidence. Speculation, in whatever form it takes, is not a substitute for proof of causation, and ‘what if’ scenarios of what may occur in the future should not be the basis for changing basic principles of tort law. The law should keep pace with science, not outrun it.

WSAJF also asserts that “[i]n determining whether [medical causation] testimony is novel or generally accepted under *Frye*, the courts should make their determination at the highest level of generality that is consistent with a reasonable degree of medical certainty.” WSAJF Br., p.

15. WSAJF does not explain how this standard would actually work, however, preferring instead to criticize the Superior Court for requiring proof “showing a causal link between exposure to organic solvents and the particular birth defect suffered by Dalton.” *Id.*

Ultimately, however, such a standard would work only if the Court were to adopt NAF’s suggestion that extrapolation is not subject to *Frye*. For instance, assume that Dr. Khattak was allowed to base his opinion on an accepted theory of general causation that exposure to organic solvents may cause brain damage in adults (as, indeed, Appellants argued on reconsideration). How then, would Dr. Khattak reach his specific opinion that Dalton Anderson’s specific brain malformations were caused by prenatal exposure to organic solvents? Only through extrapolation. As discussed above, this result would effectively eliminate medical causation opinions from *Frye* analysis. If an expert is not required to show that extrapolation from general types of brain damage in adults to particular brain malformations resulting from prenatal exposure is generally accepted, then there is literally no limit to what can be extrapolated. More importantly, there is no way for a jury unversed in teratology to judge whether such extrapolation is warranted, making it a question perfectly suited for *Frye* analysis.

The evisceration of *Frye* urged by WSAJF and NFA would reduce scientific evidence to speculation cloaked in a façade of “methodology” – that is, theories that have not proven but have merely been considered as a possibility and applied without basis. Jurors would be asked to sort out the reliability of novel scientific evidence for themselves, with little choice but to decide ultimate issues of medical or scientific causation on the basis of other factors that are not scientifically based. Sympathy and bias would become the validation of unproven scientific theory. That is not justice and it should not be the law.

D. The Court Should Affirm Dismissal of Appellants’ Wrongful Discharge Claim, Regardless of the Decision in *Cudney*.

WSAJF also writes briefly on Appellants’ third assignment of error concerning the Superior Court’s dismissal of Appellants’ retaliatory discharge claim. WSAJF asserts that the briefing in another matter presently pending before this Court – *Cudney v. ALSCO, Inc.*, S.C. No. 83124-6 – addresses the issue of “whether the statutory remedy available under RCW 49.17.160 provides an adequate basis, as a matter of law, for vindicating the public policy embodied in WISHA, thereby foreclosing a claim for wrongful discharge in violation of public policy.” WSAJF Br., pp. 19-20. The Court should decide which case better presents the issue for determination, but to the extent that the Court considers WSAJF’s

amicus brief in *Cudney* in its deliberations in this case, it should also consider ALSCO's response to it. In both cases, WSAJF argues for an unprincipled interpretation of the jeopardy element that is inconsistent with Washington's well-established view that the public policy claim is intended to be a narrow exception to Washington's at-will employment doctrine. Cf. Henry H. Perritt, Jr., *The Future of Wrongful Dismissal Claims: Where Does the Employer Self Interest Lie?*, 58 U. CIN. L. REV. 397, 407 (1989) ("The public policy tort can become an amorphous source of just cause litigation, unless standards exist for principled decision-making, especially at the summary judgment and pleadings stages."). The resolution of this issue under Washington law is controlled by *Korshund v. Dyncorp Tri-Cities Servs., Inc.*, 156 Wn. 2d 168, 125 P.3d 119 (2005), adverse to WSAJF's position in *Cudney* and in this matter. See Resp. Br., pp. 46-47.

In addition, this case differs from *Cudney* in at least one material way that suggests that regardless of how the Court resolves the jeopardy element (in *Cudney* or here), it does not require reversal of the Superior Court's dismissal of Appellants' wrongful discharge claim in this case. Unlike *Cudney*, where the administrative protections of the public policy were more remote or theoretical, Appellant Julie Anderson in this case actually availed herself of the complaint system under RCW 49.17. Her

complaints were investigated and denied. Apparently dissatisfied with the investigation, she then chose not to pursue the administrative process under RCW 49.17. CP 838. WSAJF asserts that “[i]t is unclear from the briefing whether Julie Anderson argues that a question of fact exists as to the adequacy of a remedy.” WSAJF Br., p. 20 n. 11. This is judicious, as Ms. Anderson’s failure to pursue the statutory remedy available to her is undisputed. *See* CP 838 (“Anderson asserts that the investigation conducted pursuant to WISHA was ineffective and ‘the WISHA investigator had been duped by Akzo Nobel [and] [a]t that point turning to WISHA seemed like a lost cause.’”) (quoting Ms. Anderson’s declaration). As such, the record of this case shows that WISHA responded to this employee’s complaint, investigated it, issued a decision and provided the employee a means by which she could continue the claim. In terms of adequacy, it is difficult to comprehend a system that could do more. As the Superior Court found, “because Anderson chose to ignore th[e] statutory remedy, she cannot now argue that public policy against wrongful discharge is threatened if her common law tort claim is not recognized.” CP 839. Moreover, by failing to pursue the statutory remedy Ms. Anderson failed to establish a prima facie case for wrongful discharge – itself a sufficient basis for affirming the decision below. *See Briggs v. Nova Services*, 166 Wn.2d 794, 815-16, 213 P.3d 910 (2009)

(Madsen, J., concurring) (explaining that the plaintiff's failure to make a prima facie case in response to defendant's motion for summary judgment was a primary basis for affirming summary judgment, regardless of the Court's resolution on the jeopardy question).

CONCLUSION

For all the foregoing reasons, Respondents again request that the Court affirm the rulings of the Superior Court below.

RESPECTFULLY SUBMITTED this 11th day of June, 2010.

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CERTIFICATE OF SERVICE

The undersigned declares as follows:

1. I am employed at Corr Cronin Michelson Baumgardner & Preece LLP, attorneys of record for defendant Akzo Nobel Coatings Inc.
2. On this date I caused true and correct copies of the foregoing document to be served on counsel below via hand delivery:

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I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

DATED this 11th day of June, 2010, at Seattle, Washington.



Tamara Miller

No. 82264-6

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

JULIE ANDERSON, individually and on behalf of the Estate of
DALTON ANDERSON, and DARWIN ANDERSON individually,

Appellants

v.

AKZO NOBEL COATINGS, INC., and KEITH CROCKETT,

Respondents

**APPENDIX OF NON-WASHINGTON AUTHORITIES
SUPPORTING RESPONDENTS' COMBINED ANSWER TO
BRIEFS FILED BY AMICI CURIAE WASHINGTON STATE
ASSOCIATION FOR JUSTICE FOUNDATION AND NATIONAL
FIBROMYALGIA ASSOCIATION**

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ORIGINAL

Respondents and Defendants below Akzo Nobel Coatings, Inc. and Keith Crockett respectfully submit the following non-Washington authorities in support of Respondents' Combined Answer to Briefs Filed by Amici Curiae Washington State Association For Justice Foundation and National Fibromyalgia Association:

Cases

Blackwell v. Wyeth, 408 Md. 575, 971 A.2d 235 (2009)

General Electric Co. v. Joiner, 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)

In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig., 2010 WL 1727807 (D.S.C.)

In re Hanford Nuclear Reservation Litigation, 292 F.3d 1124 (9th Cir. 2002)

Marsh v. Valyou, 977 So.2d 543 (Fla. 2007)

McClain v. Metabolife Int'l, Inc., 401 F.3d 1233 (11th Cir. 2005)

McWilliams v. Dettore, 387 Ill.App.3d 833, 901 N.E.2d 1023, 327 Ill. Dec. 290 (2009)

Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005)

People v. McDonald, 37 Cal.3d 351, 690 P.2d 709, 208 Cal. Rptr. 236 (1984)

Ratner v. McNeil-PPC, Inc., 27 Misc.3d 322, 898 N.Y.S.2d 772 (N.Y. Sup. 2010)

Ruggiero v. Warner-Lambert Co., 424 F.3d 249 (2nd Cir. 2005)

State v. Johnson, 186 Ariz. 329, 922 P.2d 294 (Ariz. 1996)

State v. Vandebogart, 136 N.H. 365, 616 A.2d 483 (N.H. 1992)

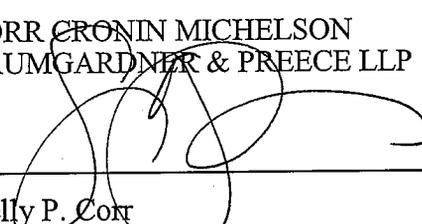
Warren v. Topolski, 2009 WL 1231099 (Del.Super. 2009)

Other Authorities

Henry H. Perritt, Jr., *The Future of Wrongful Dismissal Claims: Where Does the Employer Self Interest Lie?*, 58 U. CIN. L. REV. 397 (1989)

RESPECTFULLY SUBMITTED this 11th day of June, 2010.

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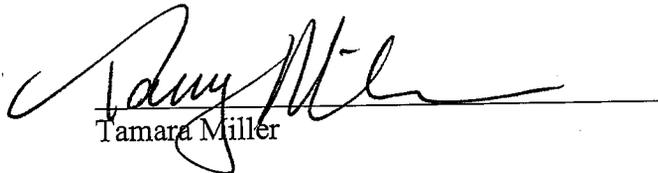
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Tacoma, WA 98403

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DATED this 11th day of June, 2010, at Seattle, Washington.



Tamara Miller

Court of Appeals of Maryland.
 Pamela BLACKWELL et al.
 v.
 WYETH d/b/a/ Wyeth, Inc., et al.
 No. 112, Sept. Term, 2008.

May 7, 2009.
 Reconsideration Denied June 11, 2009.

Background: Parents of autistic child brought products liability action against manufacturer of vaccines that contained thimerosal. Following an evidentiary hearing on manufacturer's motion in limine to preclude parents' expert testimony, the Circuit Court for Baltimore City, Stuart R. Berger, J., granted manufacturer summary judgment. Parents appealed.

Holdings: After granting certiorari, the Court of Appeals, Battaglia, J., held that:

(1) testimony of parents' expert, asserting that vaccines containing thimerosal were linked to autism in certain genetically susceptible individuals, was inadmissible due to an analytical gap in the expert's studies, and

(2) trial court did not abuse its discretion by precluding testimony of parents' experts due to lack of qualifications in the field of epidemiology.

Affirmed.

West Headnotes

[1] Evidence 157  555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Accepted scientific methodology does not mandate acceptance of conclusions ostensibly developed therefrom, under the *Frye-Reed* test for determining whether expert testimony is admissible.

[2] Evidence 157  555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

The *Frye-Reed* test for determining whether expert testimony is admissible engages trial judges in a serious gate-keeping function, to differentiate serious science from junk science.

[3] Evidence 157  555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

In order for scientific testimony to be admissible under the *Frye-Reed* test, generally accepted methodology must be coupled with generally accepted analysis in order to avoid the pitfalls of an analytical gap.

[4] Evidence 157  555.10

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  557

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k557 k. Experiments and Results

Thereof. Most Cited Cases

Testimony of medical doctor and genetic counselor retained by parents, that vaccines containing thimerosal were linked to autism in certain genetically susceptible individuals, was inadmissible under the *Frye-Reed* test in products liability action brought

971 A.2d 235
 408 Md. 575, 971 A.2d 235
 (Cite as: 408 Md. 575, 971 A.2d 235)

against vaccine manufacturer by parents of autistic child, due to an analytical gap in the doctor's studies, as the methodologies doctor used to draw his conclusions were not generally accepted as reliable; though doctor used a reliable data base in his studies allegedly linking thimerosal to autism the data upon which he relied was not tested or gathered for the purpose of testing the hypothesis that thimerosal caused autism, and differential diagnosis employed by doctor did not consider the single most suspected cause of autism, i.e., unknown genetics.

[5] Appeal and Error 30 ↪931(1)

30 Appeal and Error
 30XVI Review
 30XVI(G) Presumptions
 30k931 Findings of Court or Referee
 30k931(1) k. In General. Most Cited
 Cases

Appeal and Error 30 ↪1008.1(5)

30 Appeal and Error
 30XVI Review
 30XVI(I) Questions of Fact, Verdicts, and Findings
 30XVI(I)3 Findings of Court
 30k1008 Conclusiveness in General
 30k1008.1 In General
 30k1008.1(5) k. Clearly Erroneous Findings. Most Cited Cases

Appeal and Error 30 ↪1012.1(3)

30 Appeal and Error
 30XVI Review
 30XVI(I) Questions of Fact, Verdicts, and Findings
 30XVI(I)3 Findings of Court
 30k1012 Against Weight of Evidence
 30k1012.1 In General
 30k1012.1(3) k. Preponderance of Evidence. Most Cited Cases
 Court of Appeals reviews a challenge to the factual findings of trial judge for clear error, considering the evidence in the light most favorable to the prevailing party, and decides not whether the trial judge's conclusions of fact were correct, but only whether they were supported by a preponderance of the evidence.

[6] Evidence 157 ↪544

157 Evidence
 157XII Opinion Evidence
 157XII(C) Competency of Experts
 157k544 k. Cause and Effect. Most Cited
 Cases

Trial court did not abuse its discretions by precluding testimony of parents' experts for lack of proper qualifications, in products liability action brought against manufacturer of vaccines that contained thimerosal by parents of autistic child, as the level of complexity regarding the establishment of a causal relationship between the administration of a vaccine containing thimerosal and the onset of autism was complex, field of epidemiology was the single most relevant field of science for establishing a causal relationship, and none of parent's experts were qualified in the field of epidemiology. Md.Rule 5-702.
 **236 Thomas F. Yost, Jr. (Thomas F. Yost, Jr., P.A., Baltimore), on brief, for Appellants.

Daniel J. Thomasch (Joseph Evall, Lauren J. Elliott, Richard W. Mark, and Sean Shields, Orrick, Herrington & Sutcliffe LLP, New York City; Raymond G. Mullady, Jr., Orrick, Herrington & Sutcliffe LLP, Washington, DC), all on brief, for Appellees.

Dino S. Sangiamo, Stephen E. Marshall, David S. Gray, Venable LLP, Baltimore, brief of Amicus Curiae Merck & Co., Inc.

Argued Before BELL, C.J., HARRELL, BATTAGLIA, GREENE, MURPHY, ADKINS and BARBERA, JJ.

BATTAGLIA, Judge.

*577 In this case, we address the boundaries of *Frye-reef*^{FN1} with respect to a hypothesis proffered, on behalf of Pamela and Ernest Blackwell, Petitioner, by their expert, Dr. Mark Geier, involving whether the presence of the preservative "thimerosal"^{FN2} in **237 childhood vaccines, causes neurological defects, such as autism,^{FN3} as well as his and four other individuals' qualifications*578 to be experts under Maryland Rule 5-702,^{FN4} in a suit against Wyeth, Inc., Respondent.

FN1. *Frye-Reed* is the test in Maryland for determining whether expert testimony is admissible. The name is derived from two cases, *Frye v. United States*, 293 F. 1013 (D.C.Cir.1923), where this standard of general acceptance in the relevant scientific community was first articulated, and *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978), where we adopted the *Frye* standard.

FN2. The trial judge found that “[t]himerosal is an organic mercury based compound ... [that] has been used as a preservative in various vaccines and other biological and pharmaceutical products since the 1930’s.”

FN3. This Court once before has been presented with the substantive issue of an alleged relationship between thimerosal and autism. In *Aventis Pasteur, Inc. v. Skevofilax*, 396 Md. 405, 914 A.2d 113 (2007), we reviewed whether a circuit court judge abused his discretion when denying a motion to dismiss without prejudice and granting summary judgment in favor of Aventis Pasteur. Skevofilaxes’ expert conceded, in a deposition taken in connection with a thimerosal case pending elsewhere, that his claim of causation between thimerosal, genetic susceptibility and autism was not generally accepted in the medical community. Shortly after the expert was scheduled to be deposed in the Maryland case, the Skevofilaxes informed the judge and opposing counsel that the expert refused to participate further in the litigation. The Skevofilaxes filed a Motion for Dismissal of All Claims Without Prejudice, and Aventis Pasteur filed a Motion for Summary Judgment, the latter of which was granted. After the Court of Special Appeals reversed, holding that the unexpected withdrawal of an expert witness could not outweigh the effort and expense incurred by the Skevofilaxes, we reversed the intermediate appellate court and remanded, holding that the trial judge did not abuse his discretion in granting summary judgment because, after failing to produce an expert who could testify to specific causation, the plaintiff’s claims failed

as a matter of law.

FN4. Maryland Rule 5-702, governing testimony by experts, states:

Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony.

Pamela and Ernest Blackwell, parents and next friends of Jamarr Blackwell, sued the drug manufacturer Wyeth, Inc., its affiliates,^{FN5} and others,^{FN6} alleging that Jamarr’s autism and *579 mental retardation were caused by thimerosal-laden vaccines administered to Jamarr, when he was a baby, between the years 1985 and 1986.^{FN7} After Wyeth moved *in limine* to preclude the testimony of the Blackwells’ experts on grounds that the causal connection between thimerosal and autism is not generally accepted in the relevant scientific community and that the experts were not qualified to testify to such a causal connection, a 10-day evidentiary hearing was held before Judge Stuart R. Berger of the Circuit Court for Baltimore City, in which he addressed the seminal question of “whether the plaintiffs can support their claim of general causation with science that utilized methods and theories that are generally accepted in the relevant disciplines.”**238 After hearing the testimony of numerous experts presented by both sides,^{FN8} Judge Berger issued a 57-page Memorandum Opinion, ultimately concluding that the Blackwells had failed to demonstrate that the bases of their proffered experts’ opinions, including the theory of causation and the analytical framework in support thereof, were generally accepted as reliable in the relevant scientific community. Judge Berger also concluded that the Blackwells’ experts were not qualified to testify under Maryland Rule 5-702. Summary judgment was entered in favor of Wyeth, and the Blackwells appealed; we granted certiorari prior to any proceedings in the Court of Special Ap-

peals, *Blackwell v. Wyeth*, 406 Md. 442, 959 A.2d 792 (2008), to address two questions:

FN5. The affiliates included: Wyeth d/b/a Wyeth, Inc., Wyeth Laboratories, Wyeth-Ayerst, Wyeth-Ayerst Laboratories, Wyeth Lederle Vaccines, Lederle Laboratories (collectively "Wyeth").

FN6. Other than Wyeth and affiliates, the Blackwells' 22-count Complaint named Baltimore Gas and Electric Company, which became Constellation Energy during the course of the proceedings, Merck & Company, Inc., Sigma-Aldrich, Inc., American International Chemical, Spectrum Laboratory Products, and Eli Lilly and Company. Constellation Energy ultimately prevailed on summary judgment; Merck & Company, Inc., American International Chemical and Spectrum Laboratory Products were dismissed by stipulation; and Sigma-Aldrich, Inc., and Eli Lilly and Company were dismissed with prejudice.

FN7. Wyeth concedes in its brief that, "[a]n infant, [Jamarr] received vaccines, approved by the Food and Drug Administration and made by Defendant-Appellee, Wyeth ... [that] included thimerosal, an ethyl mercury derivative, as a preservative to prevent bacterial and fungal contamination in vaccines."

FN8. During the *Frye-Reed* hearing, the Blackwells presented the testimony of Drs. Mark Geier, M.D., Ph.D.; Stephen Siebert, M.D., M.P.H.; Elisabeth Mumper, M.D.; Richard Carlton Deth, Ph.D.; and Boyd Haley, Ph.D. Wyeth presented experts Peter M. Layde, M.D., M.Sc., Paul Kostyniak, Ph.D., Joseph Buxbaum, Ph.D., Kwame Anane-Yeboah, M.D., and Bryna Siegel, Ph.D.

1. Did the Circuit Court improperly apply the *Reed-Frye* general acceptance standard to the Blackwells' experts' *580 conclusions, rather than the bases upon which they reached their causation opinions, and impermissibly conduct a trial on the merits by using a heightened scientific certainty standard to determine the admissibility of their ex-

pert testimony?

2. Did the Circuit Court apply an erroneous legal standard and abuse its discretion in concluding that the Blackwells' experts' testimony is inadmissible because it does not meet the requirements of Md. Rule 5-702?

We shall affirm and conclude that Judge Berger appropriately precluded the Blackwells' experts' testimony under *Frye-Reed*^{FN9} and did not abuse his discretion in the application of Maryland Rule 5-702.

FN9. In *Wilson v. State*, 370 Md. 191, 201 n. 5, 803 A.2d 1034, 1040 n. 5 (2002), Judge Irma S. Raker, writing on behalf of the Court, noted:

Appellate review of a trial court's decision regarding admissibility under *Frye-Reed* is *de novo*, as both petitioner and the State concede.... [In] *Jones v. United States*, 548 A.2d 35 (D.C.1988) [t]he court found:

General acceptance means just that; the answer cannot vary from case to case. For this reason, when the ... *Frye* test ... is at issue, it becomes the 'threshold question' of admissibility, to be resolved as a matter of law before the court exercises its discretion in applying all the criteria to a particular proffered expert: The question of the reliability of a scientific technique or process is unlike the question, for example, of the helpfulness of particular expert testimony to the trier of facts in a specific case. The answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this threshold question of reliability as a matter within each trial judge's individual discretion.

But more succinctly courts should not subsume the question of qualifying the [scientific] process ... under the question of qualifying the expert. It follows that, in evaluating whether a scientific technique

has gained general acceptance, appellate courts review the trial court's analysis de novo.

(Internal citations and quotations omitted).

I. Background

In this case we must address the application of *Frye-Reed* to theories proffered as scientific and alleged to have been premised on scientifically accepted methodologies. To place *581 this quandary within the appropriate context, we shall begin by discussing the purpose of scientific inquiry and the scientific method, as well as our framework for the admission of expert testimony.

**239 The quest for truth in the courtroom and the quest for knowledge in science are not necessarily intersecting endeavors. A trial, on the one hand, may be quick and determinative; it is a process by which “advocates for each side present evidence in the light most favorable to their case, and the finder of fact sifts through it and assesses whether it establishes guilt or liability to the required degree of proof.” See Susan Haack, *Of Truth, in Science and in Law*, 73 Brook. L.Rev. 985, 985-86 (2008). The search for knowledge in science, on the other hand, is rarely quick or final; rather, it represents an ongoing cycle, in which each inquiry into an observable phenomenon is but one aspect of an ongoing quest.^{FN10}

FN10. The word *science*, itself, is defined as “[t]he branch of knowledge that produces theoretic explanations of natural phenomena based on experiments and observations.” Stedman's Medical Dictionary 1731 (28th ed.2006).

At the heart of this search for knowledge is the use of scientific method-or the analytical process by which a hypothesis is tested and analyzed and conclusions or theories are developed. This process has also been described as empirical study, that being study, “[f]ounded on practical experience, rather than on reasoning alone, but not established scientifically ... [or] testing a hypothesis by careful observation, hence rationally based on experience.” Stedman's Medical Dictionary 632 (28th ed.2006) (“empiric”).^{FN11} In basic terms, the development of a theory, using the scientific method or empirical testing,

follows characteristic steps:

FN11. An experiment is defined as, “[a] study in which the investigator intentionally alters one or more factors under controlled conditions to study the effects of doing so.” Stedman's, *supra*, at 685.

1. Observations of some phenomenon are made. For example, the movements of planets (which move in more complex orbits than the stars).

*582 2. Possible explanations (theories) are proposed for what is observed. (For the movement of planets, one such theory, radical at the time of its first suggestion, was that the movements of planets could be explained by a theory that placed the Sun and not the Earth at the center of our solar system.)

3. Hypotheses are logically derived from the theories. (If the Sun is the center of the solar system, then certain other observations should be true. If the Earth is the center of the solar system, that would lead to different predictions.)

4. Studies are designed to test the hypotheses. In essence, the study makes new observations that might disconfirm the hypothesis and thereby falsify the theory. Different theories have different implications and lead to different hypotheses. (Ideally, a study can be devised whose outcome will disconfirm one theory's hypotheses and not the other's. This is called a “critical experiment” because it permits a head-to-head test of two or more theories, and helps to determine which has done the best job of accounting for the relevant phenomena. Sometimes scientific controversies persist for a very long time because no commonly agreed upon critical experiment can be conducted.)

5. The results of such empirical tests lead to revision or abandonment of older theories or the creation of still newer and hopefully better theories.

6. The process repeats itself as more empirical tests are conducted and theories undergo continued re-evaluation.

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Evidence: The Law and Science of Expert Testimony, at 263-64 (2008). Specifically, once a theory is conceived based on an observable phenomenon, a hypothesis, which is “[a] conjecture advanced for heuristic purposes, cast in a form that is amenable to confirmation or refutation by conducting of definable experiments and the critical assembly of empiric data,” Stedman’s, *supra*, at 938, is developed, which defines the scope of an experiment. Studies then are designed to test the hypothesis and gather data:

*583 To real scientists a finding of fact is only as good as the methods used to find it. Scientific method is the logic by which the observations are made. Well designed methods permit observations that lead to valid, useful, informative answers to the questions that had been framed by the researcher. For scientists, the key word in the phrase “scientific method” is *method*. Methodology—the logic of research design, measures, and procedures—is the engine that generates knowledge that is scientific. While for lawyers and judges credibility is the key to figuring out which witnesses are speaking truth and which are not, for scientists the way to figure out which one of several contradictory studies is most likely correct is to scrutinize the methodology.

Faigman, *supra*, at 260 (emphasis in original). Once data is compiled, analysis occurs, from which conclusions are drawn; the hypothesis either remains viable or is disproven:

Note that a hypothesis or a theory is never proven or confirmed to be true. Testing is capable only of disconfirming. But theories that withstand such attempts at falsification better and longer become accepted, at least until something better comes along. The opposite approach can readily be seen in non-scientific activities of numerous kinds, where investigators engage in a search for evidence that confirms their suspicions. This confirmatory bias is based on the erroneous assumption that a theory is confirmed by the accumulation of facts consistent with the theory.... It is the diligent search for inconsistencies, for falsification, that really puts a theory to the test. A theory that can withstand such scrutiny is one that deserves credence.

Id. at 264.

“At any time there is a whole continuum of scientific

ideas, claims, and theories: some [are] so well-warranted by such strong evidence that it is most unlikely they will have to be revised; some not quite so well-warranted but still pretty solidly established; some promising but as yet far from certain;*584 some new and exciting but highly speculative and as yet untested; and some so wild that few mainstream scientists are willing even to listen.” Haack, *supra*, at 996. The strength, therefore, of a scientific theory is measured, in part, by its validity, which is “the extent to which something measures what it purports to measure.” Faigman, *supra*, at 269. See also Samuel R. Gross & Jennifer L. Mnookin, *Expert Information and Expert Evidence: A Preliminary Taxonomy*, 34 Seton Hall L.Rev. 141, 146-47 (2003) (discussing the distinction between field validity, which is whether a given “field of knowledge ... has credible tools to produce valid answers,” and method validity, which is whether “the methods that were used in this instance [were] capable of producing valid answers”). See generally Faigman, *supra*, Ch. 5, “Scientific Method: The Logic of Drawing Inferences from Empirical Evidence,” (discussing numerous research designs, methods of measurement, sampling, relationships among variables and threats to validity). The second variable**241 affecting the strength of a scientific theory is its reliability, which has been defined as,

[R]eliability refers to the ability of a measure to produce the same result each time it is applied to the same thing. Reliability refers to consistency, or reproducibility. If each time a person steps on to a bathroom scale it gives a different reading (while the person’s weight has not changed), then the scale is said to lack reliability.

Faigman, *supra*, at 269 (italics in original). Both validity and reliability, then, affect whether a scientific theory is accepted in the field in which it is offered.

General acceptance by other members of the relevant scientific field became the standard for acceptance of a theory, as a result of the opinion of the United States Court of Appeals for the District of Columbia Circuit in *Frye v. United States*, 293 F. 1013, 1014 (D.C.Cir.1923):

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere

in this twilight zone the evidential force of the principle must be recognized, and while *585 courts will go a long way in admitting expert testimony deduced from a *well-recognized* scientific principle or discovery, the thing from which the deduction is made must be *sufficiently established to have gained general acceptance in the particular field in which it belongs.*

(Emphasis added). The *Frye* “general acceptance” standard was adopted by this Court in *Reed v. State*, 283 Md. 374, 391 A.2d 364 (1978), in which we recognized that the standard did reflect assessment of a theory's validity and reliability. In *Reed*, we were confronted with whether voiceprint recognition, consisting of the use of a spectrograph machine to match patterns in an individual's voice, was admissible, for identification purposes, in a rape case. We concluded that the trial judge erred in admitting the evidence. *Id.* at 399-400, 391 A.2d at 377. In so doing, Judge John C. Eldridge, writing for this Court, recognized that scientific methodologies or techniques must be generally accepted prior to the admission into evidence of the conclusions reached:

On occasion, the validity and reliability of a scientific technique may be so broadly and generally accepted in the scientific community that a trial court may take judicial notice of its reliability. Such is commonly the case today with regard to ballistics tests, fingerprint identification, blood tests, and the like. Similarly, a trial court might take judicial notice of the invalidity or unreliability of procedures widely recognized in the scientific community as bogus or experimental. However, if the reliability of a particular technique cannot be judicially noticed, it is necessary that the reliability be demonstrated before testimony based on the technique can be introduced into evidence. Although this demonstration will normally include testimony by witnesses, a court can and should also take notice of law journal articles, articles from reliable sources that appear in scientific journals, and other publications which bear on the degree of acceptance by recognized experts that a particular process has achieved.

*586 *Id.* at 380, 391 A.2d at 367 (internal citations removed). In adopting the *Frye* test of general acceptance, Judge Eldridge gave guidance regarding its application:

That is to say, before a scientific opinion will be

received as evidence at trial, the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field. Thus, according to the *Frye* standard, if **242 a new scientific technique's validity is in controversy in the relevant scientific community, or if it is generally regarded as an experimental technique, then expert testimony based upon its validity cannot be admitted into evidence.

The identity of the relevant scientific community is, of course, a matter which depends upon the particular technique in question. In general, members of the relevant scientific community will include those whose scientific background and training are sufficient to allow them to comprehend and understand the process and form a judgment about it. In unusual circumstances, a few courts have held that the experts thus qualified might properly be from a somewhat narrower field.

Id. at 381-82, 391 A.2d at 368 (internal citations omitted).

We recognized in *Reed* that seminal scientific technologies may be rejected, because the “*Frye* standard retards somewhat the admission of proof based on new methods of scientific investigation by requiring that they attain sufficient currency and status to gain the general acceptance of the relevant scientific community,” *id.* at 385, 391 A.2d at 370, quoting *United States v. Addison*, 498 F.2d 741, 743-44 (D.C.Cir.1974), in that “[f]airness to a litigant would seem to require that before the results of a *scientific* process can be used against him, he is entitled to a *scientific* judgment on the reliability of that process.” *Id.* at 385, 391 A.2d at 369-70 (emphasis in original). We further recognized that, “*Frye* was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles” because “[l]ay jurors tend to give considerable weight to ‘scientific’ evidence when presented by ‘experts’ with impressive credentials.” *Id.* at 386, 391 A.2d at 370, quoting *587 *People v. Kelly*, 17 Cal.3d 24, 130 Cal.Rptr. 144, 549 P.2d 1240, 1245 (1976). Accordingly, we concluded that, “[a]s long as the scientific community remains significantly divided, results of controversial techniques will not be admitted, and all [litigants] will face the same burdens. If, on the other hand, a novel scientific process does achieve general acceptance in

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the scientific community, there will likely be as little dispute over its reliability as there is now concerning other areas of forensic science which have been deemed admissible under the *Frye* standard, such as blood tests, ballistics tests, etc." *Id.* at 388, 391 A.2d at 371.

Since 1978, we have had occasion to elaborate on the application of *Frye-Reed* to various aspects of the scientific method as well as specific methodologies. In *Wilson v. State*, 370 Md. 191, 803 A.2d 1034 (2002), we addressed whether a trial judge erred in rejecting expert opinion testimony, based upon a generally-accepted statistical calculus-the product rule.^{FN12} Wilson had been accused of murder after a second child of his, with a different mother, had died during a night when Wilson was the caretaker. Wilson interposed a SIDS, or Sudden Infant Death Syndrome, defense. At trial, the State proffered the testimony of two experts, who, using the product rule, would have testified that the probability of a child dying with SIDS with cerebral swelling was 1 and 100,000-arrived at by multiplying the statistic that 1 child per 1,000 live births die of SIDS by the statistic that 1 in 10 SIDS deaths involve cerebral swelling-and that the **243 chance of two SIDS deaths occurring in the same family was 1 in 4,000,000-arrived at by squaring the rate of 1 child per 2,000 live births to reach the chance of two children dying from SIDS in the same family. Wilson moved *in limine* to exclude the testimony of the State's experts, but the trial judge denied the motion. At trial, the experts testified, and in closing argument,*588 the State specifically referred to the experts' statistics, stating, "[i]f you multiply his numbers, instead of 1 in 4 million, you get 1 in 10 million that the man sitting here is innocent." *Id.* at 200, 803 A.2d at 1039. The Court of Special Appeals affirmed the conviction, and we granted certiorari to consider whether the *Frye-Reed* standard applies to the application of statistical methods, which we answered in the affirmative. *Id.* at 196, 202-03, 803 A.2d at 1036,1040-41, citing *Armstead v. State*, 342 Md. 38, 673 A.2d 221 (1996).

FN12. The product rule states: "the probability of the joint occurrence of a number of *mutually independent* events is equal to the product of the individual probabilities that each of the events will occur." *Wilson v. State*, 370 Md. 191, 198 n. 2, 803 A.2d 1034, 1038 n. 2 (2002) (emphasis in origi-

nal).

[1] After reiterating the bases of *Frye-Reed* that, "before a scientific expert opinion may be received in evidence, the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field," *id.* at 203, 803 A.2d at 1041, we addressed whether the use of a generally accepted technique required acceptance of conclusions derived from its use. We concluded that it was not mandated, because one of the necessary predicates to the application of the product rule-mutual independence of events-was not considered; genetics may have been the link between the two infants' deaths:

We hold that the trial court erred in admitting expert testimony based on the product rule because a condition necessary to the proper application of the product rule was lacking: there was inadequate proof of the independence of Brandi and Garrett's deaths. As evidenced by the authorities above cited, there is not general agreement in the scientific community as to the relationship between SIDS deaths within a single family. Stated another way, there is not general agreement in the medical community that multiple SIDS deaths in a single family are genetically unrelated. The literature continues to reflect a lively debate concerning the role of genetics in SIDS.

* * *

In light of the widespread disagreement as to the causes of SIDS, we are unable to find general acceptance of the notion that there is no genetic component to SIDS. Unanimity*589 is not required for general acceptance, but it is clear to us that a genuine controversy exists within the relevant scientific community. In sum, there was inadequate proof of the statistical independence of SIDS deaths within a single family. Therefore, based on the current state of medical opinion, the product rule should not be employed in calculating the likelihood of multiple SIDS deaths within a single family. *Id.* at 209, 210-11, 803 A.2d at 1044-45 (citations omitted). Accepted methodology, then, does not mandate acceptance of conclusions ostensibly developed therefrom.

We also have had the opportunity to apply *Frye-Reed*

when considering whether a theory, which had been accepted in the scientific and legal communities, continues to meet the standard. Comparative Bullet Lead Analysis (CBLA), by which two bullets are compared to see if they originate from the same original molten source, had gained currency as admissible scientific evidence prior to *Clemons v. State*, 392 Md. 339, 896 A.2d 1059 (2006). In *Clemons*, the State presented an FBI CBLA expert, who testified that a bullet **244 found at a crime scene and bullets found in a gun possessed by Clemons, seized two days after the crime, originated from the same original source. Clemons moved *in limine* to exclude the expert's testimony, arguing that an essential premise of CBLA theory was no longer generally accepted in the relevant scientific community—that bullets originating from a given ingot or vat of lead were uniquely homogenous. The trial judge admitted the evidence, and the Court of Special Appeals affirmed the conviction. We reversed, holding that the trial judge erred in admitting the CBLA testimony, because it was no longer generally accepted in the field of metallurgy that the elemental composition of the molten source for the creation of bullets was uniform, homogenous or unique. In so holding, we engaged in an in-depth review of the CBLA technique, observing,

Recently the assumptions regarding that uniformity or homogeneity of the molten source and the uniqueness of each molten source that provide the foundation for CBLA have *590 come under attack by the relevant scientific community of analytical chemists and metallurgists[.]

Id. at 368, 896 A.2d 1059, 1076, and concluded:

We conclude that CBLA does not satisfy the requirement under the *Frye-Reed* test for the admissibility of scientific expert testimony *because several fundamental assumptions underlying the process are not generally accepted by the scientific community*. Therefore, we reverse the judgment of the Court of Special Appeals and remand the case to the Circuit Court for Prince George's County for a new trial.

Id. at 372, 896 A.2d at 1079 (emphasis added).

More recently, in *Montgomery Mutual Insurance Company v. Chesson*, 399 Md. 314, 923 A.2d 939 (2007), we considered whether a trial judge erred in denying a defendant's *in limine* motion for a *Frye-*

Reed hearing to determine the admissibility of expert testimony that exposure to mold caused certain physical ailments, described as either sick building syndrome or bio-toxic illness, “a combination of ailments associated with exposure to modern buildings that lack proper ventilation.” *Chesson*, 399 Md. at 317 n. 1, 923 A.2d at 940-41 n. 1. Montgomery Mutual, a workers' compensation insurer, alleged that the claimant's expert's theory, regarding a causal connection between mold exposure and certain human health effects, had not been generally accepted within the relevant scientific community, nor had the tests used in developing the theory. The trial judge denied the motion without holding a hearing, and the Court of Special Appeals affirmed, stating, *inter alia*, that the experts utilized medical tests that were generally accepted in the scientific community. *Montgomery Mutual Ins. Co. v. Chesson*, 170 Md.App. 551, 570-71, 907 A.2d 873, 885 (2006). We reversed and remanded, recognizing that the tests utilized, as well as the results and theory, must be subjected to *Frye-Reed* scrutiny:

In the case *sub judice*, the Court of Special Appeals held that it was unnecessary for the Circuit Court to hold a *Frye-Reed* hearing, reasoning (1) that [the expert's] medical diagnosis was not a proper subject for *Frye-Reed* analysis, *591 and (2) that the tests [the expert] used in reaching his medical diagnoses are generally accepted in the medical community, and are therefore not subject to *Frye-Reed* analysis. We disagree and hold that, based on this record, the Circuit Court should have held a *Frye-Reed* hearing to determine whether the medical community generally accepts the theory that mold exposure causes the illnesses that respondents claimed to have **245 suffered, *and the propriety of the tests [the expert] employed to reach his medical conclusions*.

Chesson, 399 Md. at 328, 923 A.2d at 947 (citations omitted) (emphasis added). *See also State v. Smullen*, 380 Md. 233, 266, 268, 844 A.2d 429, 448, 449-50 (2004) (noting that the battered-spouse syndrome is a novel scientific theory that would have been subjected to *Frye* had not the Maryland General Assembly expressly made it admissible, in a case addressing whether battered-spouse syndrome could be used as a self-defense).

[2] From even a limited review of our *Frye-Reed*

history, it can be seen that our jurisprudence engages trial judges in a serious gate-keeping function, to differentiate serious science from “junk science.” Commentators on the *Frye* standard have recognized the importance of this role:

Courts therefore have a duty to ensure that experts are presenting reliable testimony.

This obligation is especially acute because unlike ordinary fact witnesses, who typically come from a very limited pool of witness[es], there is usually an almost unlimited pool of experts. For example, many qualified experts could testify in a typical medical malpractice case. While attorneys are stuck with the testimonial limitations of the available fact witnesses, an attorney who needs an expert can “shop” for an expert with a pleasing courtroom manner who will agree with the attorney’s theory of the case.

* * *

Some of these potential expert witnesses will be venal “hired guns.” As Judge Jack Weinstein has noted, “[a]n *592 expert can be found to testify to the truth of almost any factual theory, no matter how frivolous.” Ordinary fact witnesses may also have their biases, but attorneys can only take advantage of these biases if the witnesses already exist; they cannot normally shop for an ordinary fact witness. By contrast, attorneys can seek expert witnesses who will parrot the attorneys’ line, and, indeed, implicitly “bribe” them to do so.

Moreover, ordinary biases, such as a familial or friendly relationship to one of the parties, can typically be brought out on cross-examination. Some authorities have argued that cross-examination will also reveal an expert witness’ bias to the jury. However, it [is] not at all clear how opposing counsel can discredit a “hired gun” expert for taking money for his testimony, given that opposing counsel will have his own expert-who may be scrupulously honest-on his payroll. In any event, even if the biases of hired guns can be revealed through cross-examination, that does not resolve the problems caused by expert-shopping. Not all, and perhaps not even most experts who testify to opinions outside the mainstream of their field are venal hired guns. Our system assumes, perhaps op-

timistically, that the jury can determine if an expert is lying. But what if the expert is simply shading the truth? Or, even more likely, what if the expert is simply eccentric or outside the mainstream? Parties have every incentive to hire “outlier” experts with sincere but extreme views so long as they can conceal the outlier status. There is no reason to hire an expert, for example, who will tell the jury that a client’s losses are worth \$150,000 if an attorney can find an equally credible expert willing to testify that the true figure is \$300,000. Moreover, there is no ethical obligation on attorneys to hire mainstream experts. Indeed, their duty to zealously advocate for their clients may *require* them to **246 hire outliers if it would help their client’s case.

David E. Bernstein, *Frye, Frye Again: The Past, Present, and Future of the General Acceptance Test*, 2 Bureau of National Affairs Expert Evidence Report (Feb. 18, 2002) *593 (footnotes omitted) (emphasis in original), available at <http://litigationcenter.bna.com/pic2/lit.nsf/id/BNAP-57HQ4Q?OpenDocument> (last visited May 5, 2009).

II. Procedural History

On June 9, 2004, the Blackwells filed a 22-count complaint against various thimerosal manufacturers, numerous manufacturers of thimerosal-laden products, and BG & E, alleging that mercury contained in their products or emissions caused their son Jamarr’s autism. Wyeth, as the manufacturer of a thimerosal-laden product, was sued for defective design, breach of warranty of fitness for a specific purpose, failure to warn, strict liability, negligence, defect in manufacturing, common law fraud, negligent misrepresentation, fraudulent misrepresentation, fraudulent misrepresentation through another, deceptive trade practices under the Maryland Consumer Protection Act, breach of implied warranties, intentional infliction of emotional distress, and civil battery.

Wyeth moved to preclude the testimony of five experts offered by the Blackwells under *Frye-Reed*, arguing that the experts’ theory, that thimerosal caused Jamarr’s autism, and the various methodologies employed in reaching that conclusion, were not generally accepted in the relevant scientific community. Wyeth also alleged that the Blackwells’ experts were not qualified to testify under Maryland Rule 5-

702. The Blackwells filed reciprocal motions regarding a number of Wyeth's experts.

Between August 18-29, 2007, Judge Stuart R. Berger of the Circuit Court for Baltimore City conducted a *Frye-Reed* hearing on these motions,^{FN13} wherein testimony**247 was adduced *594 from each of the Blackwells' experts-Mark Geier, M.D., Ph.D.; Stephen Siebert, M.D., M.P.H.; Elisabeth Mumper, M.D.; Richard Carlton Deth, Ph.D.; and Boyd Haley, Ph.D.-and from Wyeth's five proposed experts-Peter M. Layde, M.D., M.Sc, Paul Kostyniak, Ph.D., Joseph Buxbaum, Ph.D., Kwame Anane-Yebo, M.D., and Bryna Siegel, Ph.D. (of whom only Drs. Yebo and Buxbaum were challenged by the Blackwells). In an order supported by an extensive memorandum opinion, Judge Berger granted Wyeth's Motion to Preclude Testimony of Plaintiff's Expert Witnesses, pursuant to *Frye-Reed* and Maryland Rule 5-702, and denied the Blackwells' Motion to Exclude Certain Defense Experts and Certain *595 Expert Testimony. Thereafter, Judge Berger granted Wyeth's motion for summary judgment, finding "no genuine dispute as to any material fact." The Blackwells noted an appeal to the Court of Special Appeals, and this Court granted certiorari prior to any proceedings in the intermediate appellate court, to address the exclusion of the Blackwells' experts' testimony.^{FN14}

FN13. In *Clemons v. State*, 392 Md. 339, 896 A.2d 1059 (2006), we discussed the procedural parameters of *Frye-Reed* and our preference that a trial judge hold a hearing prior to trial and outside the presence of the jury, to determine the admissibility of expert testimony:

Judges have discretion to defer a pre-trial ruling on a motion *in limine* and ordinarily do so where the issue can be better developed or achieve a better context based on what occurs at trial. Where evidence is subject to challenge under *Frye-Reed*, however, the issue should, whenever possible, be dealt with prior to trial. The evidence bearing on whether the challenged evidence is actually the product of a novel scientific technique and, if so, whether that technique is generally accepted in the relevant scientific community will usually be collateral to the substantive issues at

trial and may, itself, be inadmissible with respect to those substantive issues. That alone justifies resolving the issue prior to trial. Dealing with the issue pre-trial also avoids delays and diversions at trial that may inconvenience both witnesses and the jury. See Maryland Rule 5-104(c) ("Hearings on preliminary matters shall be conducted out of the hearing of the jury when required by rule or the interests of justice.").

* * *

Maryland Rule 5-103(c) also provides support for our conclusion that *Frye-Reed* examinations are better conducted in pre-trial hearings in its admonition that "[p]roceedings shall be conducted, to the extent practicable, so as to prevent inadmissible evidence from being suggested to a jury by any means, such as making statements or offers of proof or asking questions within the hearing of the jury." Conducting the hearing outside the presence of the jury would preclude its members from improperly considering evidence that is irrelevant to the task at hand and ensure that the verdict is derived from evidence properly before it.

If the issue is to be dealt with at trial, it should be addressed, in its entirety, as a preliminary matter prior to admission of the challenged evidence, not, as here, by having the challenge made only to Peters's status as an expert during the State's case and then receiving most of the evidence bearing on whether the inferences sought to be drawn from CBLA are generally accepted in the relevant scientific community during the defense case, after the challenged inferences have already been admitted. If a party raises a *Frye-Reed* objection, all evidence bearing on admissibility of the challenged evidence should be presented and considered *before* a ruling is made on the challenge.

Id. at 347-48 n. 6, 896 A.2d at 1064 n. 6 (internal quotations and citations omitted)

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(emphasis in original).

FN14. After oral argument before this Court, Wyeth filed a Motion for Judicial Notice on March 8, 2009, asking this Court to take judicial notice of various scientific articles pulled from Internet websites; the motion was opposed by the Blackwells. We need not rule on this motion, however, because we are satisfied that the record before us is sufficient, without our having to take judicial notice of any other materials.

III. Discussion

Before us, the Blackwells argue that the Judge erred in his *Frye-Reed* analysis, because he denied the admissibility of their experts' theory, that thimerosal in the vaccines produced by Wyeth and administered to their son, Jamarr, caused his autism, because it was not generally accepted in the relevant scientific community,^{FN15} and because their experts were not qualified to testify about a causal relationship between thimerosal and autism, under Maryland Rule 5-702. The Blackwells argue, in essence, that the trial judge impermissibly determined the element of causation on summary judgment and precluded the jury from appropriate fact-finding.

FN15. Specifically, in oral argument, the Blackwells asserted that the following six propositions are generally accepted in the scientific community, supporting their experts' theory that thimerosal caused or exacerbated Jamarr's autism:

1. mercury is a potent neurotoxin;
2. ethyl, the inorganic material found in thimerosal, the preservative in vaccines, is also a potent neurotoxin;
3. thimerosal could cause mental retardation;
4. there is a genetic susceptibility to mercury toxicity;
5. mercury can cause behavioral abnormalities that define autism; and

6. it is biologically plausible that thimerosal containing vaccines can cause more developmental injury and autism.

*596 Wyeth argues that the trial judge properly precluded the testimony of the Blackwells' experts, because they were not qualified under Rule 5-702 and because their conclusions and analyses were not accepted in the relevant scientific community.

A. *Frye-Reed* Analysis

The essence of the instant case is the application of the *Frye-Reed* test to the **248 analysis undertaken by an expert where the underlying data and methods for gathering this data are generally accepted in the scientific community but applied to support a novel theory. In reaching his ultimate conclusion that "the plaintiffs ... failed in their burden of proving that the bases of the expert witnesses' testimony are generally accepted as reliable within the relevant scientific field," Judge Berger discussed the importance of the threshold determination with which he was vested. He noted that "[u]nder *Reed*, the proponent of an expert witness bears the burden of proving the basis of the witness' opinion is generally accepted as reliable within the relevant scientific field." He also observed that the *Frye-Reed* test " 'was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles,' " quoting *Chesson*, 399 Md. at 328, 923 A.2d at 946, in turn quoting *Reed*, 283 Md. at 386, 391 A.2d at 370, that the test posed a minimum threshold for the admissibility of scientific evidence in Maryland, and that trial courts continued to retain discretion to exclude such testimony on other grounds—such as lack of helpfulness or expert qualification.

In discerning the factual predicates developed during the hearing, which have not been challenged for clear error,^{FN16} Judge Berger found that "[t]himerosal is an organic mercury-based compound," that has been used in "various vaccines and other biological and pharmaceutical products since the 1930's," *597 and that it was undisputed that Jamarr had received a diphtheria tetanus and whole-cell pertussis vaccine ("DTP"), at 2 months, 4 months, 6 months and 18 months, pursuant to the Centers for Disease Control and Prevention's published recommended schedule,

as well as a hemophilia influenza type b ("Hib") vaccine. According to Judge Berger, "[b]oth the DTP vaccine and the Hib vaccine contained 50 micrograms of thimerosal, which results in approximately 25 micrograms of mercury in each vaccination." Judge Berger also found that "[i]n July of 1999, the Public Health Service and the American Academy of Pediatrics issued a joint statement recommending the removal of thimerosal from vaccines" as a precautionary measure, and that "[b]y March of 2001, all vaccines on the recommended childhood immunization schedule were available without thimerosal."

FN16. At oral argument, counsel for the Blackwells pointed to findings of fact with which he took umbrage. We shall discuss these factual findings *infra*.

Turning to the issue of Jamarr's developmental challenges, Judge Berger found that, "autism or autism spectrum disorder ("ASD") are pervasive developmental disorders that are characterized by sustained impairments in social interaction, sustained impairments in verbal and nonverbal communication skills, and restricted, repetitive and stereotyped patterns of behaviors or interests," and that "[u]nder the American Psychiatric Association's Diagnostic and Statistical Manual ... the onset of autistic disorder is prior to three years of age." His review of the scientific literature regarding autism's causes, and in particular, the findings of the National Academy of Sciences' Institute of Medicine's (hereinafter "IOM") 2001 and 2004 Committees,^{FN17} led him to note that the 2001 IOM Committee, which was tasked with evaluating "the alleged connection between thimerosal-containing vaccines and a broad **249 range of neurodevelopmental disorders including autism, ADHD, and speech or language delay," concluded:

FN17. Judge Berger noted that, "[t]he National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars, created by congressional charter in 1863 to advise the federal government on scientific and technical matters."

*598 The hypothesis that thimerosal exposure through the recommended childhood immunization schedule has caused neurodevelopmental disorders is not supported by clinical or experimental evi-

dence.

* * *

[T]he evidence is inadequate to accept or reject a causal relationship between thimerosal exposures from childhood vaccines and the neurodevelopmental disorders of autism, ADHD, and speech and language delay.

These conclusions were founded upon the following bases:

- (a) low-dose thimerosal exposure in humans has not been demonstrated to be associated with effects on the nervous system;
- (b) neurodevelopmental effects have been demonstrated for prenatal but not postnatal exposures to low doses of ethylmercury;
- (c) the toxicological information regarding ethylmercury, particularly at low doses, is limited;
- (d) thimerosal exposure from vaccines has not proven to result in mercury levels associated with toxic responses;
- (e) signs and symptoms of mercury poisonings are not identical to autism, ADHD, or speech or language delay;
- (f) autism is thought primarily to originate from prenatal injury; and
- (g) there is no evidence that ethylmercury causes any of the pathophysiological changes known to be associated with autism, such as genetic defects, and there are no well-developed pathological markers of ADHD or delay of speech or language that could be compared to effects of ethylmercury on the nervous system.

The 2001 IOM Committee Report was succeeded in 2004 by another IOM Committee, which, Judge Berger found, again attempted to assess whether a causal link between the administration of thimerosal and autism had been proven in the scientific community. To assess causality, "the 2004 IOM *599 Committee used the categories of causal conclusions developed by previous IOM committees, namely: (1) no evi-

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dence; (2) evidence is inadequate to accept or reject a causal relationship; (3) evidence favors rejection of a causal relationship; (4) evidence favors acceptance of a causal relationship; (5) evidence establishes a causal relationship," according to Judge Berger's review. In that context, he continued, the 2004 Committee reviewed a vast body of literature on the subject and considered extensive presentations and submissions made by scientists during an open scientific meeting, ultimately concluding, "that the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." This rejection, Judge Berger found, was in large part, based on "[e]pidemiological studies examining [thimerosal] and autism, including three controlled observation studies (Hviid et al., 2003; Miller, 2004; Verstraeten, et al., 2003) and two uncontrolled observational studies (Madsen, et al., 2003; Stehr-Green, et al., 2003)," all of which, "consistently provided evidence of no association between [thimerosal] and autism, despite the fact that these studies utilized different methods and examined different populations (in Sweden, Denmark, the United States and the United Kingdom)."

As Judge Berger found, the 2004 IOM Committee ultimately determined that the link between thimerosal and autism was largely speculative:

****250** In the absence of experimental or human evidence that vaccination (either the MMR vaccine or the preservative thimerosal) affects metabolic, developmental, immune or other physiological or molecular mechanisms that are causally related to the development of autism, the committee concludes that the hypotheses generated to date are theoretical only.

* * *

Given the lack of direct evidence for a biological mechanism and the fact that all well-designed epidemiological studies provide evidence of no association between thimerosal and autism, the committee recommends that cost-benefit assessments*600 regarding the use of thimerosal-containing versus thimerosal-free vaccines and other biological or pharmaceutical products, whether in the United States or other countries, should not include autism as a potential risk.

Judge Berger also acknowledged that a "plethora of venerable publications reject[] the plaintiffs' theoretical link between thimerosal-containing vaccines and autism," including the Global Advisory Committee on Vaccine Safety, which advises the World Health Organization on health related issues, the Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the National Institutes of Health, all of which have taken the position that thimerosal vaccines do not cause or contribute to autism. He stated that epidemiology, or "the science that studies the distribution of diseases within populations," was the "single most relevant field of science to the general causation issue presented in this case, i.e., whether thimerosal-containing vaccines can cause autism," and recognized that none of the Blackwells' experts was qualified as an expert in epidemiology.

Turning to the opinions rendered by the Blackwells' primary expert,^{FN18} Dr. Mark Geier, Judge Berger looked first at Dr. Geier's analytical framework, whereby he purported to have completed an epidemiological analysis on scientifically accepted data compiled in various third-party databases: the Vaccine Adverse Effect Reporting System (VAERS), the Vaccine Safety Datalink, the Department of Education database, and the California Department of Social Services database. He then subjected Dr. Geier's conclusion, that thimerosal in vaccines causes autism in a small number of genetically susceptible individuals, to *Frye-Reed* scrutiny.

FN18. Judge Berger's *Frye-Reed* analysis focused primarily on Dr. Geier, because he was the only expert proffered by the Blackwells as an expert in the field of epidemiology.

Judge Berger began by observing that the *only* published epidemiological studies purporting to show a causal link between thimerosal-containing vaccines and autism were the studies undertaken by Dr. Mark Geier and his son, Dr. David *601 Geier, which suggested that the VAERS database could be extrapolated to show a causal connection between thimerosal and autism. He recognized the distinction between the use of data that is scientifically accepted and analysis purportedly based on that data, when the analysis employed is inappropriate to the data produced, which is dependent on the context in which it

was produced and the hypothesis under scrutiny:

It is significant to this Court that the IOM Committee criticized the technique utilized in [one of the Geier studies] ... expressly noting that:

VAERS cannot be used to calculate incidence rates because the VAERS database does not have complete reporting of all adverse events and because**251 many report events lack a confirmed diagnosis or confirmed attribution to vaccine.

Admittedly, Dr. Geier acknowledged that [this study] is controversial. Indeed, the American Academy of Pediatrics (“AAP”), in a May, 2003 posting to their website, strongly denounced the Geier and Geier publication ... stating:

This paper uses data from the [VAERS] inappropriately and contains numerous conceptual and scientific flaws, omissions of fact, inaccuracies, and misstatements fail[ing] to acknowledge the inherent limitations of the VAERS database when drawing conclusions of adverse event associations ... [and] [c]omparing the occurrence of late onset, chronic conditions like autism by using acute vaccine reactions like fever, pain and vomiting (presumably attributable to other vaccine components) as controls makes no sense as a measure of relative adverse event rates.

Dr. Geier presented several additional publications that also contained studies in which the Geiers compared adverse event reports filed with VAERS with regard to thimerosal-containing and thimerosal-free vaccines. In each of the studies, Geier and Geier continued assigning (despite the absence of total mercury exposure data), a higher cumulative thimerosal total to one group of children (those who filed a VAERS report regarding a TCV) than the other group *602 (those who filed a VAERS report regarding a thimerosal-free vaccine.) As a result, Geier and Geier concluded that the greater the total exposure to mercury from thimerosal, the greater the risk of neurological disorders. Critically, with regard to the pre-2004 published Geier and Geier VAERS database studies, the [IOM] opined:

(1) [t]he three studies have *serious methodologi-*

cal limitations that make their results uninterpretable;

(2) [t]he results of their studies are likewise improbable;

(3) [t]he articles also lack a complete and transparent description of their methods and underlying data, making it difficult to confirm or evaluate their findings.

Accordingly, the 2004 IOM Committee concluded that the Geier and Geier VAERS studies were not helpful with regard to the causation issue it considered, that is, whether thimerosal-containing vaccines can cause autism or autistic spectrum disorders. The 2004 IOM Committee Report concluded:

As a result of these significant methodological limitations, the committee finds the results of [Geier and Geier's] studies to be uninterpretable and, as such, they are noncontributory with respect to causality.

In addition, Geier and Geier analyzed the VSP database on no less than two occasions. The Geiers presented to the 2004 IOM Committee an unpublished analysis of USD data, but did not describe the basis for their calculation or their methods leading the 2004 IOM Committee to conclude that it “found the results of their analysis using VSP data uninterpretable, primarily due to the lack of a complete description of their methods.” Finally, the 2004 IOM Report reviewed Geier and Geier's Department of Education database and found that “[t]hese studies are characterized by serious methodological problems.”

Judge Berger concluded that, as a result of flawed analysis of acceptable data, Dr. Geier's epidemiological studies did not pass scrutiny under *Frye-Reed*:

*603 In sum, the plaintiffs rely on Dr. Geier's six epidemiological studies that purport **252 to find an association between thimerosal in vaccines and autism. However, *this Court finds that Dr. Geier's epidemiological studies do not constitute generally accepted bases for plaintiffs' causation opinions inasmuch as those studies have been rejected by the relevant scientific community due to severe methodological flaws that render them unreliable. Indeed, the venerable IOM Committee concluded*

that Dr. Geier's studies were not only flawed methodologically, but "uninterpretable," and therefore "noncontributory."

* * *

As a result, this Court finds expressly that Dr. Geier's epidemiological studies are not generally accepted in the scientific community because they utilize a methodology that is fundamentally flawed.

* * *

For the purposes of the *Frye-Reed* test, the "relevant scientific community" includes the full community of scientists with sufficient training and expertise to permit them to comprehend novel scientific methods, and may not properly be restricted to those who practice or otherwise adhere to the methods at issue. *Reed v. United States [State]*, *supra*, 283 Md. at 444, 391 A.2d 364. For the reasons stated in this Memorandum Opinion, the plaintiffs have failed to satisfy their burden of proof under *Frye-Reed*, because they have failed to show that the methodologies underlying their expert witness' opinions are generally accepted to be reliable in the relevant scientific community.

The consensus of the scientific community with expertise relevant to the issue of general causation in this case is reflected by the comprehensive and venerable report published by the Institute of Medicine in 2004. Moreover, other organizations have issued statements that comport with the comprehensive analysis supplied in the 2004 IOM Committee Report.

* * *

**604 It is well established that where an expert witness offers a novel medical theory of causation, the bases of the expert's opinion, including the theory of causation, and the methodologies, must all be generally accepted or reliable in the relevant scientific community. See Montgomery Mut. Ins. Co. v. Chesson, supra, 399 Md. at 327, 923 A.2d 939 (2007). This Court finds that it is generally accepted in the relevant scientific community that autism is genetic in origin except in rare instances of prenatal exposures to certain substances at defined*

periods during pregnancy. Further, for the reasons explicated in this Memorandum Opinion, this Court notes that it is generally accepted in the relevant scientific community that thimerosal in vaccines does not cause or contribute to neurodevelopmental disorders such as autism.

Critical to this Court's analysis is the 2004 IOM Report. IOM Reports are highly regarded in the relevant scientific community, and their reliability has been recognized by numerous courts.... After careful consideration by this Court, the 2004 Committee's finding that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism" is generally accepted in the relevant scientific community.

*After reviewing the testimony and evidence, this Court finds that the fields of epidemiology and toxicology and genetics are central to many of the issues in **253 this case, including the causation issues that have been presented in this proceeding. For the reasons stated in this Memorandum Opinion, Dr. Geier's epidemiological studies purporting to show an association between thimerosal-containing vaccines and autism were not conducted in accordance with generally accepted epidemiological methods.*

(Emphasis added).

Although we have not in the past had occasion to scrutinize the analytical phase of a scientific process underlying a novel scientific opinion, where the underlying data may otherwise be generally accepted in the scientific community, various federal *605 courts have had occasion to scrutinize the *reliability* of the analytical framework utilized by an expert in formulating a novel theory of science, and to them we turn, recognizing that they utilized the *Daubert* standard rather than *Frye*.^{FN19} We explore what they have opined, nevertheless, when they are speaking about reliability.

FN19. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589, 113 S.Ct. 2786, 2794, 125 L.Ed.2d 469, 480 (1993), the Supreme Court held that Federal Rules of Evidence superseded the common law and that *Frye* is an "austere standard, absent from, and incompatible with, the Federal

Rules of Evidence” that “should not be applied in federal trials.” Currently under Federal Rules of Evidence, Rule 702, expert opinion testimony is admissible if the subject matter is one where “scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, ... the witness qualified as an expert by knowledge, skill, experience, training, or education ... [and] (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” Fed.R.Evid. 702. See generally *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999); *Daubert*, 509 U.S. at 579, 113 S.Ct. at 2786, 125 L.Ed.2d at 469.

The Supreme Court in *General Electric Company v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997), recognized that the analysis employed by an expert must be reliable. In *Joiner*, an electrician, alleging that his small cell lung cancer was caused by exposure to polychlorinated biphenyls (PCBs) and to furans and dioxins (PCB derivatives), sued the manufacturers of the products and attempted to introduce expert testimony linking his exposure to the chemicals to his small cell lung cancer. The trial judge excluded the testimony, reasoning that the expert's conclusions did not rise above “subjective belief or unsupported speculation,” *Joiner v. General Electric Co.*, 864 F.Supp. 1310, 1326 (N.D.Ga.1994), and then granted summary judgment in favor of the manufacturer. The Court of Appeals for the Eleventh Circuit reversed, *Joiner v. General Electric Co.*, 78 F.3d 524, 533 (11th Cir.1996), holding that the District Court should not have excluded expert testimony that merely “drew different conclusions from the research than did each of the experts,” and that the *606 court should have permitted the “jury to decide the correctness of competing expert opinions.”

The Supreme Court reversed the Eleventh Circuit and excluded the expert's testimony. The Court recognized that the analysis of data or extrapolation requires more than mere conjecture to pass reliability scrutiny:

[Joiner] claims that because the District Court's disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error and was properly reversed by the Court of Appeals. *But conclusions and methodology are not entirely distinct from one another.* Trained experts commonly extrapolate from existing data. But *nothing* in either *Daubert* or the Federal Rules of Evidence *requires**254 a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.*

Joiner, 522 U.S. at 146, 118 S.Ct. at 519, 139 L.Ed.2d at 518-19, citing *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.1992) (When “[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects is too wide a jury should not be asked to speculate on the issue of causation.”). In calling attention to the “analytical gap” between existing data and the opinion proffered by an expert, the Court admonished against reliance solely on an expert's word that his conclusion is appropriate to the underlying data and methods. *Id.* This concept of “analytical gap” had been employed by federal courts before *Joiner*, see *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir.1996) (“When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the [trial] court should be wary that the method has not been faithfully applied.”), and even before *Daubert*. See *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1115 (5th Cir.1991) (en banc) (“When analyzing the validity of an expert's methodology, we seek to determine *607 whether it connects the facts to the conclusion in a scientifically valid way. We answer this question by applying the *Frye* test: whether the methodology or reasoning that the expert uses to connect the facts to his conclusion is generally accepted within the relevant scientific community.”).

Since *Joiner*, the concept of the “analytical gap” also has been applied by numerous federal appellate courts. See, e.g., *Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 898 (8th Cir.2008) (affirming a trial judge's exclusion of expert testimony from plaintiff's treating physician, who linked plaintiff's exercised-

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induced asthma to her inhalation and ingestion of freon that was allegedly sprayed into her water bottle by a Verizon employee, and holding that there was “simply too great an analytical gap” between “the data identified and [the expert’s] proffered opinion” because the expert “lacked knowledge regarding what level of exposure to freon constitutes an appreciable risk of causing asthma and the specific concentration and degree of [plaintiff’s] exposure to the freon”); *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254-255 (2d Cir.2005) (excluding expert testimony that medication was capable of causing or exacerbating cirrhosis because the expert’s failure to consider other causes when employing differential diagnosis created “too great an analytical gap between the data and the opinion proffered”); *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir.2003) (discussing the “analytical gap” when holding, “[t]he problem with the proposed testimony in this case does not lie in the quality of [the experts’] research ... [but in] the absence of an empirical link between that research and the opinion that [defendant] likely gave a false confession”).

The “analytical gap” concept also has been employed by some of our sister states in a *Frye* analysis. In *Goeb v. Tharaldson*, 615 N.W.2d 800, 816 (Minn.2000), for example, the Minnesota Supreme Court upheld the exclusion of expert testimony because the methodology was unreliable and the conclusions proffered exhibited “too great a leap” from the data gathered. The Goebes had sued a pesticide applicator, Tharaldson, and Dow Chemical, the manufacturer, alleging *608 that exposure to the insecticide Dursaban, after it was sprayed in the house into which they were moving, **255 caused injury to them and their child. The Goebes offered the testimony of two experts, both of whom would have testified, based on the Goebes’ medical records referring to adverse health affects, as well as on the toxic levels of the chemical chlorpyrifos in their bodies,^{FN20} that the Goebes were suffering from organophosphate^{FN21} poisoning caused by their exposure to Dursaban. *Id.* at 806-08. Dow had argued that the experts’ conclusion should be excluded under *Frye* because the Goebes’ level of exposure was not factored into their analysis. After the expert testimony was excluded, the Goebes sought review, arguing that the experts’ testimony had been based upon generally accepted methodologies. The court affirmed, accepting the contention that the experts had used generally accepted methods in completing their tests, but reject-

ing the experts’ analysis when affirming the trial judge’s conclusion “that [the expert] made too great a leap to get from ‘mere exposure of an unquantified amount of Dursban’ to his conclusions about appellants’ illnesses.” *Id.* at 816. See also *Kane v. Motorola, Inc.*, 335 Ill.App.3d 214, 221-22, 268 Ill.Dec. 688, 779 N.E.2d 302 (2002) (discussing *Joiner* and the “analytical gap” concept when applying a *Frye* analysis).

FN20. Chlorpyrifos is a chemical that is commonly used in pesticides.

FN21. Organophosphates are “[a] series of phosphorus-containing organic compounds ... [that are] [u]sed as insecticides [and] have also been used as gases in warfare.” Stedman’s, *supra*, at 1380.

[3][4] Generally accepted methodology, therefore, must be coupled with generally accepted analysis in order to avoid the pitfalls of an “analytical gap.” Dr. Geier’s faulty extrapolation from VAERS data, a potentially reliable source, manifests the *ipsa dixit* identified in the *Joiner* opinion because his conclusion is ethereal. The conclusion is ethereal because the bases of the expert’s opinion, including the theory of causation, and the methodologies, are not “generally accepted as reliable within the expert’s particular scientific field,” see *Chesson*, 399 Md. at 327, 923 A.2d at 947, and the data he relies upon was *609 not tested nor gathered for the purpose of testing the hypothesis that thimerosal in vaccines causes autism. None of Dr. Geier’s research aimed at establishing a link between thimerosal and autism, moreover, is based upon sound methodology. See, e.g., Mark R. Geier & David A. Geier, *Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication*, 228 *Experimental Biology and Med.* 660, 660-64 (2003) (relying on VAERS data); Mark R. Geier & David A. Geier, *Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States*, 8 *J. Am. Physicians and Surgeons*, Spring 2003, at 6-11 (relying on VAERS data); David A. Geier & Mark R. Geier, *An Assessment of the Impact of Thimerosal on Childhood Neurodevelopmental Disorders*, 6 *Pediatric Rehabilitation*, Apr.-June 2003, at 97-102 (relying on VAERS data); David A. Geier & Mark R. Geier, *A Comparative Evaluation of the Effects of MMR Immunization and Mercury Doses from Thimerosal-Containing*

Childhood Vaccines on the Population Prevalence of Autism, 10 Med. Sci. Monitor, Mar. 2004, at P133-39 (relying on Department of Education data); David A. Geier & Mark R. Geier, *Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis*, 23 Int'l J. of Toxicology 369, 369-376 (2004) (relying on VAERS data); Mark R. Geier & David A. Geier, *The Potential Importance of Steroids in the Treatment of Autism **256 Spectrum Disorders and Other Disorders Involving Mercury Toxicity*, 64 Med. Hypotheses 946, 946-954 (2005) (merely suggesting a series of experiments that need to be conducted to potentially develop steroid treatments to reduce the affects of mercury poisoning); David A. Geier & Mark R. Geier, *A Two Phased Population Epidemiological Study of the Safety of Thimerosal-Containing Vaccines: A Follow-Up Analysis*, 11 Med. Sci. Monitor, Apr. 2005, at CR160-70 (relying on VAERS data); David A. Geier & Mark R. Geier, *An Assessment of Downward Trends in Neurodevelopmental Disorders in the United States Following Removal of Thimerosal from Childhood Vaccines*, 12 Med. Sci. Monitor, June 2006, at CR231-39 (relying on VAERS data); David A. Geier *610 & Mark R. Geier, *An Evaluation of the Effects of Thimerosal on Neurodevelopmental Disorders Reported Following DTP and Hib Vaccines in Comparison to DTPH Vaccine in the United States*, 69 J. Toxicology and Env'tl. Health 1481, 1481-95 (2006) (relying on VAERS data); David A. Geier & Mark R. Geier, *A Meta Analysis Epidemiological Assessment of Neurodevelopmental Disorders Following Vaccines Administered from 1994 through 2000 in the United States*, 27 Neuroendocrinology Letters, May 2006, at 401-13 (relying on VAERS data); David A. Geier & Mark R. Geier, *A Clinical and Laboratory Evaluation of Methionine Cycle-Transsulfuration and Androgen Pathway Markers in Children with Autistic Disorders*, 66 Hormone Research 182, 182-188 (2006) (studying 16 pre-pubertal children, 11 and under, with previously diagnosed autism and suggesting a possible interaction between a particular alpha-amino acid cycle, the methionine cycle-transsulfuration, and androgen pathways in some children with autism); David A. Geier & Mark R. Geier, *A Prospective Assessment of Porphyrins in Autistic Disorders: A Potential Marker for Heavy Metal Exposure*, 10 Neurotoxicity Research, Aug. 2006, at 57, 62 (studying urine samples of 37 children age-7 and under and concluding, "[t]his study provides the first clinical evidence from Americans with [autism] that associ-

ates them with specific urinary porphyrin markers known to be associated with heavy metals.... The results ... provide insights into the apparent dose-response effect mercury exposure may have in some children with [autism], and suggest that additional research should be conducted to evaluate mercury exposure in [autism] ") (emphasis added); David A. Geier & Mark R. Geier, *A Clinical Trial of Combined Anti-Androgen and Anti-Heavy Metal Therapy in Autistic Disorders*, 27 Neuroendocrinology Letters, Oct. 2006, at 833-38 (administering the drugs LUPRON and CHEMET to 11 children to lower their androgen levels or heavy-metal levels respectively, and observing amelioration of autistic symptoms in some of those children obtaining reduced androgen levels).

*611 [5] In attempting to avoid the pitfalls of postulating a direct causal link between thimerosal and autism, which would require accountability for those children who had been vaccinated without becoming autistic, Dr. Geier postulated an alternative hypothesis-that thimerosal in vaccines cause autism in certain genetically susceptible individuals. According to Judge Berger's findings, this hypothesis was apparently inspired by statements made in the 2001 and 2004 IOM Report-that a link is "biologically plausible," and that it is well settled that even a large well-designed epidemiological study might fail to detect "the possibility that vaccines contribute to autism in some small subset of cases or very unusual circumstances." Two predicates of Dr. Geier's alternative theory are that (1) autism is associated **257 with certain genes-the A1298C polymorphism in the MTHFR gene, the null polymorphism of the GSTMI gene, the I105V polymorphism of the GSTPI gene, the I114T, R197Q, and K268R polymorphisms in the NATZ gene, and an unspecified variant in the CYP3A4 gene; and (2) based on a differential diagnoses analysis,^{FN22} Jamarr's neurological disorders were caused or exacerbated by his exposure to thimerosal because of his genetic susceptibility. We shall first address Judge Berger's factual findings with respect to these predicates, as well as the Blackwells' challenges thereto, under the clear error standard,^{FN23} and then shall evaluate de novo Judge Berger's ultimate conclusion-that neither the genetic susceptibility theory *612 nor the tests used to determine if Jamarr's autism was due to genetic susceptibility were generally accepted in the relevant scientific field. See *Wilson*, 370 Md. at 201-02 n. 5, 803 A.2d at 1040 n. 5.

FN22. Differential diagnosis, which essentially is a process of elimination, has been defined as, “[t]he process of weighing the probability of one disease versus that of other diseases possibly accounting for a patient’s illness. The differential diagnosis of rhinitis (a runny nose) includes allergic rhinitis (hayfever), the abuse of nasal decongestants and, of course, the common cold.” MedicineNet.com, Differential Diagnosis Definition, <http://www.medterms.com/script/main/art.asp?articlekey=2991> (last visited May 5, 2009).

FN23. We review a challenge to the factual findings of trial judge for “clear error,” considering “the evidence in the light most favorable to the prevailing party and decide not whether the trial judge’s conclusions of fact were correct, but only whether they were supported by a preponderance of the evidence.” *City of Bowie v. MIE, Props., Inc.*, 398 Md. 657, 676, 922 A.2d 509, 521 (2007).

In rejecting the association of autism with certain gene polymorphisms identified by Dr. Geier, Judge Berger found that, although “[t]he 2004 IOM Committee found that a genetic susceptibility could indeed constitute a ‘theoretical explanation’ for the fact that reliable epidemiological studies have not found any association between thimerosal exposure and autism,” it, nevertheless, “found no corroborating data in the laboratory, in animals, or in humans, linking vaccines or vaccine components for autism based on genetic susceptibility.” He also found that “there is no evidence that the presence of these polymorphisms impairs the body’s ability to excrete mercury.”

During oral argument before us, the Blackwells’ attorney specifically challenged Judge Berger’s generalized factual finding, “that there is no evidence that any of the polymorphisms identified by Dr. Geier are associated with autism,” arguing that the Blackwells submitted three studies that provided such evidence: Steven Buyske, et al., *Analysis of Case-Parent Trios at a Locus with a Deletion Allele: Association of GSTM1 with Autism*, 7 BMC Genetics, Feb. 2006, at 1-16; G.A. Westphal, et al., *Homozygous Gene Dele-*

tions of the Glutathione S-Transferases M1 and T1 Are Associated with Thimerosal Sensitization, 73 Inter. Archives of Occupational Health, 384, 384-88 (2000); and S. Jill James, et al., *Metabolic Endophenotype and Related Genotypes Are Associated with Oxidative Stress in Children With Autism*, 26 Am. J. of Med. Genetics 947, May 2006, at 947-56. Judge Berger made the contested statement in the following paragraph where he discussed his general findings with respect to Dr. Geier’s identified polymorphisms:

Autism is likely to involve multiple genes. Dr. Geier testified that the following genes are associated with autism: the A1298C polymorphism in the MTHFR gene; the null polymorphism of the GSTM1 gene; the 1105V polymorphism**258 of *613 the GSTP1 gene; the I114T, R197Q, and K268R polymorphisms in the NAT2 gene; and an unspecified variant in the CYP3A4 gene. There is no evidence that any of the polymorphisms identified by Dr. Geier are associated with autism. None of the polymorphisms is generally accepted among clinical geneticists to be causes of autism. Further, despite the theories advanced by Dr. Geier, there is no evidence that the presence of these polymorphisms impairs the body’s ability to excrete mercury.

Judge Berger subsequently supported these general findings with specific findings: first, he found that “there is no evidence that the A1298C polymorphism in the MTHFR gene is associated with autism,” based on “[a] 2004 study by Boris, et al., and a follow-up study by one of the co-authors of that 2004 study, Jill James (among others), both showed no statistically significant association between the MTHFR 1298A/C polymorphism and autism.” See Marvin Boris et al., *Association of MTHFR Gene Variants with Autism*, 9 J. of Am. Physicians and Surgeons, Winter 2004, at 106, 107; James, *supra* at 951. Judge Berger next found that “it is well established that common genetic polymorphisms that vary across ethnic groups, such as the MTHFR 1298A/C polymorphism, are not considered by geneticists to be candidates for causation of a disease, such as autism, that has equal prevalence among ethnic groups,” observing that the MTHFR 1298A/C polymorphism exhibited this variance according to a Single Nucleotide Polymorphism Cluster Report database.^{FN24} Judge Berger then addressed Dr. Geier’s identification of the null polymorphism, finding:

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FN24. The NCBI, or Single Nucleotide Polymorphism database, is provided by the National Institutes of Health and is available at <http://www.ncbi.nlm.nih.gov>. The specific Cluster Report relied upon by Judge Berger is available at http://www.ncbi.nlm.nih.gov/SNP/snp_ref.cgi?rs=1695.

The GSTMI null polymorphism refers to a condition in which the GSTMI gene is missing. The purported association between the GSTMI polymorphism and autism has been investigated and rejected in several studies. No study has found an association between the GSTMI null polymorphism*614 and autism. Further, there is no evidence that the absence of the GSTMI gene is associated with autism.

He based this determination primarily on studies by James, *supra*, at 947-56, and Buyske, *supra*, at 1-16.

The existence of articles from Buyske, Westphal and James, proffered by the Blackwells, do not contradict, with any significance, Judge Berger's specific factual findings: Buyske's article, *Analysis of Case-Parent Trios at a Locus with a Deletion Allele: Association of GSTMI with Autism*, defines what he considers to be the appropriate methodology to test for a possible association of a specific genotype with autism. Buyske, *supra*, at 1. Westphal's article, *Homozygous Gene Deletions of the Glutathione S-Transferases M1 and T1 are Associated with Thimerosal Sensitization*, discusses a study that he conducted, in which he tested allergic reactions to thimerosal in men and women over the age of 38, none of whom was identified as autistic; autism was not being studied. Westphal, *supra*, at 385. The James article, *Metabolic Endophenotype and Related Genotypes are Associated with Oxidative Stress in Children With Autism*, recognized its own limitation, "[g]iven the relatively small number of cases and controls in the present study," and suggested that "abnormal metabolic profile observed in a **259 significant proportion of autistic children suggests the provocative possibility that some autistic behaviors could be a neurologic manifestation of a genetically based systemic metabolic derangement." James, *supra*, at 954 (italics in original). Clearly, this article suggests a hypothesis for further testing—a hypothesis which does not bear on any purported relationship

between thimerosal and autism. Judge Berger supported his general finding that there was, "no evidence that any of the polymorphisms identified by Dr. Geier are associated with autism," with articles specifically addressing polymorphisms identified by Geier; he did not err in his finding.

In rejecting the methodology utilized by Dr. Geier of differential diagnosis to arrive at a genetic susceptibility thesis, Judge Berger recognized that "differential diagnosis is a methodology by which the cause of a medical problem is *615 identified by considering and then ruling out the potential causes until the most probable cause remains." According to Judge Berger, Dr. Geier had performed urinary porphyrin, ^{FN25} mercury toxicity, testosterone and genetic polymorphism ^{FN26} tests, but that none of them is "generally accepted by the medical community, including clinical geneticists and pediatricians, as appropriate tests for either the work-up of a patient with autism or to determine the underlying cause of autism." Noting as well that Dr. Geier's differential diagnosis methodology "fail[ed] to even consider the single most important alleged cause of autism"—unknown genetics—Judge Berger concluded that "causation opinions on the etiology of autism cannot be based on a differential diagnosis that includes thimerosal as a potential cause of autism because the science does not support the plaintiffs' purported theory of a causal connection between thimerosal-containing vaccines and autism":

FN25. A porphyrin urine analysis depends on testing urine for the existence of porphyrins, the excessive excretion of which may indicate the condition of porphyria. See Stedman's, *supra*, at 1542. Porphyrins are "[p]igments widely distributed throughout nature (e.g. heme, bile pigments, cytochromes)...." *Id.* at 1543. Porphyria is,

A diverse group of diseases in which the production of heme is disrupted. Porphyria is derived from the Greek word "porphyrá", which means purple. When heme production is faulty, porphyrins are overproduced and lend a reddish-purple color to urine. All forms of porphyrias are inherited. The key clinical features are skin sensitivity to sunlight and/or by intermittent acute attacks of abdominal and nerve pain.... Affected individuals are unable to

complete heme synthesis, and intermediate products, porphyrin or its precursors, accumulate....

MedicineNet.com, Porphyria Definition, <http://www.medterms.com/script/main/art.asp?articlekey=10360> (last visited May 5, 2009).

FN26. A polymorphism is “[a] variation in the DNA that is too common to be due merely to new mutation. A polymorphism must have a frequency of at least 1% in the population. Examples of polymorphisms include the genes for sickle cell disease, thalassemia and G6PD deficiency.” MedicineNet.com, Polymorphism Definition, <http://www.medterms.com/script/main/art.asp?articlekey=4992> (last visited May 5, 2009). See also Stedman's, *supra*, at 1536.

Further, Dr. Geier performed a differential diagnosis in this proceeding. It is generally accepted in the relevant scientific*616 community that differential diagnosis is a methodology by which the cause of a medical problem is identified [by] considering and then ruling out the potential causes until the most probable cause remains. It is well settled that “[g]enerally, it is not appropriate to rely on a differential diagnosis to prove general causation.” See *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F.Supp.2d 465, 477 (M.D.N.C.2006), citing, *Riggiero [Ruggiero] v. Warner-Lambert Co.*, **260 424 F.3d 249, 254 (2d Cir.2005). Indeed, “[a] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion.” *Doe v. Ortho-Clinical Diagnostics, Inc.*, *supra*, 440 F.Supp.2d at 471, quoting *Roche v. Lincoln Property Co.*, 278 F.Supp.2d 744, 751 (E.D.Va.2003), *aff'd* 175 Fed.Appx. 597, 603 (4th Cir.2006). It is noteworthy that other courts have acknowledged that Dr. Geier's methodology of differential diagnosis is fundamentally flawed, because he improperly “rules in” thimerosal as a potential cause of autism, and he cannot rule out the high likelihood that autism in any given individual was caused purely by genetic factors that do not require an environmental trigger. See *e.g. Doe v. Ortho-Clinical Diagnostics, Inc.*, *supra*, 440 F.Supp.2d [465] 405 (M.D.N.C.2006) (excluding

Dr. Geier's differential diagnosis); *Redfoot v. [B.F.] Ascher [& Co.]*, No. C 05 2045 PJH, 2007 WL 1593239 at 11. (Emphasis added).

The Blackwells contest Judge Berger's finding of fact that “Dr. Geier failed even to consider the single most important alleged cause of autism-[unknown genetics]”-when conducting differential diagnosis, arguing that Dr. Geier addressed genetics as a possible cause and that it is not generally accepted in the relevant scientific community that unknown genetics is “the single most important alleged cause” of this disorder. The Blackwells assert that Dr. Geier considered genetics and genetic interactions, but that, according to Dr. Geier, unknown genetics account for less than 5% of autism cases, and he need not discount all possible causes. Conversely,*617 Wyeth's expert, Dr. Yeboa, opined that unknown genetics “constitutes the most cases of autism,” a premise supported by the 2004 IOM Report (“Autism is a very complex disorder. A strong genetic component clearly exists.... As yet a biological marker specific for autism has not been defined. It is possible that Autism encompasses a spectrum of disease subtypes that have different etiologies.”), as well as other articles proffered to Judge Berger by both the Blackwells and Wyeth. See, *e.g.*, Boris, *supra*, at 106-07 (“Autism is a complex neurodevelopment disorder with numerous possible genetic and environmental influences.... A search for additional genomic and environmental risk factors should be undertaken.... It is unlikely that any single polymorphism accounts for the majority of autistic risk factors.”); Fatema J. Serajee et al., *Polymorphisms in Xenobiotic Metabolism Genes and Autism*, 19 J. of Child Neurology, June 2004, at 413, 413 (2004) (“Although there is an underlying genetic predisposition, the etiology of autism is currently unknown.”); A. Bailey, et al., *Autism as a Strongly Genetic Disorder: Evidence from a British Twin Study*, 25 Psychological Med. 63, 63 (1995); Lorna Wing & David Potter, *The Epidemiology of Autistic Spectrum Disorders: Is the Prevalence Rising?*, 8 Mental Retardation and Developmental Disabilities Res. Rev. 151, 152 (2002) (“As a result of the ever growing list of studies, autism is now seen as a disorder of the developing brain, mainly genetic in origin and part of a wider spectrum of disorders.”). Judge Berger did not err in finding that “a gene or series of interacting genes that have not yet been identified” is the “most prevalent alleged cause of autism,” based upon our review of the record. We

agree that Dr. Geier did not sufficiently consider genetics in his differential diagnosis equation. This conclusion is similar to that reached in *Wilson*, in which we recognized that the State's expert, in applying the product rule, did not account for a genetic **261 linkage between siblings, who may have died of SIDS, rather than been murdered by their father.

Based on Judge Berger's rejection of Dr. Geier's underlying hypothesis and methodology, i.e. the identification of specific *618 genes and differential diagnosis, we hold that Judge Berger's ultimate determination—that Dr. Geier's genetic susceptibility theory is no more than hypothesis and conjecture, devoid of a generally accepted methodology to support it—should not be disturbed by us.

B. Certification of Experts under Maryland Rule 5-702

We also address whether Judge Berger properly precluded the testimony of the Blackwells' experts based on their lack of proper qualifications under Maryland Rule 5-702, which governs the admissibility of expert testimony:

Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony.

In the context of Rule 5-702, we have previously stated that, “the admissibility of expert testimony is within the sound discretion of the trial judge and will not be disturbed on appeal unless clearly erroneous.” *Wilson*, 370 Md. at 200, 803 A.2d at 1039; *Deese v. State*, 367 Md. 293, 302-03, 786 A.2d 751, 756 (2001). Put another way, “it is well settled ... that the trial court's determination [regarding the qualification of experts] ... may be reversed if it is founded on an error of law or some serious mistake, or if the trial court clearly abused its discretion” and “will seldom constitute a ground for reversal.” *Radman v. Harold*, 279 Md. 167, 173, 367 A.2d 472, 476 (1977).

In *Radman*, we articulated the standard for evaluating the qualifications of an expert witness:

[A] witness may be competent to express an expert opinion if he is reasonably familiar with the subject under investigation, regardless of whether this special knowledge is based upon professional training, observation, actual experience, *619 or any combination of these factors. The classic formulation of this Court's views on the subject of the qualification of experts appears in [*Penn. Threshermen & Farmers'] Casualty Ins. Co. v. Messenger*], 181 Md. 295, 29 A.2d 653 (1943)], wherein it is stated:

It is a familiar rule of evidence that a witness, in order to qualify as an expert, should have such special knowledge of the subject on which he is to testify that he can give the jury assistance in solving a problem for which their equipment of average knowledge is inadequate. It is sufficient if the court is satisfied that the expert has in some way gained such experience in the matter as would entitle his evidence to credit. It is not a ground for excluding the testimony of an expert that he bases his statements in whole or in part upon what he has read, provided that his reading can be assumed to constitute part of his general knowledge adequate to enable him to form a reasonable opinion of his own. *A witness is qualified to testify as an expert when he exhibits such a degree of knowledge as to make it appear that his opinion is of some **262 value, whether such knowledge has been gained from observation or experience, standard books, maps of recognized authority, or any other reliable sources.* The knowledge of an expert in any science or art would be extremely limited if it extended no further than inferences from happenings within his own experience. His testimony is admitted because it is based on his special knowledge derived not only from his own experience, but also from the experiments and reasoning of others, communicated by personal association or through books or other sources.

Id. at 169-70, 367 A.2d at 474 (emphasis added) (internal citations omitted). Because *Radman* was a medical malpractice case, we also opined regarding specialized qualifications of medical experts:

In light of the fact that we have never treated expert medical testimony any differently than other types of expert testimony, *see Crews v. Director*, 245 Md. 174, 179, 225 A.2d 436, 439 (1967); *Ager v. Baltimore Transit Co.*, 213 Md. 414, *620 420, 132 A.2d 469, 472 (1957); *cf. Shilkret v. Annapolis Emergency Hosp.*, 276 Md. 187, 190, 349 A.2d 245, 247 (1975), we perceive no reason why a person who has acquired sufficient knowledge in an area should be disqualified as a medical expert merely because he is not a specialist or merely because he has never personally performed a particular procedure. Consequently, we are in substantial agreement with the reasoning of the Supreme Court of Connecticut as expressed in the following succinct statement from the recent case of *Fitzmaurice v. Flynn*, 167 Conn. 609, 356 A.2d 887, 892 (1975):

Recognizing the complexity of knowledge required in the various medical specialties, more than a casual familiarity with the specialty of the defendant physician is required. *The witness must demonstrate a knowledge acquired from experience or study of the standards of the specialty of the defendant physician sufficient to enable him to give an expert opinion as to the conformity of the defendant's conduct to those particular standards, and not to the standards of the witness' particular specialty if it differs from that of the defendant. It is the scope of the witness' knowledge and not the artificial classification by title that should govern the threshold question of admissibility.*

Id. at 171-72, 367 A.2d at 475 (emphasis added) (footnote omitted). *See also Ungar v. Handelsman*, 325 Md. 135, 146, 599 A.2d 1159, 1164 (1992) (citing *Radman*); *Consol. Mech. Contractors, Inc. v. Ball*, 263 Md. 328, 338-39, 283 A.2d 154, 159 (1971) (permitting expert to testify as to why that it was difficult for him to find a job for plaintiff because of plaintiffs' injuries); *Wolfinger v. Frey*, 223 Md. 184, 189-90, 162 A.2d 745, 748 (1960) (permitting general practitioner to testify as to cause of plaintiffs' injury).

[6] Before us, the Blackwells urge that Judge Berger abused his discretion by disqualifying their witnesses from testifying. Wyeth, having addressed the experts' credentials during *voir dire*, reasserts that the Black-

wells' experts lack the necessary knowledge, expertise, training or education to *621 offer an opinion about a causal relationship between thimerosal and autism. Although we agree with the Blackwells that generally there is "no reason why a person who has acquired sufficient knowledge in an area should be disqualified as a medical expert merely because he is not a specialist or merely because he has never personally performed a particular procedure," we cannot say, in this case, that Judge Berger **263 abused his discretion by adhering to "artificial classifications" of a specialty's title, without concern for "the witness' knowledge" and ability to convey valuable information to jurors. *See Radman* 279 Md. at 172, 367 A.2d at 475.

Deese v. State, 367 Md. at 302, 786 A.2d at 756, upon which the Blackwells rely, was a child abuse/felony murder case, in which a father was convicted of murdering his child, as a result of "shaken baby syndrome." There, we considered whether a doctor, who had been the director of pediatric emergency at Johns Hopkins Hospital with expertise in the areas of pediatrics and pediatric emergency medicine, could testify as to the cause of the child's death, despite admitting that he was neither a specialist nor board certified in the areas of pathology or forensic pathology.^{FN27} *Id.* at 301-04, 786 A.2d at 755-56. Quoting *Sippio v. State*, 350 Md. 633, 649, 714 A.2d 864, 872 (1998), we iterated that "[i]n order to determine whether a proposed witness is qualified to testify as an expert, the trial court must examine whether the witness has sufficient knowledge, skill, experience, training, or education pertinent to the subject of the testimony." We ultimately concluded that the trial judge did not abuse his discretion in admitting the testimony because, although forensic pathology might have been the most relevant field of expertise, "[the State's expert's] training in pediatrics and pediatric *622 emergency medicine, combined with his experience in dealing with victims of child abuse," sufficiently qualified him to testify as to the cause of the child's death. *Deese*, 367 Md. at 304, 786 A.2d at 757.

FN27. "Pathology" is, "[t]he form of medical science and specialty practice concerned with all aspects of disease, but with special reference to the essential nature, causes, and development of abnormal conditions, as well as the structural and functional changes that

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result from the disease processes.” Stedman's, *supra*, at 1442. The modifier *forensic*, moreover, as in forensic pathology, denotes “[use] in or suitable to courts of law or public debate.” Black's Law Dictionary, at 676 (8th ed.2004).

In *Massie v. State*, 349 Md. 834, 709 A.2d 1316 (1998), another case relied upon by the Blackwells, we addressed an expert's qualification in the area of forensics. Massie had been convicted of murder and argued that the trial judge abused his discretion in permitting a forensics police investigator, who was not a doctor of medicine, to testify that the victim had been dead for as long as five hours, or “from 11:15 a.m. at the earliest.” *Id.* at 838, 709 A.2d at 1317. The trial judge admitted the testimony, finding that although the investigator was not a pathologist, he had substantial experience in the area of forensic science, taught courses in the area, and was present at the scene to collect evidence and examine the victim's body. We affirmed, noting that “[t]ime of death is a subject which courts have long recognized as an appropriate one for expert testimony,” and that “[i]n the instant matter [the expert's] examination of the deceased's body gave him a sufficient factual basis to support opinion testimony,” so that the expert, “by virtue of his experience, training, and education, had special knowledge on the subject beyond the experience of the jurors and that [the] opinion would assist the jury.” *Id.* at 851, 709 A.2d at 1324.

Further, in *In re: Yve S.*, 373 Md. 551, 819 A.2d 1030 (2003), we addressed when a witness is not qualified. In that case, a mother had challenged a determination by the Montgomery County Department of Health and Human Services changing her 12-year-old daughter's permanency plan from reunification with the mother to permanent foster care-presenting a judge of the Circuit Court for Montgomery **264 County with the question of whether “the mother's mental illness had stabilized to the point where she could take care of her daughter properly ... [and whether] neglect [would] be repeated.” *Id.* at 613-14, 819 A.2d at 1067. During the review hearing, the judge permitted, over the mother's objection, the testimony of a social worker, who opined that the mother appeared to relapse into another manic episode during trial and that *623 although the mother had done “an amazing job in the last two years” of stabilizing herself, the pressure of caring for Yve S.,

who had special needs, would cause her to relapse, such that a placement with the mother would not last. *Id.* at 615, 819 A.2d at 1068. The trial judge, thereafter, entered an order establishing permanent foster care as the goal of the permanency plan, and the Court of Special Appeals affirmed; we granted certiorari, in part, to address whether the admission of the social worker's opinion was prejudicial error. In reversing and remanding, we held that the circuit court judge erred by admitting the social worker's testimony, because she was not qualified to make a “complex” medical diagnosis of mental illness nor to speculate as to the mother's future ability to control her illness:

These statements [by the social worker] are not only speculative, but amount to a lay diagnosis or prognosis regarding a complex medical issue. [The social worker] is not qualified to do that, as she was not qualified as a psychiatrist, psychologist, or licensed clinical social worker. The testimony was improper and should have been stricken.

Id. at 615-16, 819 A.2d at 1068. Hence, when “complex medical issue[s]” or diagnoses are in question, we have required a specificity of knowledge, skill, experience, training, or education for qualification.

With this in mind, we turn to Judge Berger's findings and determinations regarding the Blackwells' experts. Judge Berger initially found that the field of epidemiology was the “single most relevant field of science to the general causation issue presented in this case, i.e., whether thimerosal-containing vaccines can cause autism,” and also found that, “[a]fter reviewing the testimony and evidence, this Court finds that the fields of epidemiology, toxicology and genetics are central to many of the issues in this cause, including the causation issues that have been presented in this proceeding,”^{FN28} on the following basis:

FN28. The Blackwells do not contest the finding that epidemiology is the relevant field, but rather dispute that their experts are not qualified under Rule 5-702 to offer an opinion based upon epidemiological principles.

*624 Epidemiology is the science that studies the distribution of diseases within populations and determines diseases in populations. Accordingly,

medical causality is central to the field of epidemiology. It is the finding of this Court that epidemiology is the single most relevant field of science to the general causation issue presented in this case, i.e., whether thimerosal-containing vaccines can cause autism. The 2004 IOM Report specifically notes that “[e]pidemiologic studies carry the most weight in a causality assessment.” That is so because in epidemiology, an association between an exposure and a health outcome generally occurs more frequently in people with one type of exposure than in those who do not have the exposure. This is not to suggest that one must be an epidemiologist or rely on epidemiological studies to testify on the issues associated with this proceeding. However, it is significant to note that Drs. Haley, Deth, Mumper and Siebert are not epidemiologists, and **265 were not proffered to the Court that they were qualified in the field of epidemiology. Plaintiffs proffered Dr. Mark Geier as their lone expert witness in the field of epidemiology.

When specifically addressing the credentials of the Blackwells' five experts, Judge Berger also made the following findings regarding the experts' lack of qualification to conduct epidemiological, toxicological and genetic empirical research:

Dr. Mark Geier

With respect to Dr. Geier, Judge Berger found that, in addition to being a board-certified genetic counselor, he had been proffered as an expert in genetics, “vaccine injuries,” “differential etiology of autism,” “mercury toxicity,” medicine, “urinary porphyrin analysis” and epidemiology; that he “is not an epidemiologist or toxicologist,” with no degree or board certification in either field, and that nothing regarding “his knowledge, skill, training, experience, or education” made him *625 qualified to testify under Maryland Rule 5-702: “Dr. Geier's credentials as a medical doctor and a genetic counselor are not a foundation sufficient for him to offer an opinion that thimerosal-containing vaccines cause autism.” Judge Berger also noted that, in at least one federal case, Dr. Geier had been deemed unqualified to testify as an expert regarding the impact of the administration of thimerosal. *See, e.g., Redfoot v. B.F. Ascher & Co.*, 2007 WL 1593239, *11-12, 2007 U.S. Dist. LEXIS 40002, *36-37 (N.D.Cal.2007) (excluding the testimony of Dr. Geier under Federal Rule 702 in a case where he was proffered to testify that the Ayr Saline

Nasal Mist was defective in design because it contained thimerosal, which may have caused the plaintiffs' child's autism).

Dr. Boyd Haley

Judge Berger found that Dr. Haley is a Professor of Chemistry at the University of Kentucky at Lexington, that he was offered by the Blackwells as an expert in the fields of mercury toxicity, biochemistry and physiology, and that he was qualified in the areas of biochemistry and physiology by virtue of his knowledge, skill, experience, training and education. Judge Berger acknowledged, based in part on Dr. Haley's approximately 130 articles on neurodegeneration caused by mercury, that Dr. Haley was well-qualified to testify as to the general toxicity of mercury in human brain cells, but that he was not qualified to testify whether the administration of a vaccine containing thimerosal results in the exposure of a child's brain to mercury, whether autistic children metabolize and excrete mercury the way other children are able to, or whether thimerosal in childhood vaccines causes neurological damage in genetically susceptible children.

Dr. Richard Deth

Judge Berger found that “Dr. Deth teaches pharmacology at Northeastern University,” that “he was offered by the [Blackwells] as an expert in the areas of physiology, neuropharmacology and the effects of thimerosal in the human brain,” and that Dr. Deth was “clearly qualified to testify as an expert witness in the areas of physiology and neuropharmacology.”*626 Judge Berger, however, excluded Dr. Deth's testimony, because although he was qualified in these fields, his opinion “that exposure to mercury for thimerosal-containing vaccines causes autism,” would have required him to delve into fields of toxicology, epidemiology, neurology and genetics—all fields with which he had little or no expertise.

Dr. Elizabeth Mumper

With respect to Dr. Mumper, Judge Berger found that she is a general pediatrician in private practice in Virginia, that the Blackwells proffered her “as an expert **266 in the fields of pediatrics, in the diagnosis and treatment of children with neurodevelopmental disorders, including Attention Deficit Disorder,

learning disabilities and autism, and as an expert clinician in the field of diagnosing children with mercury toxicity, and treating children with mercury toxicity.” Although Dr. Mumper was qualified to testify regarding the diagnosis and treatment of children with neurodevelopmental disorders, Judge Berger determined that her experience was not relevant to the ability to assess the underlying cause of these conditions. Specifically, Judge Berger iterated, as he did when discussing Dr. Deth, that qualification to testify to causation would involve some expertise, knowledge or skill in the areas of epidemiology, toxicology or genetics.

Dr. Stephen Siebert

Judge Berger found that Dr. Siebert, who has a master's degree in public health and is board certified in the field of psychiatry, was qualified to testify in the fields of psychiatry and forensic psychiatry. As with the other experts of the Blackwells, however, Judge Berger found that Dr. Siebert's board certifications bore no relevance to the “appropriate basis for opinion testimony on the issue of whether thimerosal-containing vaccines can cause autism.” Further, Judge Berger noted that, although Dr. Siebert was well-qualified to testify to his diagnosis of Jamarr Blackwell as mentally retarded and autistic, he did not possess the expertise to testify regarding the causes of Jamarr's autism by nature of his knowledge and experience.

*627 In this case, Judge Berger did not receive Dr. Geier, as well as the other of the Blackwells' experts, as qualified to testify regarding causation because they were not qualified in the field of epidemiology, which he determined to be central to the Blackwells' claims. Although we recognize that Judge Berger excluded Dr. Geier's testimony under the third prong of Maryland Rule 5-702, which requires “a sufficient factual basis [to] exist [] to support the expert testimony,” and the *Frye-Reed* analysis, we, nevertheless, address Dr. Geier's credentials along with the four other experts, because *voir dire* of an expert is normally the threshold issue.

We have not had occasion to review the exclusion of witnesses based on *voir dire* of their credentials in a case where a complex and novel theory of science has been postulated. In *Massie* and *Deese*, we addressed expert specialization in the context of an ex-

pert's ability to execute a previously acceptable technique for determining the time or manner of death. In *Radman*, we held that an expert need not be specialized in a precise field where negligence had been alleged in order to opine about deviation from the standard of care. In each instance, we rebuffed challenges based on specialization in a relevant field, when we were presented with the expert's ability to perform an *accepted* technique.

When a novel theory of science is presented, however, its reliability and validity are dependent not only on the application of generally acceptable methodology and analyses, but also upon the knowledge, skill, experience, training or education of the scientist who purports to utilize them, because the expert must embody expertise in the *relevant* scientific field to be able to give an opinion regarding the results of the process of scientific discovery. One of our sister states, when confronted with this conundrum under a similar rule governing experts,^{FN29} identified three factors as **267 relevant in defining the minimal level of qualification necessary:

FN29. In *Rodgers v. State*, 205 S.W.3d 525, 527 (Tex.Crim.App.2006), the Texas Court of Criminal Appeals addressed the qualification of experts under Texas Rule 702, which is similar to Maryland Rule 5-702, and stated:

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.

*628 Appellate courts may consider several criteria in assessing whether a trial court has clearly abused its discretion in ruling on an expert's qualifications. First, is the field of expertise complex? The degree of education, training, or experience that a witness should have before he can qualify as an expert is directly related to the complexity of the field about which he proposes to testify. If the expert evidence is close to the jury's common understanding, the witness's qualifications are less important than when the evidence is well outside the jury's own experience. For example, DNA profiling is scien-

tifically complex; latent-print comparison (whether of fingerprints, tires, or shoes) is not.

Second, how conclusive is the expert's opinion? The more conclusive the expert's opinion, the more important is his degree of expertise. Testimony that "a given profile occurred one time in 2.578 sextillion (2.578 followed by 21 zeroes), a number larger than the number of known stars in the universe (estimated at one sextillion)" requires a much higher degree of scientific expertise than testimony "that the defendant's tennis shoe could have made the bloody shoe print found on a piece of paper in the victim's apartment."

And third, how central is the area of expertise to the resolution of the lawsuit? The more dispositive it is of the disputed issues, the more important the expert's qualifications are. If DNA is the only thing tying the defendant to the crime, the reliability of the expertise and the witness's qualifications to give his opinion are more crucial than if eyewitnesses and a confession also connect the defendant to the crime.

*629 *Rodgers v. State*, 205 S.W.3d 525, 528 (Tex.Crim.App.2006) (footnotes omitted). See *Radman v. Harold*, 279 Md. 167, 171 n. 2, 367 A.2d 472, 475 n. 2 (1977), quoting *Baltimore Refrigerating & Heating Co. of Baltimore v. Kreiner*, 109 Md. 361, 370, 71 A. 1066, 1070 (1909) ("[E]xpert capacity is a matter wholly relative to the subject of the particular inquiry."); See also *Faigman*, *supra*, at 41, ("[J]ust as with [federal] Rule 702 validity assessments, the judge's gate-keeping obligation should extend not merely to qualifications in the abstract, but qualifications to testify about the subject that is relevant to the issues in dispute.").

Although we do not apply the second prong, regarding the conclusiveness of the expert's opinion, because it would necessitate going to the merits of the expert's opinion prior to a review of credentials, we do believe that two of the factors are relevant in our analysis—those being whether the field of expertise is complex and whether the area of expertise is central to the resolution of the lawsuit. In the present case, clearly the level of complexity regarding the establishment of a causal relationship between the administration of a vaccine containing thimerosal and the

onset of autism is complex; to the extent that "establishing" such a conclusion is even possible, it involves the extrapolation from, and scientific review of, numerous studies spanning a gamut of fields and methodologies, and most particularly, available epidemiological studies. As Blackwells' counsel stated during oral **268 argument before this Court, their experts' causal conclusions are based on: (1) peer reviewed published epidemiological studies; (2) in vitro studies; (3) toxicological studies; (4) pharmacokinetic ^{FN30} studies that discuss the distribution of mercury throughout the body; (5) diagnostic tests of blood "to determine the level of glutathione in the body, which is a molecule necessary to eliminate mercury"; (6) porphyrin urine analysis to determine mercury toxicity; (7) differential diagnosis; and (8) "extrapolation from *630 animal studies and from other in vitro studies." It is noteworthy also, as the IOM Committee recognized in its 2004 Report, that any conclusion regarding the cause of autism is complicated by the fact that "autism," itself, is not a single disorder but a "set of developmental disorders characterized by sustained impairments in social interaction [and] communication," and that "autism," and "autistic spectrum disorders" refer to a "broad[] group of pervasive developmental disorders." IOM Report, at 3-4 (2004) (emphasis added).

FN30. Pharmacokinetics is a branch of pharmacology, "[r]elating to the disposition of drugs in the body (i.e., their absorption, distribution, metabolism, and elimination)." *Stedman's, supra*, at 1473.

That the complex field of epidemiology is central to the resolution of the lawsuit, moreover, is not disputed. The Blackwells have never challenged Judge Berger's finding that epidemiology, primarily, is the relevant field for establishing a causal relationship, nor do they dispute that the establishment of a causal relationship is dispositive to the outcome of the lawsuit. Their contention, rather, is that their experts were qualified to offer conclusions based on epidemiological principles.

Judge Berger, therefore, did not abuse his discretion when he required a specificity of knowledge, skill, experience, training or education related to the resolution of the lawsuit, and concluded that Drs. Geier's, Haley's, Deth's, Mumper's and Siebert's fields of expertise were not relevant to the specific bodies of

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science that purport to maintain generally acceptable scientific methods and analyses related to autism and its causes. Based upon all of the forgoing analysis, we agree with the well-reasoned and cogent opinion of Judge Berger.

**JUDGMENT OF THE CIRCUIT COURT FOR
BALTIMORE CITY AFFIRMED. COSTS IN
THIS COURT TO BE PAID BY APPELLANTS.**

Md.,2009.
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 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355,
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Supreme Court of the United States
 GENERAL ELECTRIC COMPANY, et al., Petition-
 ers,
 v.
 Robert K. JOINER, et ux.
 No. 96-188.

Argued Oct. 14, 1997.
 Decided Dec. 15, 1997.

City's electrician, who suffered from lung cancer, brought state court action against manufacturer of polychlorinated biphenyls (PCBs) and manufacturers of electrical transformers and dielectric fluid, alleging strict liability, negligence, fraud, and battery. Manufacturers removed action to federal court. The United States District Court for the Northern District of Georgia, 864 F.Supp. 1310, Orinda D. Evans, J., excluded testimony of electrician's experts and granted defendants' motion for summary judgment. Electrician appealed. The Eleventh Circuit Court of Appeals, Barkett, Circuit Judge, 78 F.3d 524, reversed. Certiorari was granted. The Supreme Court, Chief Justice Rehnquist, held that: (1) "abuse of discretion" standard applied to District Court's decision to exclude scientific evidence; (2) District Court did not abuse its discretion in excluding expert testimony based on studies indicating that infant mice developed cancer after receiving massive doses of PCBs; and (3) District Court did not abuse its discretion in excluding expert testimony based on epidemiological studies.

Reversed and remanded.

Justice Breyer concurred and filed opinion.

Justice Stevens concurred in part, dissented in part, and filed opinion.

West Headnotes

[1] Federal Courts 170B 823

170B Federal Courts
 170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.
 Most Cited Cases
 Abuse of discretion is the proper standard of review of district court's evidentiary rulings.

[2] Federal Civil Procedure 170A 2011

170A Federal Civil Procedure
 170AXV Trial
 170AXV(C) Reception of Evidence
 170Ak2011 k. In General. Most Cited
 Cases

Federal Courts 170B 823

170B Federal Courts
 170BVIII Courts of Appeals
 170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.
 Most Cited Cases
 Cases arise where it is very much a matter of discretion with district court whether to receive or exclude evidence; but appellate court will not reverse in such case, unless the ruling is manifestly erroneous.

[3] Evidence 157 508

157 Evidence
 157XII Opinion Evidence
 157XII(B) Subjects of Expert Testimony
 157k508 k. Matters Involving Scientific or
 Other Special Knowledge in General. Most Cited
 Cases

Evidence 157 555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.
 Most Cited Cases
 Fact that *Frye* test governing admission of expert scientific evidence was displaced by Rules of Evi-

118 S.Ct. 512
 522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48
 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355,
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dence does not mean that Rules themselves place no
 limits on admissibility of purportedly scientific evi-
 dence; nor is trial judge disabled from screening such
 evidence. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[4] Evidence 157 508

157 Evidence
 157XII Opinion Evidence
 157XII(B) Subjects of Expert Testimony
 157k508 k. Matters Involving Scientific or
 Other Special Knowledge in General. Most Cited
 Cases

Evidence 157 555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.
 Most Cited Cases
 Under Federal Rules of Evidence, trial judge must
 ensure that any and all scientific testimony or evi-
 dence admitted is not only relevant, but reliable.
 Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Evidence 157 508

157 Evidence
 157XII Opinion Evidence
 157XII(B) Subjects of Expert Testimony
 157k508 k. Matters Involving Scientific or
 Other Special Knowledge in General. Most Cited
 Cases

Evidence 157 555.2

157 Evidence
 157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.2 k. Necessity and Sufficiency.
 Most Cited Cases
 While Federal Rules of Evidence allow district courts
 to admit a somewhat broader range of scientific tes-
 timony than would have been admissible under *Frye*,
 they leave in place the "gatekeeper" role of trial
 judge in screening such evidence. Fed.Rules
 Evid.Rule 702, 28 U.S.C.A.

[6] Federal Courts 170B 823

170B Federal Courts
 170BVIII Courts of Appeals
 170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.
 Most Cited Cases
 In applying "abuse of discretion" review to rulings
 regarding admissibility of scientific testimony, court
 of appeals may not categorically distinguish between
 rulings allowing expert testimony and rulings which
 disallow it. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[7] Federal Courts 170B 823

170B Federal Courts
 170BVIII Courts of Appeals
 170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.
 Most Cited Cases
 Alleged fact that grant of summary judgment on basis
 of inadmissibility of expert scientific testimony was
 "outcome determinative" as to products liability ac-
 tion did not compel finding that it should have been
 subjected to a more searching standard of review than
 "abuse of discretion" standard. Fed.Rules
 Civ.Proc.Rule 56, 28 U.S.C.A.; Fed.Rules Evid.Rule
 702, 28 U.S.C.A.

[8] Federal Civil Procedure 170A 2543

170A Federal Civil Procedure
 170AXVII Judgment
 170AXVII(C) Summary Judgment
 170AXVII(C)3 Proceedings
 170Ak2542 Evidence
 170Ak2543 k. Presumptions. Most
 Cited Cases
 On motion for summary judgment, disputed issues of
 fact are resolved against moving party. Fed.Rules
 Civ.Proc.Rule 56, 28 U.S.C.A.

[9] Federal Civil Procedure 170A 2543

170A Federal Civil Procedure
 170AXVII Judgment
 170AXVII(C) Summary Judgment

118 S.Ct. 512
 522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48
 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355,
 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
 (Cite as: 522 U.S. 136, 118 S.Ct. 512)

170AXVII(C)3 Proceedings
 170Ak2542 Evidence
 170Ak2543 k. Presumptions. Most

Cited Cases

Question of admissibility of expert testimony is not
 issue of fact that, when disputed, is resolved against
 moving party on motion for summary judgment.
 Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; Fed.Rules
 Evid.Rule 702, 28 U.S.C.A.

[10] Federal Courts 170B 823

170B Federal Courts

170BVIII Courts of Appeals
 170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.

Most Cited Cases

Question of admissibility of expert testimony is re-
 viewable under "abuse of discretion" standard.
 Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[11] Federal Courts 170B 823

170B Federal Courts

170BVIII Courts of Appeals
 170BVIII(K) Scope, Standards, and Extent
 170BVIII(K)4 Discretion of Lower Court
 170Bk823 k. Reception of Evidence.

Most Cited Cases

Court of Appeals applied wrong standard in review-
 ing grant of summary judgment in favor of manufac-
 turers in products liability action, when Court applied
 "stringent" review based on its holding that rules
 governing admissibility of expert testimony displayed
 a preference for admissibility; such standard failed to
 give district court the deference that is the hallmark
 of abuse of discretion review. Fed.Rules
 Civ.Proc.Rule 56, 28 U.S.C.A.; Fed.Rules Evid.Rule
 702, 28 U.S.C.A.

[12] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157 557

157 Evidence

157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k557 k. Experiments and Results

Thereof. Most Cited Cases

District Court did not abuse its discretion in exclud-
 ing expert scientific testimony, offered by electrician
 as evidence that his cancer resulted from exposure to
 polychlorinated biphenyls (PCBs), based on studies
 indicating that infant mice developed cancer after
 receiving massive doses of PCBs injected directly
 into their peritoneums or stomachs; electrician was
 adult human being with far less alleged exposure to
 PCBs, and he developed different type of cancer than
 that developed by mice. Fed.Rules Evid.Rule 702, 28
 U.S.C.A.

[13] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion
 157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157 557

157 Evidence

157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k557 k. Experiments and Results

Thereof. Most Cited Cases

District Court did not abuse its discretion in exclud-
 ing expert scientific testimony, offered by electrician
 as evidence that his cancer resulted from exposure to
 polychlorinated biphenyls (PCBs), based on epide-
 miological study involving workers who had been
 exposed to PCBs; authors of study were unwilling to
 say that PCB exposure had caused workers' cancer.
 Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[14] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence
 157XII(D) Examination of Experts
 157k555 Basis of Opinion

118 S.Ct. 512
 522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Envtl. L. Rep. 20,227, 48
 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355,
 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
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157k555.10 k. Medical Testimony.
 Most Cited Cases

Evidence 157 ↪557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

District Court did not abuse its discretion in excluding expert scientific testimony, offered by electrician as evidence that his cancer resulted from exposure to polychlorinated biphenyls (PCBs), based on epidemiological study involving workers who had worked at PCB production plant; increase of incidence of cancer among workers was not statistically significant, and study did not suggest link between increase and exposure to PCBs. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[15] Evidence 157 ↪555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157 ↪557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

District Court did not abuse its discretion in excluding expert scientific testimony, offered by electrician as evidence that his cancer resulted from exposure to polychlorinated biphenyls (PCBs), based on epidemiological study involving workers who had been exposed to mineral oil; study made no mention of PCBs. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[16] Evidence 157 ↪555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.
 Most Cited Cases

Evidence 157 ↪557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

District Court did not abuse its discretion in excluding expert scientific testimony, offered by electrician as evidence that his cancer resulted from exposure to polychlorinated biphenyls (PCBs), based on epidemiological study involving workers who had been exposed to PCBs and had seen statistically significant increase in lung cancer deaths; workers had been exposed to numerous potential carcinogens. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[17] Evidence 157 ↪555.4(1)

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.4 Sources of Data

157k555.4(1) k. In General. Most

Cited Cases

District court is not required to admit opinion evidence which is connected to existing data only by ipse dixit of the expert; court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

****514 Syllabus^{FN*}**

FN* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

*136 After he was diagnosed with small-cell lung cancer, respondent Joiner and his wife (hereinafter jointly respondent) sued in Georgia state court, alleging, *inter alia*, that his disease was "promoted" by his

522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355, 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
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workplace exposure to chemical "PCB's" and derivative "furans" and "dioxins" that were manufactured by, or present in materials manufactured by, petitioners. Petitioners removed the case to federal court and moved for summary judgment. Joiner responded with the depositions of expert witnesses, who testified that PCB's, furans, and dioxins can promote cancer, and opined that Joiner's exposure to those chemicals was likely responsible for his cancer. The District Court ruled that there was a genuine issue of material fact as to whether Joiner had been exposed to PCB's, but granted summary judgment for petitioners because (1) there was no genuine issue as to whether he had been exposed to furans and dioxins, and (2) his experts' testimony had failed to show that there was a link between exposure to PCB's and small-cell lung cancer and was therefore inadmissible because it did not rise above "subjective belief or unsupported speculation." In reversing, the Eleventh Circuit applied "a particularly stringent standard of review" to hold that the District Court had erred in excluding the expert testimony.

Held:

1. Abuse of discretion-the standard ordinarily applicable to review of evidentiary rulings-is the proper standard by which to review a district court's decision to admit or exclude expert scientific evidence. Contrary to the Eleventh Circuit's suggestion, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469, did not somehow alter this general rule in the context of a district court's decision to exclude scientific evidence. *Daubert* did not address the appellate review standard for evidentiary rulings at all, but did indicate that, while the Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than did pre-existing law, they leave in place the trial judge's "gatekeeper" role of screening such evidence to ensure that it is not only relevant, but reliable. *Id.*, at 589, 113 S.Ct., at 2794-2795. A court of appeals applying "abuse-of-discretion" review to such rulings may not categorically distinguish between rulings allowing expert testimony and rulings which disallow it. Compare *Beech Aircraft Corp. v. Rainey*, 488 U.S. 137*137 153, 172, 109 S.Ct. 439, 451, 102 L.Ed.2d 445, with *United States v. Abel*, 469 U.S. 45, 54, 105 S.Ct. 465, 470, 83 L.Ed.2d 450. This Court rejects Joiner's argument that because the granting of sum-

mary judgment in this case was "outcome determinative," it should have been subjected to a more searching standard of review. On a summary judgment motion, disputed issues of fact are resolved against the moving party-here, petitioners. But the question of admissibility of expert testimony is not such an issue of fact, and is reviewable under the abuse-of-discretion standard. In applying an overly "stringent" standard, the Eleventh Circuit failed to give the trial court the deference that is the hallmark of abuse-of-discretion review. P. 517.

2. A proper application of the correct standard of review indicates that the District Court did not err in excluding the expert testimony at issue. The animal studies cited by respondent's experts were so dissimilar to the facts presented here-*i.e.*, the studies involved infant mice that developed alveogenic adenomas after highly concentrated, massive doses of PCB's were injected directly into their peritoneums or stomachs, whereas Joiner was an adult human whose small-cell carcinomas allegedly resulted from exposure on a much smaller scale-that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on those studies. Nor did the court abuse its discretion in concluding that the four epidemiological studies on which Joiner relied were not a sufficient basis for the experts' opinions, since the authors of two of those studies ultimately were unwilling to suggest a link between increases in lung cancer and PCB exposure among the workers they examined, the third study involved exposure to a particular type of mineral oil not necessarily relevant here, and the fourth involved exposure to numerous potential carcinogens in addition to PCB's. 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. Pp. 517-519.

3. These conclusions, however, do not dispose of the entire case. The Eleventh Circuit reversed the District Court's conclusion that Joiner had not been exposed to furans and dioxins. Because petitioners did not challenge that determination in their certiorari petition, the question whether exposure to furans and dioxins contributed to Joiner's cancer is still open. P. 519.

78 F.3d 524, reversed and remanded.

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REHNQUIST, C. J., delivered the opinion for a unanimous Court with respect to Parts I and II, and the opinion of the Court with respect to Part III, in which O'CONNOR, SCALIA, KENNEDY, SOUTER, THOMAS, GINSBURG, AND BREYER JJ., joined. BREYER, J., filed a concurring opinion, *138 *post*, p. 520. STEVENS, J., filed an opinion concurring in part and dissenting in part, *post*, p. 521. Steven R. Kuney, Washington, DC, for petitioner.

Lawrence G. Wallace, Washington, DC, for United States as amicus curiae.

Michael H. Gottesman, for respondents.

For U.S. Supreme Court briefs, see:1997 WL 304727 (Pet.Brief)1997 WL 436250 (Resp.Brief)1997 WL 536304 (Reply.Brief)

Chief Justice REHNQUIST delivered the opinion of the Court.

We granted certiorari in this case to determine what standard an appellate court should apply in reviewing a trial 139*139 court's decision to admit or exclude expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). We hold that abuse of discretion is the appropriate standard. We apply this standard and conclude that the District Court in this case did not abuse its discretion when it excluded certain proffered expert testimony.

I

Respondent Robert Joiner began work as an electrician in the Water & Light Department of Thomasville, Georgia (City), in 1973. This job required him to work with and around the City's electrical transformers, which used a mineral-oil-based dielectric fluid **516 as a coolant. Joiner often had to stick his hands and arms into the fluid to make repairs. The fluid would sometimes splash onto him, occasionally getting into his eyes and mouth. In 1983 the City discovered that the fluid in some of the transformers was contaminated with polychlorinated biphenyls (PCB's). PCB's are widely considered to be hazardous to human health. Congress, with limited exceptions, banned the production and sale of PCB's in 1978. See 90 Stat.2020, 15 U.S.C. § 2605(e)(2)(A).

Joiner was diagnosed with small-cell lung cancer in 1991. He ^{FN1} sued petitioners in Georgia state court the following year. Petitioner Monsanto manufactured PCB's from 1935 to 1977; petitioners General Electric and Westinghouse Electric manufactured transformers and dielectric fluid. In his complaint Joiner linked his development of cancer to his exposure to PCB's and their derivatives, polychlorinated dibenzofurans (furans) and polychlorinated dibenzodioxins (dioxins). Joiner had been a smoker for approximately eight years, his parents had both been smokers, and there was a history of lung cancer in his family. He was thus perhaps already at a heightened risk of developing lung cancer eventually. The suit alleged that his exposure to PCB's "promoted"*140 his cancer; had it not been for his exposure to these substances, his cancer would not have developed for many years, if at all.

FN1. Joiner's wife was also a plaintiff in the suit and is a respondent here. For convenience, we refer to respondent in the singular.

Petitioners removed the case to federal court. Once there, they moved for summary judgment. They contended that (1) there was no evidence that Joiner suffered significant exposure to PCB's, furans, or dioxins, and (2) there was no admissible scientific evidence that PCB's promoted Joiner's cancer. Joiner responded that there were numerous disputed factual issues that required resolution by a jury. He relied largely on the testimony of expert witnesses. In depositions, his experts had testified that PCB's alone can promote cancer and that furans and dioxins can also promote cancer. They opined that since Joiner had been exposed to PCB's, furans, and dioxins, such exposure was likely responsible for Joiner's cancer.

The District Court ruled that there was a genuine issue of material fact as to whether Joiner had been exposed to PCB's. But it nevertheless granted summary judgment for petitioners because (1) there was no genuine issue as to whether Joiner had been exposed to furans and dioxins, and (2) the testimony of Joiner's experts had failed to show that there was a link between exposure to PCB's and small-cell lung cancer. The court believed that the testimony of respondent's experts to the contrary did not rise above "subjective belief or unsupported speculation." 864 F.Supp. 1310, 1326 (N.D.Ga.1994). Their testimony

522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355, 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
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was therefore inadmissible.

The Court of Appeals for the Eleventh Circuit reversed. 78 F.3d 524 (1996). It held that “[b]ecause the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge’s exclusion of expert testimony.” *Id.*, at 529. Applying that standard, the Court of Appeals held that the District Court had erred in excluding the testimony of Joiner’s expert witnesses. The 141*141 District Court had made two fundamental errors. First, it excluded the experts’ testimony because it “drew different conclusions from the research than did each of the experts.” The Court of Appeals opined that a district court should limit its role to determining the “legal reliability of proffered expert testimony, leaving the jury to decide the correctness of competing expert opinions.” *Id.* at 533. Second, the District Court had held that there was no genuine issue of material fact as to whether Joiner had been exposed to furans and dioxins. This was also incorrect, said the Court of Appeals, because testimony in the record supported the proposition that there had been such exposure.

We granted petitioners’ petition for a writ of certiorari, 520 U.S. 1114, 117 S.Ct. 1243, 137 L.Ed.2d 325 (1997), and we now reverse.

**517 II

Petitioners challenge the standard applied by the Court of Appeals in reviewing the District Court’s decision to exclude respondent’s experts’ proffered testimony. They argue that that court should have applied traditional “abuse-of-discretion” review. Respondent agrees that abuse of discretion is the correct standard of review. He contends, however, that the Court of Appeals applied an abuse-of-discretion standard in this case. As he reads it, the phrase “particularly stringent” announced no new standard of review. It was simply an acknowledgment that an appellate court can and will devote more resources to analyzing district court decisions that are dispositive of the entire litigation. All evidentiary decisions are reviewed under an abuse-of-discretion standard. He argues, however, that it is perfectly reasonable for appellate courts to give particular attention to those decisions that are outcome determinative.

[1][2][3][4] We have held that abuse of discretion is the proper standard of review of a district court’s evidentiary rulings. *Old Chief v. United States*, 519 U.S. 172, 174 n. 1, 117 S.Ct. 644, 647 n. 1, 136 L.Ed.2d 574 (1997); *United States v. Abel*, 469 U.S. 45, 54, 105 S.Ct. 465, 470, 83 L.Ed.2d 450 (1984). Indeed, our cases on 142*142 the subject go back as far as *Spring Co. v. Edgar*, 99 U.S. 645, 658, 25 L.Ed. 487 (1879), where we said that “[c]ases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.” The Court of Appeals suggested that *Daubert* somehow altered this general rule in the context of a district court’s decision to exclude scientific evidence. But *Daubert* did not address the standard of appellate review for evidentiary rulings at all. It did hold that the “austere” *Frye* standard of “general acceptance” had not been carried over into the Federal Rules of Evidence. But the opinion also said:

“That the *Frye* test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence. Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” 509 U.S., at 589, 113 S.Ct., at 2794-2795 (footnote omitted).

[5][6][7][8][9][10] Thus, while the Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*, they leave in place the “gatekeeper” role of the trial judge in screening such evidence. A court of appeals applying “abuse-of-discretion” review to such rulings may not categorically distinguish between rulings allowing expert testimony and rulings disallowing it. Compare *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 172, 109 S.Ct. 439, 451, 102 L.Ed.2d 445 (1988) (applying abuse-of-discretion review to a lower court’s decision to exclude evidence), with *United States v. Abel*, *supra*, at 54, 105 S.Ct., at 470 (applying abuse-of-discretion review to a lower court’s decision to admit evidence). We likewise reject respondent’s argument that because the granting of summary judgment in this case 143*143 was “outcome determinative,” it

522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355, 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
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should have been subjected to a more searching standard of review. On a motion for summary judgment, disputed issues of fact are resolved against the moving party—here, petitioners. But the question of admissibility of expert testimony is not such an issue of fact, and is reviewable under the abuse-of-discretion standard.

[11] We hold that the Court of Appeals erred in its review of the exclusion of Joiner's experts' testimony. In applying an overly "stringent" review to that ruling, it failed to give the trial court the deference that is the hallmark of abuse-of-discretion review. See, e.g., *Koon v. United States*, 518 U.S. 81, 98-99, 116 S.Ct. 2035, 2046-2047, 135 L.Ed.2d 392 (1996).

III

We believe that a proper application of the correct standard of review here indicates that the District Court did not abuse its **518 discretion. Joiner's theory of liability was that his exposure to PCB's and their derivatives "promoted" his development of small-cell lung cancer. In support of that theory he proffered the deposition testimony of expert witnesses. Dr. Arnold Schecter testified that he believed it "more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure." App. 107. Dr. Daniel Teitelbaum testified that Joiner's "lung cancer was caused by or contributed to in a significant degree by the materials with which he worked." *Id.*, at 140.

Petitioners contended that the statements of Joiner's experts regarding causation were nothing more than speculation. Petitioners criticized the testimony of the experts in that it was "not supported by epidemiological studies ... [and was] based exclusively on isolated studies of laboratory animals." 3 Record, Doc. No. 46 (Defendants' Joint Memorandum in Support of Summary Judgment 3). Joiner responded by claiming that his experts had identified "relevant animal studies which support their opinions." 4 Record, Doc. No. 53 (Plaintiffs' Brief in Opposition to Defendants' 144*144 Motion for Summary Judgment 47). He also directed the court's attention to four epidemiological studies^{FN2} on which his experts had relied.

FN2. Epidemiological studies examine the pattern of disease in human populations.

[12] The District Court agreed with petitioners that the animal studies on which respondent's experts relied did not support his contention that exposure to PCB's had contributed to his cancer. The studies involved infant mice that had developed cancer after being exposed to PCB's. The infant mice in the studies had had massive doses of PCB's injected directly into their peritoneums^{FN3} or stomachs. Joiner was an adult human being whose alleged exposure to PCB's was far less than the exposure in the animal studies. The PCB's were injected into the mice in a highly concentrated form. The fluid with which Joiner had come into contact generally had a much smaller PCB concentration of between 0-to-500 parts per million. The cancer that these mice developed was alveolegenic adenomas; Joiner had developed small-cell carcinomas. No study demonstrated that adult mice developed cancer after being exposed to PCB's. One of the experts admitted that no study had demonstrated that PCB's lead to cancer in any other species.

FN3. The peritoneum is the lining of the abdominal cavity.

Respondent failed to reply to this criticism. Rather than explaining how and why the experts could have extrapolated their opinions from these seemingly far-removed animal studies, respondent chose "to proceed as if the only issue [was] whether animal studies can ever be a proper foundation for an expert's opinion." 864 F.Supp., at 1324. Of course, whether animal studies can ever be a proper foundation for an expert's opinion was not the issue. The issue was whether *these* experts' opinions were sufficiently supported by the animal studies on which they purported to rely. The studies were so dissimilar to the facts presented in this litigation*145 that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them.

[13] The District Court also concluded that the four epidemiological studies on which respondent relied were not a sufficient basis for the experts' opinions. The first such study involved workers at an Italian capacitor^{FN4} plant who had been exposed to PCB's. Bertazzi, Riboldi, Pesatori, Radice, & Zocchetti, Cancer Mortality of Capacitor Manufacturing Workers, 11 American Journal of Industrial Medicine 165 (1987). The authors noted that lung cancer deaths among ex-employees at the plant were higher than might have been expected, but concluded that "there

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were apparently no grounds for associating lung cancer deaths (although increased above expectations) and exposure in the plant." *Id.*, at 172. Given that Bertazzi et al. were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer.

FN4. A capacitor is an electrical component that stores an electric charge.

[14] The second study followed employees who had worked at Monsanto's PCB production plant. J. Zack & D. Musch, Mortality**519 of PCB Workers at the Monsanto Plant in Sauget, Illinois (Dec. 14, 1979)(unpublished report), 3 Record, Doc. No. 11. The authors of this study found that the incidence of lung cancer deaths among these workers was somewhat higher than would ordinarily be expected. The increase, however, was not statistically significant and the authors of the study did not suggest a link between the increase in lung cancer deaths and the exposure to PCB's.

[15][16] The third and fourth studies were likewise of no help. The third involved workers at a Norwegian cable manufacturing company who had been exposed to mineral oil. Ronneberg, Andersen, & Skyberg, Mortality and Incidence of Cancer Among Oil-Exposed Workers in a Norwegian Cable Manufacturing Company, 45 British Journal of Industrial*146 Medicine 595 (1988). A statistically significant increase in lung cancer deaths had been observed in these workers. The study, however, (1) made no mention of PCB's and (2) was expressly limited to the type of mineral oil involved in that study, and thus did not support these experts' opinions. The fourth and final study involved a PCB-exposed group in Japan that had seen a statistically significant increase in lung cancer deaths. Kuratsune, Nakamura, Ikeda, & Hirohata, Analysis of Deaths Seen Among Patients with Yusho-A Preliminary Report, 16 Chemosphere, Nos. 8/9, p. 2085 (1987). The subjects of this study, however, had been exposed to numerous potential carcinogens, including toxic rice oil that they had ingested.

[17] Respondent points to *Daubert*'s language that the "focus, of course, must be solely on principles and methodology, not on the conclusions that they

generate." 509 U.S., at 595, 113 S.Ct., at 2797. He claims that because the District Court's disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error and was properly reversed by the Court of Appeals. But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. See *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (C.A.6), cert. denied, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992). That is what the District Court did here, and we hold that it did not abuse its discretion in so doing.

We hold, therefore, that abuse of discretion is the proper standard by which to review a district court's decision to admit or exclude scientific evidence. We further hold that, because it was within the District Court's discretion to conclude that the studies upon which the experts relied were not 147*147 sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCB's contributed to his cancer, the District Court did not abuse its discretion in excluding their testimony. These conclusions, however, do not dispose of this entire case.

Respondent's original contention was that his exposure to PCB's, furans, and dioxins contributed to his cancer. The District Court ruled that there was a genuine issue of material fact as to whether Joiner had been exposed to PCB's, but concluded that there was no genuine issue as to whether he had been exposed to furans and dioxins. The District Court accordingly never explicitly considered if there was admissible evidence on the question whether Joiner's alleged exposure to furans and dioxins contributed to his cancer. The Court of Appeals reversed the District Court's conclusion that there had been no exposure to furans and dioxins. Petitioners did not challenge this determination in their petition to this Court. Whether Joiner was exposed to furans and dioxins, and whether if there was such exposure, the opinions of Joiner's experts would then be admissible, remain open questions. We accordingly reverse the judgment

522 U.S. 136, 118 S.Ct. 512, 177 A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355, 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284
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of the Court of Appeals and remand this case for proceedings consistent with this opinion.

It is so ordered.

****520** Justice BREYER, concurring.

The Court's opinion, which I join, emphasizes *Daubert*'s statement that a trial judge, acting as "gatekeeper," must "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Ante*, at 517 (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589, 113 S.Ct. 2786, 2795, 125 L.Ed.2d 469 (1993)). This requirement will sometimes ask judges to make subtle and sophisticated determinations about scientific methodology and its relation to the conclusions an expert witness seeks to offer—particularly when a case arises in an area where the science itself is tentative or 148*148 uncertain, or where testimony about general risk levels in human beings or animals is offered to prove individual causation. Yet, as *amici* have pointed out, judges are not scientists and do not have the scientific training that can facilitate the making of such decisions. See, e.g., Brief for Trial Lawyers for Public Justice as *Amicus Curiae* 15; Brief for New England Journal of Medicine et al. as *Amici Curiae* 2 ("Judges ... are generally not trained scientists").

Of course, neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the "gatekeeper" duties that the Federal Rules of Evidence impose—determining, for example, whether particular expert testimony is reliable and "will assist the trier of fact," Fed. Rule Evid. 702, or whether the "probative value" of testimony is substantially outweighed by risks of prejudice, confusion or waste of time, Fed. Rule Evid. 403. To the contrary, when law and science intersect, those duties often must be exercised with special care.

Today's toxic tort case provides an example. The plaintiff in today's case says that a chemical substance caused, or promoted, his lung cancer. His concern, and that of others, about the causes of cancer is understandable, for cancer kills over one in five Americans. See U.S. Dept. of Health and Human Services, National Center for Health Statistics, Health, United States 1996-97 and Injury Chartbook 117 (1997) (23.3% of all deaths in 1995). Moreover, scientific evidence implicates some chemicals as potential causes of some cancers. See, e.g., U.S. Dept.

of Health and Human Services, Public Health Service, National Toxicology Program, 1 Seventh Annual Report on Carcinogens, pp. v-vi (1994). Yet modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals. And it may, therefore, prove particularly important to see that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate 149*149 strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones. It is, thus, essential in this science-related area that the courts administer the Federal Rules of Evidence in order to achieve the "end [s]" that the Rules themselves set forth, not only so that proceedings may be "justly determined," but also so "that the truth may be ascertained." Fed. Rule Evid. 102.

I therefore want specially to note that, as cases presenting significant science-related issues have increased in number, see Judicial Conference of the United States, Report of the Federal Courts Study Committee 97 (Apr. 2, 1990) ("Economic, statistical, technological, and natural and social scientific data are becoming increasingly important in both routine and complex litigation"), judges have increasingly found in the Rules of Evidence and Civil Procedure ways to help them overcome the inherent difficulty of making determinations about complicated scientific, or otherwise technical, evidence. Among these techniques are an increased use of Rule 16's pretrial conference authority to narrow the scientific issues in dispute, pretrial hearings where potential experts are subject to examination by the court, and the appointment of special masters and specially trained law clerks. See J. Cecil & T. Willging, Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706, pp. 83-88 (1993); J. Weinstein, Individual Justice in Mass Tort Litigation 107-110 (1995); cf. Kaysen, In Memoriam: Charles E. Wyzanski, Jr., 100 Harv.L.Rev. 713, 713-715 (1987) (discussing a judge's use of an economist as a law clerk in *United States v. United Shoe Machinery Corp.*, 110 **521 F.Supp. 295 (Mass.1953), *aff'd*, 347 U.S. 521, 74 S.Ct. 699, 98 L.Ed. 910 (1954)).

In the present case, the New England Journal of Medicine has filed an *amici* brief "in support of nei-

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ther petitioners nor respondents" in which the Journal writes:

"[A] judge could better fulfill this gatekeeper function if he or she had help from scientists. Judges should be 150*150 strongly encouraged to make greater use of their inherent authority ... to appoint experts Reputable experts could be recommended to courts by established scientific organizations, such as the National Academy of Sciences or the American Association for the Advancement of Science." Brief, *supra*, at 18-19.

Cf. Fed. Rule Evid. 706 (court may "on its own motion or on the motion of any party" appoint an expert to serve on behalf of the court, and this expert may be selected as "agreed upon by the parties" or chosen by the court); see also Weinstein, *supra*, at 116 (a court should sometimes "go beyond the experts proffered by the parties" and "utilize its powers to appoint independent experts under Rule 706 of the Federal Rules of Evidence"). Given this kind of offer of cooperative effort, from the scientific to the legal community, and given the various Rules-authorized methods for facilitating the courts' task, it seems to me that *Daubert*'s gatekeeping requirement will not prove inordinately difficult to implement, and that it will help secure the basic objectives of the Federal Rules of Evidence, which are, to repeat, the ascertainment of truth and the just determination of proceedings. Fed. Rule Evid. 102.

Justice STEVENS, concurring in part and dissenting in part.

The question that we granted certiorari to decide is whether the Court of Appeals applied the correct standard of review. That question is fully answered in Parts I and II of the Court's opinion. Part III answers the quite different question whether the District Court properly held that the testimony of plaintiff's expert witnesses was inadmissible. Because I am not sure that the parties have adequately briefed that question, or that the Court has adequately explained why the Court of Appeals' disposition was erroneous, I do not join Part III. Moreover, because a proper answer to that question requires a study of the record that can be 151*151 performed more efficiently by the Court of Appeals than by the nine Members of this Court, I would remand the case to that court for application of the proper standard of review.

One aspect of the record will illustrate my concern.

As the Court of Appeals pointed out, Joiner's experts relied on "the studies of at least thirteen different researchers, and referred to several reports of the World Health Organization that address the question of whether PCBs cause cancer." 78 F.3d 524, 533 (C.A.11 1996). Only one of those studies is in the record, and only six of them were discussed in the District Court opinion. Whether a fair appraisal of either the methodology or the conclusions of Joiner's experts can be made on the basis of such an incomplete record is a question that I do not feel prepared to answer.

It does seem clear, however, that the Court has not adequately explained why its holding is consistent with Federal Rule of Evidence 702,^{FN1} as interpreted in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).^{FN2} In general, scientific testimony that is both relevant and reliable must be admitted and testimony that is irrelevant or unreliable **522 must be excluded. *Id.*, at 597, 113 S.Ct., at 2798-2799. In this case, the District Court relied on both grounds for exclusion.

FN1. Rule 702 states: "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."

FN2. The specific question on which the Court granted certiorari in *Daubert* was whether the rule of *Frye v. United States*, 54 App.D.C. 46, 293 F. 1013 (1923), remained valid after the enactment of the Federal Rules of Evidence, but the Court went beyond that issue and set forth alternative requirements for admissibility in place of the *Frye* test. Even though the *Daubert* test was announced in dicta, see 509 U.S., at 598-601, 113 S.Ct., at 2799-2800 (REHNQUIST, C.J., concurring in part and dissenting in part), we should not simply ignore its analysis in reviewing the District Court's rulings.

The relevance ruling was straightforward. The Dis-

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trict Court correctly reasoned that an expert opinion that exposure*152 to PCB's, "furans" and "dioxins" together may cause lung cancer would be irrelevant unless the plaintiff had been exposed to those substances. Having already found that there was no evidence of exposure to furans and dioxins, 864 F.Supp. 1310, 1318-1319 (N.D.Ga.1994), it necessarily followed that this expert opinion testimony was inadmissible. Correctly applying *Daubert*, the District Court explained that the experts' testimony "manifestly does not fit the facts of this case, and is therefore inadmissible." 864 F.Supp., at 1322. Of course, if the evidence raised a genuine issue of fact on the question of Joiner's exposure to furans and dioxins-as the Court of Appeals held that it did-then this basis for the ruling on admissibility was erroneous, but not because the District Judge either abused her discretion or misapplied the law.^{FN3}

FN3. Petitioners do not challenge the Court of Appeals' straightforward review of the District Court's summary judgment ruling on exposure to furans and dioxins. As today's opinion indicate, *ante*, at 519, it remains an open question on remand whether the District Court should admit expert testimony that PCB's, furans, and dioxins *together* promoted Joiner's cancer.

The reliability ruling was more complex and arguably is not faithful to the statement in *Daubert* that "[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." 509 U.S., at 595, 113 S.Ct., at 2797-2798. Joiner's experts used a "weight of the evidence" methodology to assess whether Joiner's exposure to transformer fluids promoted his lung cancer.^{FN4} They did not suggest that any 153*153 one study provided adequate support for their conclusions, but instead relied on all the studies taken together (along with their interviews of Joiner and their review of his medical records). The District Court, however, examined the studies one by one and concluded that none was sufficient to show a link between PCB's and lung cancer. 864 F.Supp., at 1324-1326. The focus of the opinion was on the separate studies and the conclusions of the experts, not on the experts' methodology. *Id.*, at 1322 ("Defendants ... persuade the court that Plaintiffs' expert testimony would not be admissible ... by attacking the conclusions that Plaintiffs' experts draw from the studies they cite").

FN4. Dr. Daniel Teitelbaum elaborated on that approach in his deposition testimony: "[A]s a toxicologist when I look at a study, I am going to require that that study meet the general criteria for methodology and statistical analysis, but that when all of that data is collected and you ask me as a patient, Doctor, have I got a risk of getting cancer from this?' That those studies don't answer the question, that I have to put them all together in my mind and look at them in relation to everything I know about the substance and everything I know about the exposure and come to a conclusion. I think when I say, 'To a reasonable medical probability as a medical toxicologist, this substance was a contributing cause,' ... to his cancer, that that is a valid conclusion based on the totality of the evidence presented to me. And I think that that is an appropriate thing for a toxicologist to do, and it has been the basis of diagnosis for several hundred years, anyway." Supp.App. to Brief for Respondents 19.

Unlike the District Court, the Court of Appeals expressly decided that a "weight of the evidence" methodology was scientifically acceptable.^{FN5} To this extent, the Court of Appeals' opinion is persuasive. It is not intrinsically "unscientific" for experienced professionals to arrive at a conclusion by weighing all available scientific evidence-this is not the sort of "junk science" with which *Daubert* was concerned.^{FN6} After all, as Joiner points out, the Environmental Protection Agency (EPA) uses the same methodology to assess risks, albeit using a somewhat **523 different threshold than that required in a trial. Brief for Respondents 40-41 (quoting 154*154 EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed.Reg. 33992, 33996 (1986)). Petitioners' own experts used the same scientific approach as well.^{FN7} And using this methodology, it would seem that an expert could reasonably have concluded that the study of workers at an Italian capacitor plant, coupled with data from Monsanto's study and other studies, raises an inference that PCB's promote lung cancer.^{FN8}

FN5. The court explained: "Opinions of any kind are derived from individual pieces of

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evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion, one reliable enough to be submitted to a jury along with the tests and criticisms cross-examination and contrary evidence would supply." 78 F.3d 524, 532 (C.A.11 1996).

FN6. An example of "junk science" that should be excluded under *Daubert* as too unreliable would be the testimony of a phrenologist who would purport to prove a defendant's future dangerousness based on the contours of the defendant's skull.

FN7. See, e.g., Deposition of Dr. William Charles Bailey, Supp. App. to Brief for Respondents 56 ("I've just reviewed a lot of literature and come to some conclusions...").

FN8. The Italian capacitor plant study found that workers exposed to PCB's had a higher-than-expected rate of lung cancer death, though " 'the numbers were small [and] the value of the risk estimate was not statistically significant.' " 864 F.Supp. 1310, 1324 (N.D.Ga.1994). The Monsanto study also found a correlation between PCB exposure and lung cancer death, but the results were not statistically significant. *Id.*, at 1325. Moreover, it should be noted that under Georgia law, which applies in this diversity suit, Joiner need only show that his exposure to PCB's " 'promoted' " his lung cancer, not that it was the sole cause of his cancer. Brief for Respondents 7, n. 16 (quoting Brief for Appellants in No. 94-9131 (C.A.11), pp. 7-10).

The Court of Appeals' discussion of admissibility is faithful to the dictum in *Daubert* that the reliability inquiry must focus on methodology, not conclusions. Thus, even though I fully agree with both the District Court's and this Court's explanation of why each of the studies on which the experts relied was by itself unpersuasive, a critical question remains unanswered: when qualified experts have reached relevant conclusions on the basis of an acceptable methodology, why are their opinions inadmissible?

Daubert quite clearly forbids trial judges to assess the validity or strength of an expert's scientific conclusions, which is a matter for the jury. ^{FN9} Because I am persuaded 155*155 that the difference between methodology and conclusions is just as categorical as the distinction between means and ends, I do not think the statement that "conclusions and methodology are not entirely distinct from one another," *ante*, at 519, is either accurate or helps us answer the difficult admissibility question presented by this record.

FN9. The Court stated in *Daubert*: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.... Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, Fed. Rule Civ. Proc. 50(a), and likewise to grant summary judgment, Fed. Rule Civ. Proc. 56.... These conventional devices, rather than wholesale exclusion under an uncompromising general acceptance test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702." 509 U.S., at 596, 113 S.Ct., at 2798.

In any event, it bears emphasis that the Court has not held that it would have been an abuse of discretion to admit the expert testimony. The very point of today's holding is that the abuse-of-discretion standard of review applies whether the district judge has excluded or admitted evidence. *Ante*, at 517. And nothing in either *Daubert* or the Federal Rules of Evidence requires a district judge to reject an expert's conclusions and keep them from the jury when they fit the facts of the case and are based on reliable scientific methodology.

Accordingly, while I join Parts I and II of the Court's opinion, I do not concur in the judgment or in Part III of its opinion.

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139 L.Ed.2d 508, 66 USLW 4036, 28 Env'tl. L. Rep. 20,227, 48 Fed. R. Evid. Serv. 1, Prod.Liab.Rep. (CCH) P 15,120, 18 O.S.H. Cas. (BNA) 1097, 97 Cal. Daily Op. Serv. 9355, 97 Daily Journal D.A.R. 15,051, 97 CJ C.A.R. 3361, 11 Fla. L. Weekly Fed. S 284

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Slip Copy, 2010 WL 1727807 (D.S.C.)
(Cite as: 2010 WL 1727807 (D.S.C.))

Only the Westlaw citation is currently available.

United States District Court,
D. South Carolina,
Charleston Division.

In re BAUSCH & LOMB INC. CONTACTS LENS
SOLUTION PRODUCTS LIABILITY
LITIGATION.

This order relates to:

Rudolph V. Declet-Flores, et. al., Plaintiffs,

v.

Bausch & Lomb Inc., Defendant.

Eva I. Garcia, et. al., Plaintiffs,

v.

Bausch & Lomb Inc., Defendant.

MDL No. 1785.

C/A No. 2:06-MN-7777-DCN.

Nos. 2:06-CV-03272-DCN, 2:06-CV-03273-DCN.

April 26, 2010.

Eric M. Quetglas, Quetglas Law Office, San Juan,
PR, Gary E. Mason, Mason Law Firm, Washington,
DC, for Bausch & Lomb Inc. Contact Lens Solution
Products Liability Litigation.

ORDER

DAVID C. NORTON, Chief Judge.

*1 This matter is currently before the court on defendant's motion for summary judgment on all claims and causes of action asserted by non-*Fusarium* plaintiffs. On February 17, 2010, the court granted this motion in part, resolving most of the non-*Fusarium* cases. In that order, the court held several cases under advisement, including the cases cited above. These plaintiffs, through attorney John Mudd, requested a continuance of the hearing on defendant's motion to accommodate Mr. Mudd's schedule, as well as a Puerto Rican religious holiday. Because these plaintiffs expressed a desire to participate in oral argument on this matter, the court held defendant's motion as to these plaintiffs under advisement and instructed Mr. Mudd to contact the court to either schedule a hearing or withdraw his request for argument. On February

22, 2010, Mr. Mudd sent an e-mail advising the court that oral argument would not be necessary. Therefore, defendant's motion for summary judgment as to plaintiffs Rudolph Declet-Flores, et. al. (06-3272) and Eva I. Garcia, et. al. (06-3273) is now ready for ruling.

In its February 17, 2010 order, the court noted that plaintiffs would be required to prove that defendant's Renu with MoistureLoc caused the eye infections they experienced. Order at 3. As the court observed, causation can be divided into general causation and specific causation, with proof of general causation being a prerequisite to proving specific causation. *Id.* at 3-4. Because the court had previously excluded the testimony of Dr. Elisabeth Cohen, plaintiffs' only general causation expert, the court ruled that most non-*Fusarium* plaintiffs' claims could not survive and granted defendant's motion as to those non-*Fusarium* plaintiffs. *Id.* at 4-5.

The court has thoroughly reviewed defendant's and plaintiffs' written submissions on this motion. The court sees no distinguishing factors in these cases that would lead to a different result here than the court reached in its February 17, 2010 order. In their response to defendant's summary judgment motion, plaintiffs advance several arguments in opposition, including that Puerto Rican law does not require evidence of general causation, that plaintiffs do not need expert testimony, that they can use a differential diagnosis to prove causation, and that they still have a valid failure to warn claim. The court addressed these arguments in its February 17, 2010 order. Specifically, regarding differential diagnoses, the court observed,

Plaintiffs also argue that, the exclusion of their general causation expert notwithstanding, individual plaintiffs may be able to prove causation through physicians' differential diagnoses. "A differential diagnosis, which courts have recognized as a reliable methodology when conducted properly, 'is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.'" *Foster v. Legal Sea Foods, Inc.*, 2008 WL 2945561, at *10 (D.Md.2008) (quoting *Westberry*

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v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir.1999)). “To be reliable, a differential diagnosis must first ‘rule in’ a plaintiff’s proposed cause and then ‘rule out’ alternative causes.” *Id.* (citing *Westberry*, 178 F.3d at 263). “‘Ruling in’ a cause, also known as proving ‘general causation’, ‘is established by demonstrating that exposure to a substance can cause a particular disease.’” *Id.* (quoting *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F.Supp.2d 465, 471 (M.D.N.C.2006)). “To complete a differential diagnosis, an expert must then ‘rule out’ alternative causes, which means opining as to ‘specific or individual causation’ by ‘demonstrating that a given exposure is the cause of a particular individual’s disease.’” *Id.* (citation omitted). “As a general rule, ‘it is not appropriate to rely on a differential diagnosis to prove general causation,’ but establishing general causation is an essential prerequisite to proving specific causation.” ⁴ *Id.* (emphasis added) (citation omitted).

FN4: Plaintiffs cite *Westberry* in support of their argument that a differential diagnosis can be used to show general causation. Their reliance is misplaced because *Westberry* did not involve a prior *Daubert* ruling by the court that there was no reliable general causation evidence. In fact, the *Westberry* court apparently found evidence of general causation, as it noted that the defendant had admitted in its Material Safety Data Sheet that inhalation of talc dust caused sinus irritation. *Westberry*, 178 F.3d at 264.

*2 Even where differential diagnosis opinions are permitted regarding specific causation, such evidence satisfies the *Daubert* standard only if general causation has already been established. See, e.g., *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1253 (11th Cir.2005) (noting that differential diagnosis satisfies *Daubert* only if expert can show general toxicity of drug by reliable methods); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 885 (10th Cir.2005) (holding that plaintiffs’ “reliance on differential diagnosis without supporting epidemiological evidence is misplaced”); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1413 (D.Or.1996) (holding that differential diagnosis cannot establish general causation because the method “assumes that general causation has been proven”). Thus, to allow plaintiffs to rely on differ-

ential diagnoses to establish causation would amount to allowing an impermissible end-run around the general causation requirement.

Order at 5-6. Regarding plaintiffs’ other arguments, the court addressed those as follows when discussing the same arguments made by similarly situated Puerto Rico plaintiffs:

Plaintiff Enery Fernandez Pinero, et. al. (06-2702)

These Puerto Rico plaintiffs argue that Puerto Rico law does not recognize general causation, that Puerto Rico law does not always require expert testimony to prove causation, and that they have stated a valid failure to warn cause of action. As to the first argument, general causation as a prerequisite to specific causation appears to be a universally accepted concept, and the court has found no Puerto Rico case that holds otherwise. Plaintiffs contend that *Puerto Rico v. M/V Emily S.*, 158 F.R.D. 9 (D.P.R.1994), stands for the proposition that Puerto Rico courts have rejected the concept of general causation. Their argument misconstrues the holding of the case. The *M/V Emily S.* court refused to certify the putative class in that case because it rejected the plaintiffs’ argument that causation could be established on a class-wide basis. *Id.* at 15. As the court noted,

The relevant question, therefore, is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it did cause harm and to whom. That determination is highly individualistic, and depends upon the characteristics of individual plaintiffs (e.g., state of health, lifestyle) and the nature of their exposure to Agent Orange.

Id. (quoting *In re Agent Orange Prod. Liab. Litig.*, 818 F.2d 145, 165 (2d Cir.1987)). Thus, while these plaintiffs have submitted affidavits from doctors attesting to the possible link between MoistureLoc and non-*Fusarium* infections, this general causation issue has already been decided in the order rejecting Dr. Cohen’s testimony.

Regarding expert testimony, to prove causation Puerto Rico law requires an expert’s opinion when “the matter is sufficiently beyond common experience.” *Collazo-Santiago v. Toyota Motor Corp.* ..

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937 F.Supp. 134, 140 (D.P.R.1996). As the *Daubert* hearing revealed, this case involves complex medical causation questions involving ophthalmology, microbiology, as well as other scientific specialties that are outside the realm of "common experience." Therefore, expert testimony is required under Puerto Rico law.

*3 Plaintiffs also assert they have stated a valid failure to warn cause of action. However, causation is a required element in every product liability case. As the Supreme Court of Puerto Rico has noted, a strict liability cause of action requires proof of both product defect and causation, and a manufacturer's failure to warn is a type of product defect. *Rivera Santana v. Superior Pkg., Inc.*, 132 D.P.R. 115, 126-28 (P.R.1992). Thus, plaintiffs' failure to warn claim fails.

Order at 7-8. For the foregoing reasons, as well as the reasons stated in the court's February 17, 2010 order, defendant's motion for summary judgment is **GRANTED** as to plaintiffs Rudolph Declet-Flores, et. al. (06-3272) and Eva I. Garcia, et. al. (06-3273).

AND IT IS SO ORDERED.

D.S.C.,2010.
In re Bausch & Lomb Inc. Contact Lens Solution
Products Liability Litigation
Slip Copy, 2010 WL 1727807 (D.S.C.)

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Nuclear Reg. Rep. P 20,621, 292 F.3d 1124, 53 Fed.R.Serv.3d 119, 32 Envtl. L. Rep. 20,747, 58 Fed. R. Evid. Serv. 1247, 02 Cal. Daily Op. Serv. 5365, 2002 Daily Journal D.A.R. 6777

(Cite as: Nuclear Reg. Rep. P 20,621, 292 F.3d 1124)

United States Court of Appeals,
Ninth Circuit.

In re HANFORD NUCLEAR RESERVATION
LITIGATION,

Jeanne Jaros, et al., on their own behalf and as representatives of classes of similarly situated persons,
Plaintiffs-Appellants,

v.

E.I. DuPont, Defendant-Appellee.

In re Hanford Nuclear Reservation Litigation,
E.S. Criswell, Arel Quessenberry, Luther Stacy, Jr.,
Raymond L. Swaim, Betty L. Swaim, James R.
Swaim and John S. Swaim, on their own behalf and
as representatives of classes of similarly situated
persons, Plaintiffs-Appellants,

v.

E.I. DuPont de Nemours and General Electric Com-
pany, Defendants-Appellees.

In re Hanford Nuclear Reservation Litigation,
Chuck Seaman, as personal representative for
Frieda Theresa Seaman, Deceased; Mark Seaman,
Jr.; Chuck Seaman, Plaintiffs-Appellants,

v.

E.I. DuPont de Nemours and Company, a Delaware
corporation; General Electric Company, a New
York Corporation, Defendants-Appellees.

In re Hanford Nuclear Reservation Litigation,
Andra L. Evenson, et al., Plaintiffs-Appellants,

v.

E.I. DuPont de Nemours and Company, Defendant-
Appellee,

and

U.S. Environmental Protection Agency, et al., De-
fendants.

In re Hanford Nuclear Reservation Litigation,
Kathryn Hamilton, Diana Cottam, James and Janet
Boyd and Connie Soper, on their own behalf and as
representatives of classes of similarly situated per-
sons, Plaintiffs-Appellants,

v.

E.I. DuPont de Nemours and Company; General
Electric Co.; UNC, Inc., Atlantic Richfield Com-

pany, Rockwell International Corporation, Westing-
house Electric Corporation and Westinghouse Han-
ford Company, Defendants-Appellees.

In re Hanford Nuclear Reservation Litigation,
Rosemary Miller, Plaintiff-Appellant,

v.

E.I. DuPont de Nemours; General Electric, Defend-
ants-Appellees.

**Nos. 98-36142 to 98-36144, 98-36147, 98-36149
and 98-36173.**

Argued and Submitted Sept. 14, 2000.

Submission Vacated Sept. 18, 2001.

Resubmitted Oct. 15, 2001.

Filed June 18, 2002.

Individuals allegedly exposed to radioactive emis-
sions from federal nuclear facility brought action
against entities that operated the facility under con-
tract with the United States. The United States Dis-
trict Court for the Eastern District of Washington,
Alan A. McDonald, J., 1998 WL 775340, granted
defendants' motions for summary judgment during
"generic causation" phase of discovery, and
plaintiffs appealed. The Court of Appeals,
Schroeder, Chief Circuit Judge, held that: (1) dis-
trict court was required to limit its ruling on sum-
mary judgment motion to whether evidence showed
alleged emissions were capable of causing illnesses
from which plaintiffs suffered, and could not con-
sider whether plaintiffs met specific threshold dose
levels of exposure, and (2) plaintiffs were not re-
quired to show that they were exposed level of radi-
ation that doubled their risk of illness when com-
pared to risk faced by the general population.

Reversed and remanded.

West Headnotes

[1] Negligence 272 ↪ 404

272 Negligence

272XIII Proximate Cause

272k404 k. Dangerous Instrumentalities and

292 F.3d 1124

Nuclear Reg. Rep. P 20,621, 292 F.3d 1124, 53 Fed.R.Serv.3d 119, 32 Env'tl. L. Rep. 20,747, 58 Fed. R. Evid. Serv. 1247, 02 Cal. Daily Op. Serv. 5365, 2002 Daily Journal D.A.R. 6777

(Cite as: Nuclear Reg. Rep. P 20,621, 292 F.3d 1124)

Substances. Most Cited Cases

"Individual causation," in context of toxic tort litigation, refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance.

[2] Negligence 272 ↪404

272 Negligence

272XIII Proximate Cause

272k404 k. Dangerous Instrumentalities and Substances. Most Cited Cases
Appropriate understanding of "generic causation" in toxic tort case is whether exposure to a substance for which a defendant is responsible, such as radiation, is capable of causing a particular injury or condition in the general population.

[3] Negligence 272 ↪404

272 Negligence

272XIII Proximate Cause

272k404 k. Dangerous Instrumentalities and Substances. Most Cited Cases
To establish both generic and individual causation in toxic tort case based on plaintiffs' alleged exposure to radioactive emissions from federal nuclear facility operated by defendants under license from government, plaintiffs were required to establish not only that the toxic substances released from facility were capable of causing conditions complained of, but in addition, that the emissions were the cause-in-fact of their specific conditions.

[4] Federal Civil Procedure 170A ↪2515

170A Federal Civil Procedure

170AXVII Judgment

170AXVII(C) Summary Judgment

170AXVII(C)2 Particular Cases

170Ak2515 k. Tort Cases in General.

Most Cited Cases

During generic causation phase of discovery in toxic tort case based on exposure to radioactive emissions from federal nuclear facility, district court was required to limit its ruling on summary judgment

motion to whether evidence showed alleged emissions were capable of causing illnesses from which plaintiffs suffered, and could not consider whether plaintiffs met specific threshold dose levels of exposure; because discovery had not yet commenced on issues of individual causation, individual determinations of causation were inappropriate.

[5] Negligence 272 ↪404

272 Negligence

272XIII Proximate Cause

272k404 k. Dangerous Instrumentalities and Substances. Most Cited Cases
To establish generic causation in toxic tort case based on exposure to radioactive emissions from federal nuclear facility operated by defendants under license from government, plaintiffs had to establish by scientific evidence that radiation was capable of causing the type of injuries that they actually suffered, not that they were exposed level of radiation that doubled their risk of illness when compared to risk faced by the general population; "doubling dose" requirement forced plaintiffs to prove they were exposed to specific level of radiation, without regard to individualized factors, such as heredity, that could raise likelihood of illness at lower levels of exposure.

[6] Federal Civil Procedure 170A ↪1877.1

170A Federal Civil Procedure

170AXIII Reference

170Ak1877 Particular Proceedings and Issues

170Ak1877.1 k. In General. Most Cited Cases

District court, after appointing neutral scientific advisor as a special master in toxic tort litigation to help court review findings of federal commission formed to estimate and reconstruct all radionuclide emissions from federal nuclear facility, did not abuse its discretion by limiting its reliance on master to issues related to those findings; court was not required to seek advice of master when ruling on motions in limine.

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 Nuclear Reg. Rep. P 20,621, 292 F.3d 1124, 53 Fed.R.Serv.3d 119, 32 Envtl. L. Rep. 20,747, 58 Fed. R. Evid. Serv.
 1247, 02 Cal. Daily Op. Serv. 5365, 2002 Daily Journal D.A.R. 6777
 (Cite as: Nuclear Reg. Rep. P 20,621, 292 F.3d 1124)

[7] Federal Civil Procedure 170A ↪1873

170A Federal Civil Procedure

170AXIII Reference

170Ak1873 k. Discretion and Power of
 Court. Most Cited Cases

It is within a district court's discretion to appoint a
 master, and to decide the extent of the duties of a
 special master.

[8] Evidence 157 ↪528(1)

157 Evidence

157XII Opinion Evidence

157XII(B) Subjects of Expert Testimony

157k526 Cause and Effect

157k528 Injuries to the Person

157k528(1) k. Cause. Most Cited

Cases

When considering relevancy of proffered expert
 testimony under *Daubert* in toxic tort litigation
 based on alleged radioactive emissions from federal
 nuclear facility, district court was required to assess
 the testimony as it related to generic causation in-
 quiry, i.e., whether the radiation released from the
 facility had the capacity to cause illnesses alleged
 by the plaintiffs.

[9] Evidence 157 ↪546

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

157k546 k. Determination of Question of
 Competency. Most Cited Cases

District courts are not required to hold a *Daubert*
 hearing before ruling on the admissibility of sci-
 entific evidence.

[10] Evidence 157 ↪546

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

157k546 k. Determination of Question of
 Competency. Most Cited Cases
Daubert hearing was not required to determine if

proffered scientific evidence was relevant in toxic
 tort case, if district court determined that record be-
 fore it, which included experts' reports, some de-
 position testimony, and the experts' affidavits, was
 adequate to make its ruling.

*1126 Merrill G. Davidoff and Peter Nordberg,
 Berger & Montague, Philadelphia, PA, Tom H.
 Foulds, Seattle, WA, Roy S. Haber, Eugene, OR,
 Michael Bloom and Michael Axline, Eugene, OR,
 Stanley M. Chesley, Waite, Schneider, Bayless &
 Chesley, Co, Cincinnati, OH, John S. Moore, Ve-
 likanje, Moore & Shore, P.C. Yakima, WA, for the
 plaintiffs-appellants.

William R. Jentes and Kevin T. Van Wart, Kirkland
 & Ellis, Chicago, IL, William R. Squires III, Sum-
 mit Law Group, Seattle, WA and Lee Radford,
 Moffatt, Thomas, Barrett, Rock & Fields, Idaho
 Falls, ID, for the defendants-appellees.

Appeal from the United States District Court for the
 Eastern District of Washington; Alan A. McDonald,
 District Judge, Presiding. D.C. Nos. CV-
 90-03017-AAM, CV-90-03069-AAM, CV-
 90-03106, CV-91-03015-AAM and CV-
 91-03080-AAM.

Before: SCHROEDER, Chief Judge, GOODWIN
 and HAWKINS, Circuit Judges.

SCHROEDER, Chief Judge.

These appeals raise fundamental questions concern-
 ing how courts should grapple with causation issues
 in mass tort cases. The appellants are among thou-
 sands of plaintiffs who filed suit for damages al-
 legedly arising out of their exposure to harmful
 levels of radioactive emissions *1127 from the
 Hanford Nuclear Reservation over a period of many
 years. They filed these actions under the Price-
 Anderson Act, 42 U.S.C. § 2011 *et seq.*, against E.I.
 DuPont and other entities who operated the nuclear
 facility under license agreements with the federal
 government during the relevant period. Appellants
 appeal the district court's summary judgment dis-

missal of their claims at the end of the second of three scheduled phases of discovery, when the court determined that appellants had not demonstrated individual exposure to a threshold level of radiation the court deemed capable of causing harm. The court established that threshold harmful level by determining the radiation exposure level for each of various categories of plaintiffs, grouped by age and gender, that would double the risk of illness when compared to the risk faced by the general population. That level is sometimes referred to as the "doubling dose."

Appellants here contend that the district court prematurely ruled on the merits of their individual claims because the second phase of discovery was to deal with issues of generic rather than individual causation, issues that were reserved for a later phase. They also contend that the district court erred as a matter of law in requiring plaintiffs to establish exposure to a threshold, "doubling dose" level of radiation as an element of generic causation. In addition, they challenge evidentiary rulings that disallowed the opinions of several experts on causation issues.

After a review of the record in this case and of the evolving case law in the area of toxic exposure, we conclude that the district court should not have dismissed the appellants' claims at this stage of the litigation. This is principally because the district court inappropriately relied upon cases that deal with the test to apply in order to determine whether a substance has the capacity to cause harm. *See Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir.1995) (considering expert testimony regarding the morning sickness drug Bendectin's capacity to cause limb defects). More relevant guidance for this case is found in cases dealing with whether a known toxic substance, like radiation, was in fact responsible for plaintiffs' illnesses. *See In re TMI Litig.*, 193 F.3d 613 (3d Cir.1999), *amended by* 199 F.3d 158 (3d Cir.2000). Such guidance will also be helpful to the district court in reexamining the proffered opinions of plaintiffs' experts. We there-

fore reverse and remand for further proceedings, with a suggestion that the district court rule promptly upon the pending requests for class certification.

BACKGROUND

The Hanford Nuclear Weapons Reservation ("Hanford"), was constructed during World War II and was the first large-scale plutonium manufacturing facility in the world. It occupies a 560-square mile area of southeastern Washington and abuts the Columbia River. Hanford's operations began in 1944 and soon grew to produce the majority of the plutonium used in the nation's nuclear weapons program, including the plutonium for the atomic bomb dropped on Nagasaki. In addition to plutonium (Pu-239), other radionuclides, including radioactive iodine (I-131), were created in the plutonium manufacturing process. Each of the five defendants in this case serially operated Hanford under contract with the United States for differing time periods between 1943 and 1987. The defendants are E.I. Du Pont de Nemours & Company, General Electric Company, UNC Nuclear Industries, Incorporated, Atlantic Richfield Company, and Rockwell International Corporation, (collectively, "defendants").

*1128 In 1987, the United States Department of Energy ("DOE") created the Hanford Environmental Dose Reconstruction Project ("HEDR"), overseen by the Centers for Disease Control. The underlying purpose of the HEDR was to estimate and reconstruct all radionuclide emissions from Hanford from 1944 to 1972, in order to ascertain whether neighboring individuals and animals had been exposed to harmful doses of radiation. Analyzing Hanford emissions over a 75,000 square mile area, the HEDR created a series of computer models and algorithms to estimate the timing of radionuclide releases into the air and the water of the Columbia River. The HEDR also examined the environmental and atmospheric transport of the releases, i.e. how radiation traveled through the air, settled into the soil, and dispersed into ground and surface water,

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and the resulting exposure to individuals who lived in the surrounding urban and suburban areas. Of particular concern to the HEDR were the estimated doses of I-131 received by the thyroid glands of humans, principally through consumption of milk from cows that ingested contaminated vegetation on neighboring farms and pastures. The HEDR concluded that I-131 emissions peaked during the period from 1944 to 1946, when an estimated 88% (685,000 curies) of Hanford's total iodine emissions occurred. HEDR explained that in later years, emissions declined because of technological advances.

In 1990, the Technical Steering Panel of HEDR released a report entitled *Initial Hanford Radiation Dose Estimates* which publicly disclosed for the first time that large quantities of radioactive and non-radioactive substances had been released from Hanford, beginning in the 1940s. This disclosure sparked a blaze of litigation. Thousands of individual plaintiffs filed complaints in the District Court for the Eastern District of Washington, alleging varying illnesses caused by exposure to Hanford's toxic emissions. Plaintiffs alleged that defendants acted intentionally or negligently, and that the radioactive and other toxic emissions reached numerous off-site residents through ingestion of contaminated vegetables, meat, fish, drinking water and milk, swimming in the irradiated Columbia River, and inhalation of toxic air. Many plaintiffs also claimed loss of real property value. In the district court's words:

[P]laintiffs, who conceivably could number into the hundreds of thousands, consist of all those persons who, at some time during the last 50 years, resided and/or had some property interest in an area which covers most of southeastern Washington, a portion of northeastern Oregon, and a small portion of western Idaho.... Given the scope of the plaintiffs' claims, particularly with regard to the number and differing types of emissions and the differing harms alleged to have resulted from each, the potential enormity of this litigation, as well as the dollar amount of any re-

covery, is almost staggering.

In 1991, the district court consolidated all of the Hanford-related actions and directed preparation of one consolidated complaint, designating specific lead and liaison counsel for all parties. The joint consolidated complaint was filed as a class action, but the district court has not yet ruled on class certification, and the plaintiffs proceeded individually. Several other plaintiff groups joined in the litigation after the filing of the joint consolidated complaint, alleging the same tort claims as those contained in the joint consolidated complaint. Collectively, the plaintiffs pleaded claims of negligence, strict liability, trespass, nuisance, misrepresentation, negligent and intentional infliction of emotional distress, wrongful death, and conspiracy. They sought compensatory damages for physical, emotional, and economic *1129 harm, punitive damages, medical monitoring, compelled disclosure of all relevant information, and abatement and remediation of ongoing and threatened releases of radioactive and non-radioactive hazardous substances.

The district court's partial summary judgment order that is the subject of this appeal, addressed only those claims for present and future injury based on state tort claims brought under the Price-Anderson Act, 42 U.S.C. § 2210(n)(2).

The district court filed its first Case Management Discovery Plan on February 20, 1992. It set forth a sensible discovery schedule divided into three phases. Phase I, projected to last for one year, permitted discovery through document production and interrogatories. Plaintiffs were to obtain information about Hanford's operating and emissions history, and defendants were to conduct discovery pertaining to plaintiffs' exposures, medical histories, and relevant illnesses and injuries. Phase II discovery would focus on causation and provided for designation and disclosure of all scientific expert witnesses and for the filing of the experts' proffered reports. A separate rebuttal period would conclude Phase II, affording each party the opportunity to re-

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(Cite as: Nuclear Reg. Rep. P 20,621, 292 F.3d 1124)

spond to opposing expert witnesses. The parties and the district court anticipated dispositive motions on the critical issues of causation at the close of Phase II. Phase III discovery would encompass general liability and any other remaining pre-trial issues.

The district court extended Phase I three times in three years, with Phase I finally winding down in March 1995. At the beginning of Phase II, and at the parties' request, the district court allowed for limited discovery on liability and operations at Hanford, but reiterated that Phase II would focus on causation and conclude with dispositive motions.

Meanwhile, plaintiffs' motions for class certification remained outstanding. The district court addressed the issue in an August 1994 order, concluding that it would not, at that time, alter its order consolidating plaintiffs into groups. Instead, the court reserved decision on the propriety of class certification pending further discovery on causation issues.

Once Phase II discovery was underway, the district court, on October 3, 1995, adopted plaintiffs' proposal to bifurcate discovery on issues regarding "generic causation," from discovery on issues of "individual causation." The order did not define the terms. "Generic causation" has typically been understood to mean the capacity of a toxic agent, such as radiation, to cause the illnesses complained of by plaintiffs. If such capacity is established, "individual causation" answers whether that toxic agent actually caused a particular plaintiff's illness. See *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1200 (6th Cir.1988) (defining generic causation as "whether the combination of the chemical contaminants and the plaintiffs' exposure to them had the capacity to cause the harm alleged" and separate from individual proximate cause determinations); *In re "Agent Orange" Product Liab. Litig. MDL No. 381*, 818 F.2d 145, 165 (2d Cir.1987) ("[t]he relevant question, therefore, is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it *did* cause harm and to whom") (emphasis in original).

In its order bifurcating Phase II discovery, the district court directed the parties to proceed with discovery related only to generic causation and to anticipate dispositive motions before proceeding further. Discovery on individual medical causation was deferred to an unspecified date in the future.

*1130 Over the following years, the parties bitterly debated discovery matters. In particular, the parties disputed the appropriate burden of proof plaintiffs would need to meet in order to survive dispositive motions on issues of generic causation. Plaintiffs, relying on their own understanding of generic causation and the district court's earlier discovery orders, consistently maintained that at the generic causation stage of the proceedings, they needed to prove only that the emissions released from Hanford had the capacity to cause the claimed illnesses. Plaintiffs retained and prepared their scientific experts accordingly, with the expectation that the deferred phase of causation discovery would allow them to garner causation evidence about the individual, particularized illnesses of each plaintiff.

Defendants, on the other hand, argued that plaintiffs' distinction between generic and individual causation was "academic." They claimed that to establish generic causation, this court's opinion in *Daubert v. Merrell Dow Pharms., Inc.* ("*Daubert II*"), 43 F.3d 1311 (9th Cir.1995), required plaintiffs to demonstrate that they had been exposed to a specific dose of radiation that statistically "doubled their risk" of harm. Unless exposed to such a "doubling dose," defendants alleged, plaintiffs could not prove by a preponderance of the evidence that their claimed illnesses, which also appear in the unexposed general population, were more likely than not caused by Hanford's emissions.

As generic causation discovery progressed, the district court strictly enforced the deadlines it had established for the exchange of reports prepared by scientific expert witnesses. The court emphasized that requests for extensions of time or leave to supplement expert reports would be intensely scrutin-

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ized and allowed "only upon a showing of clear necessity." In the court's Third Case Management Discovery Order, issued March 13, 1996, the court stated that it would allow the parties to supplement their proffered scientific evidence with information not available until after the court's deadline only upon a "compelling demonstration from records actually produced that it is the only appropriate relief."

Plaintiffs stress that they had a difficult time complying with the district court's directives and that their case suffered as a result. They complain that inadequate compliance with discovery orders had impeded their efforts to timely review all necessary documents. They were not allowed to supplement their experts' reports with updated scientific evidence, including cutting edge research from Chernobyl. Nor were plaintiffs permitted to correct errors in one report prepared by an important atmospheric dispersion expert who, on his own, discovered a coding error in his model simulating the distribution of iodine and plutonium.

The parties' divergent views of generic causation became clear in the summary judgment motions filed by defendants in March and June of 1997. Defendants argued that plaintiffs could not proceed with discovery unless they could offer admissible expert evidence to prove that, for each of the complained of illnesses, the relevant plaintiff had been exposed to that specific dose of radiation that statistically doubled the risk of persons in the general population contracting those illnesses. Defendants claimed that plaintiffs could not prove such exposure for any ailment other than thyroid cancer, and asked the court to limit the litigation to (1) claims allegedly caused by iodine releases during the peak emission period of 1944-51, and (2) thyroid cancer claims. To support their motion, defendants offered hundreds of exhibits, affidavits, and scientific reports detailing what they claimed were deficiencies in the *1131 plaintiffs' causation evidence. Defendants linked their summary judgment motion to dozens of in limine motions challenging the ad-

missibility of plaintiffs' expert witnesses, commonly known as "*Daubert* motions." See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Defendants urged the district court to exclude the testimony of any scientific expert witness who could not link his or her opinion to statistical evidence demonstrating that exposure to Hanford emissions more than doubled a plaintiff's risk of harm.

Each plaintiff group filed its own opposition to defendants' consolidated motion for summary judgment. All groups insisted that at the generic causation stage of the proceedings, they needed only to prove that the emissions released from Hanford were capable of causing their various claimed illnesses, and that they had offered sufficient evidence to meet this burden. The doubling of the risk standard had no place at this stage of the case, they claimed, because radiation is capable of causing cancer and other serious illnesses at even the lowest levels of exposure. Plaintiffs' opposition motions were accompanied by their own plethora of expert affidavits and scientific reports.

Defendants supported their reply with additional affidavits to respond to plaintiffs' evidence. Plaintiffs then moved for leave to file sur-replies in order to respond to the additional affidavits. The district court denied plaintiffs' motion, but construed it as a continuing motion to strike. Plaintiffs nevertheless attempted to file additional expert affidavits, but the court found their attempts "intolerable" and instructed that any future attempts to circumvent the court's directives would result in sanctions.

In December 1997, after more than five years of discovery, the district court held oral argument to address plaintiffs' burden of proof. The parties addressed their views on whether plaintiffs' claims could survive without epidemiological proof of causation, i.e. the "doubling of the risk" standard, and they addressed the appropriate standard of proof under Washington state tort law. The court did not hold an evidentiary hearing on the admissibility of any of the scientific expert testimony.

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Almost nine months later, the district court entered a 762-page order granting in large part defendants' motion for summary judgment. See *In re Hanford Nuclear Reservation Litig.*, No. CY-91-3015-AAM, 1998 WL 775340 (E.D.Wash. Aug.21, 1998). The order set forth rulings on all pending *Daubert* motions, refused an evidentiary hearing on those motions, and denied plaintiffs' requests for oral argument.

Relying on our decision in *Daubert II*, the district court agreed with defendants that to survive summary judgment on issues of generic causation, each individual plaintiff had to prove not only that radiation is capable of causing injury, but that he or she had been exposed to a threshold dose of radiation that statistically doubled the risk of harm over the risk that exists for the general population. The court reasoned that plaintiffs lacked direct proof that Hanford's radioactive emissions caused their asserted health conditions (which also occur in the unexposed, general population), and therefore could never establish generic causation without statistical, epidemiological evidence. The court stated that "[s]tatistical proof is sufficient to get a claim before a jury only if it shows a 'doubling of risk' between exposure and the condition. In cases where statistical proof must be resorted to, such proof meets the 'more likely than not' sufficiency standard only if a 'doubling of risk' is shown." The district court thus established a threshold for generic causation for *1132 each claimed illness, based on the specific dose of radiation an average individual would need to be exposed to in order to "double" his or her risk of harm in comparison to unexposed individuals in the general population.

After determining the applicable burden of proof to survive summary judgment on generic causation, the court considered the admissibility of each challenged scientific expert opinion by applying the "doubling of the risk" standard. Expert testimony indicating only that the radiation emitted from Hanford was capable of causing a disease was excluded as irrelevant unless it also passed muster under the

"doubling of the risk" standard, i.e., unless the expert opined that the radiation emissions amounted to a "doubling dose." In all, the district court excluded the testimony and opinions of seventeen of plaintiffs' proposed expert witnesses, either completely or in part, as unreliable and/or irrelevant under *Daubert*. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Any plaintiff whose claim necessarily relied on an excluded expert's opinion was dismissed from the litigation.

From plaintiffs' remaining scientific expert evidence, the court derived specific dose amounts and adopted them as the threshold "doubling doses." Any individual plaintiff who had been exposed to less than the official "doubling dose"—which varied according to a plaintiff's age and proximity to Hanford at the time of exposure and the particular illness alleged—was dismissed from the litigation, irrespective of whether that individual suffered from a documented medical condition. For example, the district court ruled that plaintiffs asserting thyroid cancer claims could not proceed to trial unless there was proof of I-131 exposure in excess of: 5 rads for those aged 0 to 4 at the time of exposure; 10 rads for those aged 5 to 9 at the time of exposure; 33 rads for those aged 10 to 19 at the time of exposure; and 100 rads for those aged 20 and over at the time of exposure. All thyroid cancer claims, including claims for thyroid nodules and adenomas, based on exposures equivalent to or less than the articulated "doubling doses" were dismissed with prejudice.

In the end, the few claims that survived summary judgment were those meeting the court's time, age, proximity, and dose requirements for (1) thyroid cancer, (2) non-autoimmune clinical and subclinical hypothyroidism, (3) bone cancer, (4) lung cancer, (5) salivary cancer, and (6) breast cancer if the female plaintiff was lactating at the time of exposure. Any plaintiff who asserted an emotional distress claim based on exposure to radiation could proceed with discovery only if he or she first proved exposure in excess of at least one of the "doubling

doses.” In the absence of such actual exposure, the district court determined that “fear of contracting a physical condition is not reasonable because there is not the requisite level of increased risk.”

The district court properly certified its partial summary judgment order as a final judgment for appeal pursuant to Fed.R.Civ.P. 54(b), because it disposed of some but fewer than all claims. *See Arizona State Carpenters Pension Trust Fund v. Miller*, 938 F.2d 1038, 1039-40 (9th Cir.1991); *Texaco, Inc. v. Ponsoldt*, 939 F.2d 794, 798 (9th Cir.1991). After plaintiffs' motion to alter or amend the judgment, pursuant to Fed.R.Civ.P. 59(e), was denied, they filed these timely appeals.

This appeal is separate from other Hanford related litigation in *Berg, et. al., v. E.I. DuPont de Nemours & Co., et. al.*, Nos. 99-35979 and 00-35062. Plaintiffs-appellants in that appeal also brought state law tort claims under the Price-Anderson Act and were originally part of this litigation. The *Berg* plaintiffs were severed from this action on September 20, 1996 when delays peculiar to that litigation threatened to interfere with the district court's case management schedule. Additional plaintiffs, denominated the *Jim* plaintiffs, were consolidated with the *Berg* plaintiffs on September 1, 1998. Their appeal was briefed and argued separately to this panel and we also decide it today.

DISCUSSION

I. Generic Causation v. Individual Causation: Violation of the Discovery Plan

Plaintiffs contend that the district court's discovery order led them reasonably to believe that to survive summary judgment on generic causation, they needed only to prove that they were exposed to the type of radioactive and non-radioactive emissions released from Hanford that were capable of causing the alleged illnesses. Plaintiffs argue that by adopting the defendants' “doubling of the risk” standard, the court deviated from its own discovery orders

and prematurely decided issues of individual causation. Moreover, they contend that by changing the rules so late in the game, the district court prejudiced their case because their mistaken expectations shaped their production of expert reports and response to dispositive motions.

[1] The relevant case law and the record here reflect that plaintiffs' expectations about the parameters of generic causation described in the district court's discovery orders were justified. Causation in toxic tort cases is typically discussed in terms of generic and specific causation. *See e.g., Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371, 1376 (D.C.Cir.1997). General, or “generic” causation has been defined by courts to mean whether the substance at issue had the capacity to cause the harm alleged, while “individual causation” refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance. *See Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 928 (8th Cir.2001); *Sterling*, 855 F.2d at 1200 (explaining the difference between generic and individual causation); *In re “Agent Orange”*, 818 F.2d at 165 (“[t]he relevant question ... is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it did cause harm and to whom. That determination is highly individualistic, and depends upon the characteristics of individual plaintiffs (e.g. state of health, lifestyle) and the nature of their exposure to Agent Orange”); *Jones v. Allercare, Inc.*, 203 F.R.D. 290, 301 (N.D. Ohio 2001) (“relevant question in this case will not be whether the products have the capacity to cause harm, but whether the products caused harm and to whom. Thus, the real causation issue in this case is individual, not general, in nature”). *See also Hilao v. Estate of Marcos*, 103 F.3d 767, 788 (9th Cir.1996) (Rymer, J. dissenting in part and concurring in part) (contrasting “generic causation—that the defendant was responsible for a tort which had the capacity to cause the harm alleged—with individual proximate cause and individual damage”).

[2] Defendants have not cited a case that articulates

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a contrary understanding of generic causation. Given this authority, we believe the appropriate understanding of generic causation is the one plaintiffs assert: whether exposure to a substance for which a defendant is responsible, such as radiation at the level of exposure alleged by plaintiffs, is capable of causing a particular injury or condition in the general population.

*1134 [3] In order to prevail on their claims, however, plaintiffs must establish both generic *and* individual causation. This means that they must establish not only that the toxic substances released from Hanford are capable of causing the conditions complained of, but in addition, that Hanford emissions were the cause-in-fact of their specific conditions. Given this two-step process, the district court's decision to bifurcate discovery on issues of causation was reasonable.

[4] Plaintiffs argue, however, that the "doubling dose" test plays no part in the initial generic causation inquiry and that they were prejudiced by the district court's decision to apply that standard. It is this ruling by the district court that is at the heart of this appeal.

The district court's order bifurcating discovery in October 1995 did not itself put plaintiffs on notice that the court would use the "doubling dose" test to weigh the sufficiency of their generic causation evidence. For example, in that Phase II discovery order, the court explained that it decided to bifurcate causation discovery because "general issues of generic causation logically must occur prior to calculation of an individual's dose." At that time, the district court deferred discovery on questions of individual medical causation and did not refer to the "doubling of the risk" standard. Nor did the district court mention, in its Third Case Management Discovery Plan of January 1996, setting deadlines for the exchange of generic causation reports and contemplating related dispositive motions, any nexus between generic causation and "doubling of the risk."

Because the district court's discovery orders were not clear, the plaintiffs could not reasonably have anticipated that most of their case would be dismissed on the ground they had failed to prove individualized exposure to specific threshold doses. The plaintiffs offered expert reports to establish that radiation is capable of causing their alleged illnesses. These included estimates of dose ranges received by certain categories of plaintiffs. The defendants point out that the plaintiffs' expert reports contain dosage estimates and defendants contend this demonstrates that plaintiffs were aware that the district court intended to adopt "doubling doses" as part of generic causation. Plaintiffs' expert evidence is, however, consistent with their claimed understanding of generic causation, since plaintiffs would have to show exposure to more than de minimis emissions to establish generic causation. Indeed, even the district court repeatedly acknowledged that plaintiffs firmly believed the "capable of causing" standard, and not "doubling of the risk," defined generic causation up until the time the court granted summary judgment for defendants.

We conclude plaintiffs are correct in their understanding of generic causation, and we believe their case was prejudiced by the district court's belated decision that required plaintiffs to meet specific threshold dose levels of exposure. The district court erred in dismissing plaintiffs' claims on that ground before discovery reached the phase of individual causation. The court should, consistent with its own discovery orders, have limited its ruling to whether the evidence showed the defendants' alleged emissions were capable of causing the illnesses from which plaintiffs' suffered.

The district court blurred its own two-step causation inquiry by looking to cases about substances that are not known to cause harm. By accepting defendants' argument that plaintiffs' case could be established only by epidemiological evidence, the court discounted plaintiffs' scientific evidence of generic causation. The court in essence skipped the

generic causation *1135 inquiry and decided issues of individual causation without the benefit of full discovery or particularized medical evidence. According to the court's own orders, the parties were to grapple with individual causation issues at a later stage.

Such a distinction between generic and individual causation is not new in the area of toxic torts. We agree with the Sixth Circuit that where the distinction is made, it must be strictly observed. In *Sterling v. Velsicol Chemical Corp.*, the Sixth Circuit faced a class action comprised of plaintiffs who claimed injuries resulting from drinking water contaminated by defendant's chemical waste burial site. 855 F.2d 1188 (6th Cir.1988). The critical issue before the court was whether sufficient evidence supported a finding of causation between defendant's disposal of toxic chemicals and plaintiffs' injuries. See *id.* at 1198. In that order, the court recognized the appropriateness, up to a point, of separating generic from individual causation, but stressed that generalized proofs cannot establish individualized damages.

[A]s is appropriate in this type of mass tort class action litigation, [the trial court] divided its causation analysis into two parts. It was first established that Velsicol was responsible for the contamination and that the particular contaminants were *capable* of producing injuries of the types allegedly suffered by the plaintiffs. Up to this point in the proceeding, the five representative plaintiffs were acting primarily in their representative capacity to the class as a whole. This enabled the court to determine a kind of generic causation—whether the combination of the chemical contaminants and the plaintiffs' exposure to them had the capacity to cause the harm alleged. This still left the matter of *individual* proximate cause to be determined. Although such generic and individual causation may appear to be inextricably intertwined, the procedural device of the class action permitted the court initially to assess the defendant's potential liability for its conduct

without regard to the individual components of each plaintiff's injuries. However, from this point forward, it became the responsibility of each individual plaintiff to show that his or her specific injuries or damages were proximately caused by ingestion or otherwise using the contaminated water. We cannot emphasize this point strongly enough because generalized proofs will not suffice to prove individual damages. The main problem on review stems from a failure to differentiate between the general and the particular. This is an understandably easy trap to fall into in mass tort litigation. Although many common issues of fact and law will be capable of resolution on a group basis, individual particularized damages still must be proved on an individual basis.

Id. at 1200 (emphasis in original).

At the close of the first half of the causation phase of discovery in this case, the only relevant question for the district court, under its own discovery orders, was similar to that recognized by the Sixth Circuit in *Sterling* as the question capable of generic treatment: “whether the combination of the chemical contaminants and the plaintiffs' exposure to them had the capacity to cause the harm alleged.” See *id.* Because discovery in this case had not yet commenced on issues of individual causation, the district court should not have ventured into individual determinations at this stage of discovery when there had not yet been full disclosure of individual plaintiff's circumstances.

II. “Doubling of the Risk”

[5] Plaintiffs further contend that the threshold level the district court required the plaintiffs to meet, a level that doubled *1136 the risk of suffering the alleged injuries, is not relevant to a case in which there is scientific evidence that the substance is capable of causing the injuries complained of. Defendants contend on appeal that the district court properly employed the “doubling of the risk” test as the appropriate standard for determining whether

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Hanford's emissions were capable of causing plaintiffs' harms.

The only Ninth Circuit cases defendants offer to support this argument are the same cases the district court relied upon: *Daubert II*, 43 F.3d 1311; and *Schudel v. General Elec. Co.*, 120 F.3d 991 (9th Cir.1997), *abrogated on other grounds by Weisgram v. Marley Co.*, 528 U.S. 440, 120 S.Ct. 1011, 145 L.Ed.2d 958 (2000). These cases, however, are inapposite because they deal with substances for which there was no scientific evidence of capacity to cause the plaintiffs' injuries. For that reason statistical epidemiological evidence was held to be necessary.

The critical issue in *Daubert II* was whether the plaintiffs' expert witnesses could produce enough evidence to survive summary judgment on the causation question of whether the morning sickness drug Bendectin, that plaintiffs' mothers ingested during pregnancy, caused the plaintiffs' individual birth defects. *See Daubert II*, 43 F.3d at 1313. Because there was no definitive evidence that Bendectin is a substance capable of causing birth defects, plaintiffs' case was entirely circumstantial. The only evidence plaintiffs had that Bendectin caused their own birth defects was (1) proof that their mothers took Bendectin during pregnancy, and (2) epidemiological evidence that mothers who used Bendectin during pregnancy bore more children with birth defects than mothers who did not use Bendectin. *See id.* at 1314-15.

In reviewing the admissibility of expert testimony, we required plaintiffs to show that their experts could offer testimony that Bendectin "more likely than not" caused their birth defects. *See id.* at 1320 (relying on California tort law). Because plaintiffs relied primarily on epidemiological evidence, this meant that plaintiffs had to establish "not just that their mothers' ingestion of Bendectin increased somewhat the likelihood of birth defects, but that it more than doubled it." *Id.* We said that "only then can it be said that Bendectin is more likely than not the source of their injury." *Id.* In *Daubert II*, the ex-

perts were unable to provide this type of evidence and their testimony was excluded.

Two years later, we decided *Schudel*, where plaintiffs alleged neurological and respiratory problems resulting from exposure to allegedly toxic cleaning solvents. *See Schudel*, 120 F.3d at 993. Defendants argue on appeal that scientific expert testimony was improperly admitted at trial. To determine whether the testimony was relevant and thus properly admitted, we looked to Washington state's burden of proof, which requires a plaintiff to "show that the act complained of probably or more likely than not caused the subsequent disability." *See id.* at 996 (quoting *O'Donoghue v. Riggs*, 73 Wash.2d 814, 440 P.2d 823, 830 (1968)) (internal quotations omitted). We described Washington's standard as being "virtually the same standard under California tort law applied in *Daubert II*," so we evaluated the expert testimony in light of the "more likely than not," standard used in *Daubert II*. *Id.* Because the "sole causation evidence" was testimony that the substance "could possibly" have caused one of plaintiff's neurological symptoms, we reversed. *Id.* at 996-98. There was no other scientific evidence of generic toxicity or individual causation.

It is critical to stress that the plaintiffs in *Daubert II* had no scientific evidence *1137 that Bendectin was capable of causing birth defects (generic causation), and therefore were required to produce epidemiological studies to prove that Bendectin more likely than not caused their own particularized injuries (individual causation). Similar considerations motivated the court in *Schudel*.

The case before us is different. Radiation is capable of causing a broad range of illnesses, even at the lowest doses. This has been recognized by scientific and legal authority. *See In re TMI Litigation*, 193 F.3d at 643 ("there is scientific consensus that ionizing radiation can cause cancer"); Wash. Rev.Code § 70.99.010 (2002) ("[r]adioactive wastes are highly dangerous, in that releases of radioactive materials and emissions to the environment are in-

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imical to the health and welfare of the people of the state of Washington, and contribute to the occurrences of harmful diseases, including excessive cancer and leukemia"). To show generic causation, plaintiffs had to establish by scientific evidence that radiation was capable of causing the type of injuries plaintiffs actually suffered. Plaintiffs offered expert testimony to show the generic capacity of levels of radiation emitted from the Hanford facility to cause the illnesses experienced by the plaintiffs.

The district court's choice of the "doubling dose" forced the plaintiffs to prove that they were exposed to a specific level of radiation, without regard to individualized factors, such as heredity, that might raise the likelihood of contraction of cancer at lower levels of exposure. The district court erred in requiring epidemiological evidence which would, like the standard rejected by the Third Circuit in *In re TMI Litig.*, require a plaintiff to prove exposure to a specific threshold level of radiation that created a relative risk of greater than 2.0.

Although, as noted in our discussion of the physics involved here, many observations of atomic behavior lead to counter-intuitive conclusions, we nevertheless think that common sense alone mitigates against establishing a bright line threshold for safe irradiation. We do not believe, for example, that a person who has been exposed to 10 rem of radiation is at risk for developing a neoplasm, but someone exposed to 9.99 rem is not.

In re TMI Litig., 193 F.3d at 727 n. 179.

We agree with the Third Circuit that the validity of a claim should not depend on whether a plaintiff was exposed to a fraction of a rem lower than the "doubling dose."

This analysis is fully consistent with the "Reference Guide on Epidemiology" contained in the Federal Judicial Center's *Reference Manual on Scientific Evidence* and upon which defendants rely. The Manual explains how epidemiological proof can be

adapted to meet the "more likely than not" burden of proof by requiring statistics to reflect a relative risk factor of 2.0 before a plaintiff can recover. The discussion there, however, recognizes that when available, known individual risk factors are also relevant. The Manual states that it limits its discussions to the role of epidemiology in proving individual causation. Federal Judicial Center, *Reference Manual on Scientific Evidence*, 167-169 (1st ed.1994). See also Federal Judicial Center, *Reference Manual on Scientific Evidence*, 386 (2d ed.2000) (concluding that the court should consider other available factors "[b]efore any causal relative risk from an epidemiologic study can be used to estimate the probability that the agent in question caused an individual plaintiff's disease").

III. Emotional Distress Claims

The plaintiffs' complaints also included claims for intentional and negligent infliction of emotional distress based on an increased*1138 risk of disease rather than a present physical injury. The district court dismissed all such emotional distress claims unless the individual plaintiff could demonstrate exposure in excess of one of the "doubling doses" it had adopted.

We hold in the companion appeal, *Berg, et al., v. E.I. DuPont de Nemours & Co., et al.*, that the district court lacks jurisdiction to consider such claims under the Act absent physical injury. On remand, the district court should reconsider plaintiffs' emotional distress claims in light of that holding.

IV. Evidentiary Rulings

Plaintiffs also raise several challenges related to the district court's rulings on the defendants' motions in limine challenging the experts' reports plaintiffs proffered.

[6][7] Early in 1994, the district court appointed a neutral scientific advisor, Dr. Thomas Pigford, as a special master under Fed.R.Civ.P. 53, to help the

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court in reviewing the HEDR findings. Dr. Pigford eventually prepared an independent report that he filed under seal with the district court in December 1994. The plaintiffs argue that the district court should have sought advice from Dr. Pigford in making its rulings on the motions in limine. It is within a district court's discretion to appoint a master, and to decide the extent of the duties of a special master. See *Johnson Controls, Inc., v. Phoenix Control Sys., Inc.*, 886 F.2d 1173, 1176 (9th Cir.1989). The district court did not abuse its discretion by limiting its reliance on Dr. Pigford to issues related to the HEDR findings.

[8] The plaintiffs also challenge the district court's failure to hold an evidentiary hearing in response to the defendants' *Daubert* motions and the district court's rulings on those motions. The plaintiffs submitted two sets of expert reports in the generic causation phase of discovery. The first set addressed how much radiation was released from Hanford, where the radiation traveled, and how plaintiffs were exposed to radiation. The second set addressed the health effects from such exposures. It consisted of expert testimony, reports, and declarations that attempted to demonstrate that radiation is capable of causing the diseases and conditions alleged.

The defendants filed in limine motions challenging many of plaintiffs' experts on *Daubert* grounds. The district court ruled on those motions in its summary judgment order. The court excluded seventeen of plaintiffs' experts' evidence either wholly or in part and plaintiffs challenge all of those rulings on appeal. The defendants' challenges and the district court's rulings involved at least in part an assessment that the experts' opinions were not relevant because they did not offer opinions about the doses necessary to double the risk of contracting the plaintiffs' alleged illnesses.

The district court thus relied on a standard we have determined to be erroneous in assessing the relevancy, or "fit," of plaintiffs' experts. We therefore reverse. On remand, the district court should assess

the plaintiffs' proffered expert testimony as it relates to the generic causation inquiry, i.e., whether the radiation released from Hanford has the capacity to cause the illnesses alleged by plaintiffs.

[9][10] The district court did not necessarily abuse its discretion in refusing to hold an evidentiary hearing on the defendants' *Daubert* motions. District courts are not required to hold a *Daubert* hearing before ruling on the admissibility of scientific evidence. *United States v. Alatorre*, 222 F.3d 1098, 1100 (9th Cir.2000). The district court could have determined that it has an adequate record before it to make *1139 its ruling. It had the experts' reports, some deposition testimony, and the experts' affidavits. See *Oddi v. Ford Motor Co.*, 234 F.3d 136, 154 (3d Cir.2000) (finding no abuse of discretion for failure to hold an evidentiary hearing when district court had depositions and affidavits of plaintiffs' experts). Nevertheless, because we are remanding the case for reconsideration of the district court's rulings on the motions in limine in light of our decision on the "doubling dose" standard employed by the district court, we encourage the court to hold a hearing on remand to provide plaintiffs with an opportunity to respond to the defendants' challenges, including an opportunity to question defendants' expert opinions, submitted in support of their *Daubert* motions. The parties should also be allowed to supplement their expert reports on remand.

CONCLUSION

For all of the foregoing reasons, we conclude that the district court erred by granting summary judgment and dismissing individual claims that failed to meet a specific, threshold, "doubling dose" during the generic causation phase of discovery. We therefore reverse and remand to the district court for resolution of generic causation issues before determining individual causation issues. We recommend that the court resolve the pending motions for class certification as soon as possible, and suggest that the court consider such certification only for questions

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of generic causation common to plaintiffs who suffer from the same or a materially similar disease.

Phase II discovery should be permitted to proceed and encompass the time, geography, and source terms of emissions as well as expert evidence as to the levels of exposure capable of causing each of the alleged illnesses in question. Individual determinations of causation should then be made in accordance with Washington state common law. See 42 U.S.C. § 2014(hh); *Kennedy v. Southern California Edison Co.*, 268 F.3d 763, 767 (9th Cir.2001).

REVERSED AND REMANDED.

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977 So.2d 543, 32 Fla. L. Weekly S750
(Cite as: 977 So.2d 543)

Supreme Court of Florida.
Jill MARSH, Petitioner,
v.

Robert Earl VALYOU, Jr., et al., Respondents.
No. SC06-118.

Nov. 21, 2007.

Rehearing Denied March 10, 2008.

Background: Motorist who sustained injuries in four separate car accidents brought action against series of four defendants, alleging that the accidents caused fibromyalgia. The Circuit Court, Orange County, George A. Sprinkel, IV, J., entered summary judgment in favor of defendants. Plaintiff appealed. The District Court of Appeal, Griffin, J., 917 So.2d 313, affirmed and certified conflict. Plaintiff applied for review.

Holdings: The Supreme Court held that:

- (1) *Frye* does not apply to expert testimony of a causal link between trauma and fibromyalgia, and
- (2) even if subject to *Frye*, expert testimony linking trauma to fibromyalgia satisfies it.

Decision of District Court of Appeal quashed.

Anstead, J., specially concurred and filed opinion in which Pariente, J., concurred.

Cantero, J., dissented and filed opinion in which Wells and Bell, JJ., concurred.

West Headnotes

[1] Appeal and Error 30 ↪861

30 Appeal and Error
30XVI Review
30XVI(A) Scope, Standards, and Extent, in General
30k857 Extent of Review Dependent on Mode of Review
30k861 k. Cases or Questions Reported, Reserved, or Certified. Most Cited Cases

Issue of whether *Frye* test for admitting expert testimony that espoused new or novel theories applied to expert testimony causally linking automobile accidents to myofascial pain syndrome was beyond the scope of certified conflict, and thus Supreme Court declined to address it.

[2] Evidence 157 ↪555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

The proponent of expert testimony that espouses new or novel theories bears the burden of establishing by a preponderance of the evidence the general acceptance of the underlying scientific principles and methodology.

[3] Appeal and Error 30 ↪983(1)

30 Appeal and Error
30XVI Review
30XVI(H) Discretion of Lower Court
30k983 Proceedings After Judgment
30k983(1) k. In General. Most Cited

Cases

Appellate court reviews *Frye* issues regarding the admissibility of expert testimony that espouses new or novel theories de novo, with general acceptance of the underlying scientific principles and methodology considered as of the time of the appeal.

[4] Evidence 157 ↪555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

The *Frye* standard for determining the admissibility of expert testimony only applies when an expert attempts to render an opinion that is based upon new or novel scientific techniques.

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[5] Evidence 157  555.10

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.10 k. Medical Testimony.

Most Cited Cases

For purposes of determining the admissibility of expert testimony, differential diagnosis is an established scientific methodology in which the expert eliminates possible causes of a medical condition to arrive at the conclusion as to the actual debilitating factor.

[6] Evidence 157  555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

A disagreement among experts does not transform an ordinary opinion on medical causation into a new or novel principle subject to *Frye* test for determining admissibility of expert testimony that espouses new or novel theories.

[7] Evidence 157  555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Frye test for determining admissibility of expert testimony that espouses new or novel theories is inapplicable to pure opinion testimony.

[8] Evidence 157  555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Under *Frye* test for determining admissibility of ex-

pert testimony that espouses new or novel theories, the inquiry must focus only on the general acceptance of the scientific principles and methodologies upon which an expert relies in rendering his or her opinion.

[9] Evidence 157  555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Evidence 157  570

157 Evidence
157XII Opinion Evidence
157XII(F) Effect of Opinion Evidence
157k569 Testimony of Experts
157k570 k. In General. Most Cited

Cases

Once the *Frye* test for determining the admissibility of expert testimony that espouses new or novel theories is satisfied through proof of general acceptance of the basis of an opinion, the expert's opinions are to be evaluated by the finder of fact and are properly assessed as a matter of weight, not admissibility.

[10] Evidence 157  574

157 Evidence
157XII Opinion Evidence
157XII(F) Effect of Opinion Evidence
157k574 k. Conflict with Other Evidence.

Most Cited Cases

Trial courts must resist the temptation to usurp the jury's role in evaluating the credibility of experts and choosing between legitimate but conflicting scientific views.

[11] Evidence 157  555.10

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.10 k. Medical Testimony.

Most Cited Cases

Frye test for determining admissibility of expert tes-

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timony that espouses new or novel theories does not apply to expert testimony of a causal link between trauma and fibromyalgia.

[12] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Even if subject to *Frye* test for determining admissibility of expert testimony that espouses new or novel theories, expert testimony linking trauma to fibromyalgia satisfies it.

[13] Evidence 157  555.2

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

The purpose of *Frye* test for determining admissibility of expert testimony that espouses new or novel theories is to ensure the reliability of expert testimony.

[14] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

A lack of studies conclusively demonstrating a causal link between trauma and fibromyalgia and calls for further research do not preclude admission of expert testimony causally linking trauma to fibromyalgia.

[15] Evidence 157  555.2

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Frye test for determining admissibility of expert testimony that espouses new or novel theories does not require unanimity.

*544 John T. Stemberger and Shannon L. Akins, Orlando, FL, for Petitioner.

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Philip M. Burlington of Burlington and Rockenbach, P.A., West Palm Beach, FL, and Michael S. Finch, Stetson University College of Law, Gulfport, FL, on behalf of Academy of Florida Trial Lawyers; and Tracy Raffles Gunn of Fowler, White, Boggs, and Banker, P.A., Tampa, FL, on behalf of Florida Defense Lawyers Association, as Amicus Curiae.

PER CURIAM.

In this case, we decide whether *Frye v. United States*, 293 F. 1013 (D.C.Cir.1923), applies to expert testimony causally linking trauma to fibromyalgia. We review *Marsh v. Valyou*, 917 So.2d 313 (Fla. 5th DCA 2005), which certified conflict with *State Farm Mutual Automobile Insurance Co. v. Johnson*, 880 So.2d 721 (Fla. 2d DCA 2004). In *Marsh*, the Fifth District Court of Appeal held that *Frye* does apply and, applying that test, held the testimony inadmissible. See *Marsh*, 917 So.2d at *545 327, 329. The Second District Court of Appeal, on the other hand, concluded that *Frye* did not apply. *Johnson*, 880 So.2d at 723. We have jurisdiction to resolve the certified conflict, see art. V, § 3(b)(4), Fla. Const., and granted review. See *Marsh v. Valyou*, 940 So.2d 1125 (Fla.2006) (granting review). We conclude that *Frye* does not apply to expert testimony causally linking trauma to fibromyalgia and that, even if it did, such testimony satisfies it. Therefore, we quash *Marsh* and approve the conflicting opinion in *Johnson*.

I. FACTS AND PROCEDURAL HISTORY

After sustaining injuries in four separate car accidents between August 1995 and January 1998, the petitioner, Jill Marsh, filed a negligence action against a series of four defendants—the Valyou's; the Burkes; PVC Holding Corp., d/b/a Avis Rent-a-Car (“Avis”);

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and Scott David Chilcut (no longer a party). *Marsh*, 917 So.2d at 315. She claimed the accidents caused fibromyalgia, which is a “syndrome of widespread pain, a decreased pain threshold, and characteristic symptoms including non-restorative sleep, fatigue, stiffness, mood disturbance, irritable bowel syndrome, headache, paresthesias, and other less common features.” *Id.* (quoting Frederick Wolfe, et al., *The Fibromyalgia Syndrome: A Consensus Report on Fibromyalgia and Disability*, 23 J. Rheumatology 534, 534 (1996) [hereinafter *Consensus Report*]).

Avis moved to preclude Marsh from presenting expert testimony that the accidents caused her fibromyalgia, arguing that the testimony did not meet the *Frye* standard for admissibility because the premise that trauma can cause fibromyalgia had not been generally accepted in the scientific community. *Id.* The trial court held a *Frye* hearing and, after reviewing numerous documents related to fibromyalgia and hearing arguments of counsel, granted the motion. *Id.* at 315-17. It later became apparent that Marsh intended to introduce evidence that the accidents caused “myofascial pain syndrome” (MPS). *Id.* at 318. Again, Avis challenged the testimony under *Frye* and the trial court precluded evidence of a causal link between trauma and MPS. *Id.* Marsh then announced she had no claims apart from fibromyalgia and MPS, and the trial court entered summary judgment. *Id.* at 319.

[1] Petitioner appealed, arguing: (1) the evidence is “pure opinion testimony” not subject to *Frye*; and (2) only the basis for an expert’s opinions is subject to *Frye*, not the opinions and deductions drawn from those principles. *Id.* The Fifth District rejected these arguments and affirmed. *Id.* at 329. The district court likewise affirmed the order related to MPS.^{FN1} During the pendency of the appeal, the Second District decided *Johnson*, holding that testimony that trauma from an automobile accident caused fibromyalgia is admissible as “ ‘pure opinion testimony’ based solely on the expert’s personal experience and training.” 880 So.2d at 723 (quoting *U.S. Sugar Corp. v. Henson*, 787 So.2d 3, 14 n. 10 (Fla. 1st DCA 2000), *approved*, 823 So.2d 104 (Fla.2002)). The Fifth District disagreed, concluding that testimony that trauma caused the plaintiff’s fibromyalgia requires “an underlying *546 scientific assumption—that trauma can cause fibromyalgia—which is not involved in pure opinion testimony cases,” and certified conflict with *Johnson*.

Marsh, 917 So.2d at 327, 329.

FN1. Marsh apparently has abandoned the MPS issue, as it was not addressed at oral argument and was largely ignored in her briefs. Because the issue is beyond the scope of the certified conflict, we decline to address it. See *Borden v. East-European Ins. Co.*, 921 So.2d 587, 596 n. 8 (Fla.2006) (recognizing an issue as beyond the scope of the certified conflict); *Kelly v. Cmty. Hosp. of the Palm Beaches, Inc.*, 818 So.2d 469, 470 n. 1 (Fla.2002) (declining to address issues beyond the basis for the Court’s conflict jurisdiction).

II. ANALYSIS

For purposes of our review, the parties do not dispute Marsh’s diagnosis of fibromyalgia, or that fibromyalgia is a legitimate condition. Instead, the issue is whether expert testimony causally linking trauma (the car accidents) to the onset of fibromyalgia is subject to the *Frye* test. Below we first explain why the testimony is not subject to *Frye*; and then explain that, even if the testimony had to satisfy *Frye*, it does.

A. *Frye* Does Not Apply

Many years ago, the United States Court of Appeals for the District of Columbia Circuit established a test for admitting expert testimony that espoused new or novel theories. In *Frye*, 293 F. at 1013, the court considered the admissibility of expert testimony as to the result of a “systolic blood pressure deception test,” an early polygraph. The D.C. Circuit held:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the field in which it belongs.

We think the systolic blood pressure deception

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test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made.

Id. at 1014.

Many state courts, as well as other federal courts, adopted the *Frye* test. *See, e.g.*, 29 Charles Alan Wright & Victor James Gold, *Federal Practice and Procedure* § 6266 (1997) (recognizing that *Frye* was the “dominate [sic] standard for decades”); Alice B. Lustre, Annotation, *Post-Daubert Standards for Admissibility of Scientific and Other Expert Evidence in State Courts*, 90 A.L.R. 5th 453, § 2 (2001) (“[*Frye*] was quickly adopted by most states as well as the other federal courts.”). We expressly adopted *Frye* in *Bundy v. State*, 471 So.2d 9, 18 (Fla.1985), and *Stokes v. State*, 548 So.2d 188, 195 (Fla.1989).

Seventy years after *Frye*, the United States Supreme Court held that the adoption of the Federal Rules of Evidence superseded the *Frye* test. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 587, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). *Daubert* adopted a different test for admissibility under which the *Frye* test-general acceptance in the scientific community-is simply one factor among several. *Id.* at 594, 113 S.Ct. 2786. Courts and commentators have since debated whether the *Daubert* standard is more lenient or more strict. *See, e.g.*, *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1312 (11th Cir.1999) (“While Allison argues that the thrust of the Rules and of the Eleventh Circuit has been for liberal admissibility of evidence, she fails to appreciate the tempering qualities of Rules 403, 702 and 703 under *Daubert* and the fact that this Circuit has been twice overruled on *Daubert* decisions in precedent setting Supreme Court decisions in [*General Electric Co. v. Joiner*], 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)] and *Kumho Tire [Co. *547 v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999)], both of which imposed stricter admissibility standards than the Eleventh Circuit had deemed appropriate.”); *Berry v. CSX Transp., Inc.*, 709 So.2d 552, 570 n. 16 (Fla. 1st DCA 1998) (“It is yet a matter of debate whether the *Daubert* test ... will be more liberal and allow more expert testimony than the *Frye* requirement....”); David E. Bernstein & Jeffrey D. Jackson, *The Daubert Trilogy in the States*, 44 *Jurimetrics J.*

351, 352 (2004) (“Courts and commentators disagreed, however, regarding whether this ‘revolution’ in how judges were to go about deciding whether to admit scientific evidence would lead to more permissive or more restrictive admissibility rulings.”) (footnote omitted); Edward K. Cheng & Albert H. Yoon, *Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards*, 91 Va. L.Rev. 471, 471, 510 (2005) (questioning whether a state’s adoption of *Frye* or *Daubert* makes any practical difference, but noting that “[c]ommentators have extensively debated which is the stricter standard”). Some commentators have suggested that, in practice, it makes no difference which test is used. *See, e.g.*, Cheng & Yoon, *supra*, at 510.

Despite the Supreme Court’s decision in *Daubert*, we have since repeatedly reaffirmed our adherence to the *Frye* standard for admissibility of evidence. *See, e.g.*, *Ibar v. State*, 938 So.2d 451, 467 (Fla.2006) (“Florida courts do not follow *Daubert*, but instead follow the test set out in *Frye*.”), *cert. denied*, 549 U.S. 1208, 127 S.Ct. 1326, 167 L.Ed.2d 79 (2007); *Brim v. State*, 695 So.2d 268, 271-72 (Fla.1997) (“Despite the federal adoption of a more lenient standard in [*Daubert*], we have maintained the higher standard of reliability as dictated by *Frye*.”); *Hadden v. State*, 690 So.2d 573, 578 (Fla.1997) (“Our specific adoption of that test after the enactment of the evidence code manifests our intent to use the *Frye* test as the proper standard for admitting novel scientific evidence in Florida, even though the *Frye* test is not set forth in the evidence code.”); *Flanagan v. State*, 625 So.2d 827, 829 n. 2 (Fla.1993) (“We are mindful that the United States Supreme Court recently construed Rule 702 of the Federal Rules of Evidence as superseding the *Frye* test. However, Florida continues to adhere to the *Frye* test for admissibility of scientific opinions.”) (citation omitted). Other states have adhered to *Frye* as well. *See, e.g.*, Wright & Gold, *supra*, § 6266 (noting that many states have adopted *Daubert*, but others have declined to do so); Bernstein & Jackson, *supra*, at 356 (noting that *Frye* “remains the rule in a significant minority of states”); Cheng & Yoon, *supra*, at 473 (noting that a number of states have formally adopted *Daubert*, but many have chosen to retain the *Frye* standard).

[2][3][4] Under *Frye*, “[t]he proponent of the evidence bears the burden of establishing by a preponderance of the evidence the general acceptance of the

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underlying scientific principles and methodology.” *Castillo v. E.I. Du Pont De Nemours & Co., Inc.*, 854 So.2d 1264, 1268 (Fla.2003). We review *Frye* issues de novo, with general acceptance considered as of the time of the appeal. *Id.* “By definition, the *Frye* standard only applies when an expert attempts to render an opinion that is based upon new or novel scientific techniques.” *U.S. Sugar Corp. v. Henson*, 823 So.2d 104, 109 (Fla.2002) (emphasis added). Therefore, we have recognized that *Frye* is inapplicable in the “vast majority” of cases. *Id.*; see also *Rickgauer v. Sarkar*, 804 So.2d 502, 504 (Fla. 5th DCA 2001) (“Most expert testimony is not subject to the *Frye* test.”).

*548 [5] The expert medical causation testimony at issue here is not “new or novel.” The American College of Rheumatology published classification criteria for fibromyalgia in 1990. *Consensus Report, supra*, at 534, 536 (“FM is widely accepted as a common generalized pain syndrome associated with characteristic symptoms and the finding of generalized tenderness. The 1990 ACR Criteria for the Classification of Fibromyalgia have been established and recommended for classification purposes in research studies.”) (footnote omitted). Marsh’s experts based their diagnoses and opinions about the cause of her fibromyalgia on a review of her medical history, clinical physical examinations, their own experience, published research, and differential diagnosis.^{FN2}

FN2. Differential diagnosis is “an established scientific methodology in which the expert eliminates possible causes of a medical condition to arrive at the conclusion as to the actual debilitating factor.” *U.S. Sugar*, 823 So.2d at 106.

[6] Experts routinely form medical causation opinions based on their experience and training. See, e.g., *Cordoba v. Rodriguez*, 939 So.2d 319, 322 (Fla. 4th DCA 2006) (“Medical expert testimony concerning the causation of a medical condition will be considered pure opinion testimony and admissible when it is based solely on the expert’s training and experience.”); *Gelsthorpe v. Weinstein*, 897 So.2d 504, 510 (Fla. 2d DCA 2005) (“[M]edical expert testimony concerning the causation of a medical condition will be considered pure opinion testimony—and thus not subject to *Frye* analysis—when it is based solely on the expert’s training and experience.”); *Fla. Power & Light Co. v. Tursi*, 729 So.2d 995, 996 (Fla. 4th DCA

1999) (finding *Frye* inapplicable where the physician was qualified to testify about the cause of a cataract based on his knowledge and experience). And there is always the possibility that two experts may reach dissimilar opinions based on their individual experience. However, a disagreement among experts does not transform an ordinary opinion on medical causation into a new or novel principle subject to *Frye*. See *Gelsthorpe*, 897 So.2d at 511 (recognizing that “a typical opinion on medical causation” should not be treated as a “new principle, subject to *Frye* analysis, simply because some other experts disagree with it and because the challenged expert does not rely on any specific authority to support his particular opinion”); *Tursi*, 729 So.2d at 997 (recognizing that an ophthalmologist’s opinion on causation was not based on “novel scientific evidence,” as “[i]t was no more novel than an orthopedist testifying that a neck injury, which did not manifest itself with symptoms until four years after a rear-end collision, was caused by the accident”); *Berry*, 709 So.2d at 571 (recognizing that the trial will be a battle of the experts and the fact that they derived their opinions from the same studies, but disagree on how to interpret them, is not a valid reason for excluding their testimony).

[7] It is well-established that *Frye* is inapplicable to “pure opinion” testimony:

[P]ure opinion testimony, such as an expert’s opinion that a defendant is incompetent, does not have to meet *Frye*, because this type of testimony is based on the expert’s personal experience and training. While cloaked with the credibility of the expert, this testimony is analyzed by the jury as it analyzes any other personal opinion or factual testimony by a witness.

Flanagan, 625 So.2d at 828; see also *Hadden*, 690 So.2d at 579-80 (same); *Herlihy v. State*, 927 So.2d 146, 148 (Fla. 1st DCA 2006) (“[A] diagnosis based on an expert’s *549 opinion and experience, versus a specific scientific test, would not be subject to a *Frye* hearing.”); *Gelsthorpe*, 897 So.2d at 510-11 (finding *Frye* inapplicable to “pure opinion testimony based upon clinical experience” where the “testimony did not rely on any study, test, procedure, or methodology that constituted new or novel scientific evidence,” but instead was based on an analysis of medical records and differential diagnosis). Because testimony causally linking trauma to fibromyalgia is

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based on the experts' experience and training, it is "pure opinion" admissible without having to satisfy *Frye*. See *Johnson*, 880 So.2d at 723.

[8][9] Marsh's experts did not base their opinions on new or novel scientific tests or procedures, and Respondents did not challenge the patient history, examination methods, clinical practices, or other methodologies upon which they did rely. In fact, Respondents could not challenge the underlying methodology, as we have previously held that differential diagnosis is a generally accepted method for determining specific causation. *Castillo*, 854 So.2d at 1271; *U.S. Sugar*, 823 So.2d at 110 ("[T]here is no question that the differential diagnosis technique ... is generally accepted in the scientific community."); see also *Johnson*, 880 So.2d at 723 (recognizing that a challenge to the underlying methodology would be unsuccessful because differential diagnosis is a "standard scientific technique"). Instead, Respondents challenged the experts' conclusions that trauma caused Marsh's fibromyalgia. However, as we stated in *U.S. Sugar*, 823 So.2d at 110:

[U]nder *Frye*, the inquiry must focus only on the general acceptance of the scientific principles and methodologies upon which an expert relies in rendering his or her opinion. Certainly the opinion of the testifying expert need not be generally accepted as well. Otherwise, the utility of expert testimony would be entirely erased, and "opinion" testimony would not be opinion at all—it would simply be the recitation of recognized scientific principles to the fact finder.... We reaffirm our dedication to the principle that once the *Frye* test is satisfied through proof of general acceptance of the basis of an opinion, the expert's opinions are to be evaluated by the finder of fact and are properly assessed as a matter of weight, not admissibility.

See also *Castillo*, 854 So.2d at 1276 (holding that the district court erred in considering "not just the underlying science, but the application of the data generated from that science in reaching the expert's ultimate conclusion"); *Berry*, 709 So.2d at 567 ("[W]hen the expert's opinion is well-founded and based upon generally accepted scientific principles and methodology, it is not necessary that the expert's opinion be generally accepted as well.").

[10] Trial courts must resist the temptation to usurp

the jury's role in evaluating the credibility of experts and choosing between legitimate but conflicting scientific views. See *Castillo*, 854 So.2d at 1275 ("[I]t is important to emphasize that the weight to be given to stated scientific theories, and the resolution of legitimate but competing scientific views, are matters appropriately entrusted to the trier of fact.") (quoting *Berry*, 709 So.2d at 569 n. 14); *Rodriguez v. Feinstein*, 793 So.2d 1057, 1060 (Fla. 3d DCA 2001) (same). A challenge to the conclusions of Marsh's experts as to causation, rather than the methods used to reach those conclusions, is a proper issue for the trier of fact. See *U.S. Sugar*, 823 So.2d at 110; *Castillo*, 854 So.2d at 1270, 1272, 1276; *Rodriguez*, 793 So.2d at 1060 (recognizing that "to involve judges in an evaluation of the acceptability of an expert's opinions and conclusions would convert judges into fact-finders" to *550 an extent not contemplated by Florida's *Frye* jurisprudence).

[11] For these reasons, we hold that *Frye* does not apply to testimony of a causal link between trauma and fibromyalgia.

B. The Testimony Satisfies *Frye*

[12][13] Even if subject to *Frye*, testimony linking trauma to fibromyalgia satisfies it. The purpose of *Frye* is to ensure the reliability of expert testimony. See, e.g., *Hadden*, 690 So.2d at 578 ("Reliability is fundamental to issues involved in the admissibility of evidence."); *Berry*, 709 So.2d at 568 ("At this admissibility stage of the proceedings, under *Frye* the court is asked to decide whether the basis of the evidence upon which plaintiffs' experts rely has a sufficient indicia of reliability."). Numerous published articles and studies recognize an association between trauma and fibromyalgia.^{FN3} Respondents' own expert testified that he has seen situations where he thought trauma indirectly led to fibromyalgia.

FN3. See, e.g., A.W. Al-Allaf et al., *A Case-Control Study Examining the Role of Physical Trauma in the Onset of Fibromyalgia Syndrome*, 41 *Rheumatology* 450, 452 (2002) (concluding that the results of the study suggested "that physical trauma was significantly associated with the onset" of fibromyalgia); Dan Buskila et al., *Increased Rates of Fibromyalgia Following Cervical Spine Injury*, 40 *Arthritis & Rheumatism*

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446, 451 (1997) (concluding that “trauma to the neck is associated with a higher incidence of FMS”); Anil Kumar Jain et al., *Fibromyalgia Syndrome: Canadian Clinical Working Case Definition, Diagnostic and Treatment Protocols-A Consensus Document*, 11 J. Musculoskeletal Pain 3, 44 (2003) (“There is strong consistency in documentation that physical trauma such as a fall or motor vehicle accident, particularly a whiplash or spinal injury, can trigger FMS in some patients.”); Samuel A. McLean et al., *Fibromyalgia After Motor Vehicle Collision: Evidence and Implications*, 6 Traffic Injury Prevention 97, 99 (2005) (“There is no disagreement regarding a close temporal association between [a motor vehicle collision] and the development of [fibromyalgia.]”); Roland Staud, *Fibromyalgia Pain: Do We Know the Source?*, 16 Current Opinion in Rheumatology, 157, 158 (March 2004) (recognizing physical trauma as one of the “triggers” associated with fibromyalgia); Muhammad B. Yunus et al., *Fibromyalgia Consensus Report: Additional Comments*, 3 J. Clinical Rheumatology 324, 325 (1997) (“[I]t seems more than 51% likely that trauma does play a causative role in some FMS patients....”).

[14] A lack of studies conclusively demonstrating a causal link between trauma and fibromyalgia and calls for further research do not preclude admission of the testimony. See *Castillo*, 854 So.2d at 1270 (“While epidemiology is considered generally accepted in the scientific community as a way of studying causal links between disease and chemicals, these types of studies are not necessarily required for a party to meet its burden of showing a causal link by a preponderance of the evidence.”); *U.S. Sugar*, 823 So.2d at 110 (“[I]t is well settled that a lack of epidemiological studies does not defeat submission of expert testimony and opinions as expressed in this case.”); *Berry*, 709 So.2d at 568 n. 12 (“[T]he fact that an epidemiological study calls for further research does not indicate uncertainty on the part of the researchers.”).

[15] *Frye* does not require unanimity. *Brim*, 695 So.2d at 272. While the precise etiology of fibromyalgia may not be fully understood, we hold that

Marsh has sufficiently demonstrated the reliability of her experts' testimony, and the trial court erred in excluding it. See *Berry*, 709 So.2d at 568 (“While ... there continues to be scientific debate ... we find the epidemiological science and methodology underlying [the expert's] testimony to be established, reliable, and well-founded.”).

*551 III. CONCLUSION

For the reasons explained above, we hold that *Frye* does not apply to expert testimony causally linking trauma to fibromyalgia. We further hold that, even if applicable, the testimony satisfies *Frye*. Therefore, we quash the Fifth District's decision in *Marsh*, 917 So.2d at 313, and approve the Second District's conflicting decision in *Johnson*, 880 So.2d at 721.

It is so ordered.

LEWIS, C.J., and ANSTEAD, PARIENTE, and QUINCE, JJ., concur.

ANSTEAD, J., specially concurs with an opinion, in which PARIENTE, J., concurs.

CANTERO, J., dissents with an opinion, in which WELLS and BELL, JJ., concur. ANSTEAD, J., specially concurring.

I concur in the majority's holding that the expert opinion evidence in question was admissible. However, I do so not only for the reasons set out in the majority opinion, but also on my belief the *Frye* standard did not survive the adoption of Florida's Evidence Code.

While this Court has continued to apply *Frye* in determining the admissibility of scientific expert opinion testimony after the adoption of the Florida Rules of Evidence, it has done so without confronting the fact that those rules do *not* mention *Frye* or the test set out in *Frye*. Hence, unlike the United States Supreme Court, we have never explained how *Frye* has survived the adoption of the rules of evidence. Because, like the United States Supreme Court, I find no basis for concluding that *Frye* has survived Florida's adoption of an evidence code similar to the federal code, I would recede from our cases continuing to apply *Frye* and hold that the rules of evidence do not include a *Frye* test for determining the admission of expert testimony. In fact, the adoption of these evidence codes was intended to apply a straightforward relevancy test to expert evidence and, in essence, to

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establish a rule favoring admissibility once relevancy was established, while leaving it to the fact-finder to determine the credibility and weight of such evidence.

DAUBERT

As the United States Supreme Court explained in its seminal decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 585-89, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993):

In the 70 years since its formulation in the *Frye* case, the "general acceptance" test has been the dominant standard for determining the admissibility of novel scientific evidence at trial. See E. Green & C. Nesson, *Problems, Cases, and Materials on Evidence* 649 (1983). Although under increasing attack of late, the rule continues to be followed by a majority of courts, including the Ninth Circuit. [n.3]

[N.3.] For a catalog of the many cases on either side of this controversy, see P. Giannelli & E. Imwinkelried, *Scientific Evidence* § 1-5, pp. 10-14 (1986 and Supp.1991).

The *Frye* test has its origin in a short and citation-free 1923 decision concerning the admissibility of evidence derived from a systolic blood pressure deception test, a crude precursor to the polygraph machine. In what has become a famous (perhaps infamous) passage, the then Court of Appeals for the District of Columbia described the device and its operation and declared:

"Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force *552 of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.*" 54 App. D.C., at 47, 293 F., at 1014 (emphasis added).

Because the deception test had "not yet gained

such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made," evidence of its results was ruled inadmissible. *Ibid.*

The merits of the *Frye* test have been much debated, and scholarship on its proper scope and application is legion. [n.4] Petitioners' primary attack, however, is not on the content but on the continuing authority of the rule. They contend that the *Frye* test was superseded by the adoption of the Federal Rules of Evidence. [n.5] We agree.

[N.4.] See, e.g., Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U.L.Rev. 643 (1992) (hereinafter Green); Becker & Orenstein, *The Federal Rules of Evidence After Sixteen Years—the Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash. L.Rev. 857, 876-885 (1992); Hanson, *James Alphonzo Frye is Sixty-Five Years Old; Should He Retire?*, 16 West. St. U.L.Rev. 357 (1989); Black, *A Unified Theory of Scientific Evidence*, 56 Ford. L.Rev. 595 (1988); Imwinkelried, *The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony*, 67 N.C.L.Rev. 1 (1988); *Proposals for a Model Rule on the Admissibility of Scientific Evidence*, 26 *Jurimetrics J.* 235 (1986); Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 *Colum. L.Rev.* 1197 (1980); *The Supreme Court, 1986 Term*, 101 *Harv. L.Rev.* 7, 119, 125-127 (1987).

Indeed, the debates over *Frye* are such a well-established part of the academic landscape that a distinct term—"Frye-ologist"—has been advanced to describe those who take part. See Behringer, *Introduction, Proposals for a Model Rule on the Admissibility of Scientific Evidence*, 26 *Jurimetrics J.* 237, 239 (1986), quoting Lacey, *Scientific Evidence*, 24 *Jurimetrics J.* 254, 264 (1984).

[N.5.] Like the question of *Frye's* merit, the dispute over its survival has divided courts and

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commentators. Compare, e.g., *United States v. Williams*, 583 F.2d 1194 (C.A.2 1978) (*Frye* is superseded by the Rules of Evidence), cert. denied, 439 U.S. 1117[, 99 S.Ct. 1025, 59 L.Ed.2d 77] (1979), with *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111, 1115-1116 (C.A.5 1991) (en banc) (*Frye* and the Rules coexist), cert. denied, 503 U.S. 912[, 112 S.Ct. 1280, 117 L.Ed.2d 506] (1992), 3 J. Weinstein & M. Berger, *Weinstein's Evidence* ¶ 702[03], pp. 702-36 to 702-37 (1988) (hereinafter Weinstein & Berger) (*Frye* is dead), and M. Graham, *Handbook of Federal Evidence* § 703.2 (3d ed. 1991) (*Frye* lives). See generally P. Giannelli & E. Imwinkelried, *Scientific Evidence* § 1-5, at 28-29 (citing authorities).

*553 We interpret the legislatively enacted Federal Rules of Evidence as we would any statute. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 [, 109 S.Ct. 439, 102 L.Ed.2d 445] (1988). Rule 402 provides the baseline:

“All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.”

“Relevant evidence” is defined as that which has “any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Rule 401. The Rule’s basic standard of relevance thus is a liberal one.

Frye, of course, predated the Rules by half a century. In *United States v. Abel*, 469 U.S. 45[, 105 S.Ct. 465, 83 L.Ed.2d 450] (1984), we considered the pertinence of background common law in interpreting the Rules of Evidence. We noted that the Rules occupy the field, *id.*, at 49[, 105 S.Ct. 465], but, quoting Professor Cleary, the Reporter, explained that the common law nevertheless could serve as an aid to their application:

“In principle, under the Federal Rules no common law of evidence remains. “All relevant evidence is admissible, except as otherwise provided....” In reality, of course, the body of com-

mon law knowledge continues to exist, though in the somewhat altered form of a source of guidance in the exercise of delegated powers.’” *Id.*, at 51-52[, 105 S.Ct. 465].

We found the common-law precept at issue in the *Abel* case entirely consistent with Rule 402’s general requirement of admissibility, and considered it unlikely that the drafters had intended to change the rule. *Id.*, at 50-51[, 105 S.Ct. 465]. In *Bourjaily v. United States*, 483 U.S. 171[, 107 S.Ct. 2775, 97 L.Ed.2d 144] (1987), on the other hand, the Court was unable to find a particular common-law doctrine in the Rules, and so held it superseded.

Here there is a specific Rule that speaks to the contested issue. Rule 702, governing expert testimony, provides:

“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.”

*Nothing in the text of this Rule establishes “general acceptance” as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that rule 702 or the Rules as a whole were intended to incorporate a “general acceptance” standard. The drafting history makes no mention of Frye, and a rigid “general acceptance” requirement would be at odds with the “liberal thrust” of the Federal Rules and their “general approach of relaxing the traditional barriers to ‘opinion’ testimony.” Beech Aircraft Corp. v. Rainey, 488 U.S., at 169[, 109 S.Ct. 439] (citing Rules 701 to 705). See also Weinstein, Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended, 138 F.R.D. 631 (1991) (“The Rules were designed to depend primarily upon lawyer-adversaries and sensible triers of fact to evaluate conflicts”). Given the Rules’ permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention *554 “general acceptance,” the assertion that the Rules somehow assimilated *Frye* is unconvincing. *Frye* made “general acceptance” the exclusive test for admitting expert scientific testimony. That austere*

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standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials. [n.6]

[N.6.] Because we hold that *Frye* has been superseded and base the discussion that follows on the content of the congressionally enacted Federal Rules of Evidence, we do not address petitioners' argument that application of the *Frye* rule in this diversity case, as the application of a judge-made rule affecting substantive rights, would violate the doctrine of *Erie R. Co. v. Tompkins*, 304 U.S. 64[, 58 S.Ct. 817, 82 L.Ed. 1188] (1938).

509 U.S. at 585-89, 113 S.Ct. 2786 (emphasis supplied). Hence, a unanimous United States Supreme Court concluded that *Frye's* "austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials." *Id.* at 589, 113 S.Ct. 2786. This Court should reach the same conclusion for Florida.^{FN4}

FN4. While I agree with the Supreme Court's analysis in *Daubert* rejecting *Frye's* viability after the evidence code was adopted, I also agree with the separate opinion of Chief Justice Rehnquist that the balance of the majority's opinion was unnecessary. See *Daubert*, 509 U.S. at 598, 113 S.Ct. 2786 (Rehnquist, C.J., concurring in part and dissenting in part). Hence, while I would conclude that *Frye* no longer controls, I would apply the relevancy standard set out in Florida's Evidence Code to determine whether expert opinion evidence should be admitted.

FLORIDA'S EVIDENCE CODE

Of course, Florida's Evidence Code is patterned substantially upon the Federal Rules of Evidence. Section 90.702 of Florida's code is essentially identical to Federal Rule 702. And, to paraphrase the United States Supreme Court's opinion in *Daubert*, nothing in section 90.702 or elsewhere in Florida's Evidence Code establishes "general acceptance" as a prerequisite to the admissibility of expert opinion evidence. Indeed, such a rigid test is at odds with both the Florida code and "the liberal thrust" of the [code] ... and ... [its] 'general approach of relaxing the traditional

barriers to "opinion" testimony.' " 509 U.S. at 589, 113 S.Ct. 2786 (quoting *Beech*, 488 U.S. at 169, 109 S.Ct. 439).

Daubert was decided in 1993, years after the adoption of both the federal rules and the Florida Evidence Code. However, following the adoption of Florida's Evidence Code a number of Florida appellate decisions came to the same conclusion as the Supreme Court in *Daubert*, years before *Daubert* was decided. And, while this Court has clung to its reliance upon *Frye*, no opinion of the Court has ever confronted or explained how *Frye* is consistent with the provisions of Florida's Evidence Code. The plain fact is, as fully and cogently explained by the United States Supreme Court in *Daubert*, *Frye* is not consistent with Florida's code.

While this Court has never directly confronted the issue, the district courts have discussed the tension between *Frye* and the terms of the Evidence Code, and reached the same conclusion the United States Supreme Court later reached in *Daubert*. See, e.g., *Brown v. State*, 426 So.2d 76 (Fla. 1st DCA 1983). In *Brown*, the First District explained:

The relevancy approach [of the Evidence Code] is preferred over the *Frye* rule because of problems inherent in the application of *Frye* and due to policy reasons. See Giannelli, *supra*. One *555 of the major criticisms directed against applying the *Frye* rule to a given scientific technique is that it would indiscriminately bar the admissibility of such evidence despite whether it meets the twin tests of logical and legal relevance. For example, as pointed out by Professor Giannelli, a rigid application of *Frye* would require a court to await the passage of time until such time as a new test or procedure has been developed to the point that the test or procedure has been developed to the point that the test or procedure has become "generally accepted." This creates a "cultural lag" during the technique's development, requiring that relevant evidence which might be demonstrated to be completely reliable must be excluded from consideration. See Giannelli, *supra*, at 1223 nn. 201 & 202; contrast *United States v. Addison*, 498 F.2d 741, 743-744 (D.C.Cir.1974). Plainly, the *Frye* rule engenders an impediment to the admissibility of reliable evidence without considering the cost to society. *Admissibility of Testimony Influenced by Hypnosis*,

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supra, 67 Va. L.Rev. at 1214, n. 77; *see also Hurd*, 432 A.2d at 94.

Brown, 426 So.2d at 87 n. 17. In addition, the *Brown* opinion quoted *McCormick's Handbook of the Law of Evidence* § 203 (Edward W. Cleary ed., 2nd ed.1972):

The practice approved in the last mentioned case [*Coppolino v. State*, 223 So.2d 68 (Fla. 2nd DCA 1968)] is the one which should be followed in respect to expert testimony and scientific evidence generally. "General scientific acceptance" is a proper consideration for taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence. Any relevant conclusions which are supported by a qualified expert witness should be received unless there are other reasons for exclusion. Particularly, probative value may be overborne by the familiar dangers of prejudicing or misleading the jury, and undue consumption of time. If the courts used this approach, instead of repeating a supposed requirement of "general acceptance" not elsewhere imposed, they would arrive at a practical way of utilizing the results of scientific advances.

Brown, 426 So.2d at 88 (quoting *McCormick*, § 203).

In *Hawthorne v. State*, 470 So.2d 770 (Fla. 1st DCA 1985), the First District, without a mention of *Frye*, found no error in the trial court's exclusion of an expert witness's testimony without prejudice to the reconsideration of that issue upon retrial. In a separate opinion, however, Judge Ervin provided an extensive and scholarly analysis concluding that the *Frye* test did not survive the adoption of Florida's Evidence Code. 470 So.2d at 774 (Ervin, C.J., concurring in part and dissenting in part). I commend Judge Ervin's compelling analysis to the reader and quote here only his concluding remarks:

It is time for the judiciary system to recognize that the Evidence Code establishes a different standard in assessing the admissibility of novel scientific theories or techniques than does *Frye*. Their admissibility is not dependent solely upon proof that they have not generally been accepted by the relevant field-although lack of general acceptance, when balanced against all counterweights, pursuant to section 90.403, is clearly a component to be considered in determining whether the probative value

of such evidence is substantially outweighed by countervailing factors. If the challenged evidence, such as that in the present case, is logically relevant, and if balancing does not reveal it to be *substantially* outweighed by the factors *556 enumerated in section 90.403, the trial judge should tip his hand in favor of admissibility.

Had the trial court below been appropriately directed to follow the procedure that appears to be required by the Evidence Code, and if it had nevertheless exercised its discretion to exclude, such decision would have constituted an abuse of discretion. The weight and quality of the evidence clearly demonstrate that Dr. Walker's proffered testimony should have been admitted-particularly when it is considered that such evidence was crucial to appellant's claim of self-defense. [n.10]

[N.10.] A trial court's denial of a defendant's use of probative evidence in a criminal trial may rise to the level of constitutional dimension. Although a defendant has no constitutional right to introduce irrelevant evidence, if the evidence has probative worth, it should be measured by a different standard than the usual test of abuse of discretion. *See State v. Dorsey*, 87 N.M. 323, 532 P.2d 912 (Ct.App.); *aff'd*, 88 N.M. 184, 539 P.2d 204 (1975). *See also Westen, The Compulsory Process Clause*, 73 Mich. L.Rev. 73, 149-59 (1974). *Cf. United States v. Dwyer*, 539 F.2d 924, 928 (2nd Cir.1976) (trial court erred in excluding the testimony of the only defense witness who could establish the insanity of defendant).

Today's opinion points out the need for a definitive statement from the Florida Supreme Court defining the respective roles of the trial and appellate courts, when carrying out their responsibilities under the Florida Evidence Code, in determining the admissibility of new scientific theories or techniques. Pursuant to Florida Rule of Appellate Procedure 9.030(a)(2)(A)(v), I would certify the following question to be one of great public importance:

HAS THE *FRYE* STANDARD OF GENERAL ACCEPTANCE WITHIN THE PARTICULAR SCIENTIFIC COMMUNITY, AS A PRECONDITION TO THE ADMISSIBILITY

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OF NOVEL SCIENTIFIC EVIDENCE, SURVIVED THE ADOPTION OF THE FLORIDA EVIDENCE CODE? AND IF IT HAS NOT, DOES IT NEVERTHELESS REMAIN A FACTOR TO BE CONSIDERED WHEN BALANCING THE PROBATIVE WORTH OF THE PROFFERED EVIDENCE AGAINST COUNTERVAILING FACTORS, AS PROVIDED BY SECTION 90.403, FLORIDA STATUTES?

470 So.2d at 787-88. Unfortunately, *Hawthorne* was not reviewed by this Court, and, although this Court has subsequently rejected *Daubert* in favor of *Frye*, Judge Ervin's proposed question has never been properly answered by this Court other than in summary fashion. See, e.g., *Ibar v. State*, 938 So.2d 451, 467 (Fla.2006) (summarily stating Florida adheres to *Frye* despite ruling in *Daubert*), cert. denied, 549 U.S. 1208, 127 S.Ct. 1326, 167 L.Ed.2d 79 (2007).

Following the *Hawthorne* decision, the Fourth District, in *Kruse v. State*, 483 So.2d 1383 (Fla. 4th DCA 1986), followed Judge Ervin's lead in concluding that Florida's Evidence Code, and not *Frye*, should control the admission of expert opinion evidence:

The Florida Evidence Code became effective in criminal cases in 1979. Sections 90.401 and 90.402, Florida Statutes (1983), set out a general relevancy standard for the admission of evidence. Sections 90.702 and 90.703 deal specifically with expert testimony:

*557 90.702 Testimony by experts.-If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial.

90.703 Opinion on ultimate issue.-Testimony in the form of an opinion or inference otherwise admissible is not objectionable because it includes an ultimate issue to be decided by the trier of fact.

In addition, section 90.403 provides:

90.403 Exclusion on grounds of prejudice or confusion.-Relevant evidence is inadmissible if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues, misleading the jury, or needless presentation of cumulative evidence. This section shall not be construed to mean that evidence of the existence of available third-party benefits is inadmissible.

Section 90.702 contains three requirements: (1) that the opinion evidence be helpful to the trier of fact; (2) that the witness be qualified as an expert; and (3) that the opinion evidence can be applied to evidence offered at trial. These provisions embody a liberal policy on the admission of expert evidence, generally rendering such evidence admissible to the extent that it is helpful to the trier of fact. Section 90.403 adds a fourth test barring evidence that, although technically relevant, presents a substantial danger of unfair prejudice that outweighs its probative value.

In *Brown v. State*, 426 So.2d 76 (Fla. 1st DCA 1983), Judge Ervin discussed the evolution in Florida decisions, from a rigid test of admissibility of evidence relating to new scientific procedures, to the more generous relevancy standard contained in the evidence code. *Id.* at 85-90; see also *Fay v. Mincey*, 454 So.2d 587, 593-94 (Fla. 2d DCA 1984), and *Hawthorne v. State*, 470 So.2d 770 (Fla. 1st DCA 1985) (Ervin, J., concurring in part and dissenting in part). The more rigid standard evolved from the decision in *Frye v. United States*, 293 Fed. 1013 (D.C.Cir.1923), which barred the admission of the results of a lie detector test because the test had not been generally accepted by the scientific community. Hence, the requirement of general acceptance was imposed. As Judge Ervin noted in his partial dissent in *Hawthorne*, the evidence code contains no reference to general acceptance in regard to the receipt of expert opinion evidence.

With some qualification, we believe the relevancy approach set out in the evidence code is the appropriate standard for determining the admissibility of expert testimony on child sexual abuse. The statutory relevancy standard also comports with the holdings of the Florida Supreme Court in

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the area of expert testimony. The court has stated that while trial courts have broad discretion in determining the range of subjects on which an expert may testify, such testimony should usually be received only where the disputed issue for which the evidence is offered, is beyond the ordinary understanding of the jury. *Johnson v. State*, 393 So.2d 1069, 1072 (Fla.1980). This view is consistent with the first requirement of section 90.702, that the opinion evidence be helpful to the trier of fact, as well as the provisions of section 90.403, that the danger of prejudice may outweigh the value of the evidence.

*558 483 So.2d at 1384-85.^{FN5} Despite the numerous district court decisions finding *Frye* superseded by the Evidence Code, this Court subsequently announced in summary fashion its continued reliance on *Frye*, while not directly confronting the impact of the application of the Evidence Code to the issue. See *Ibar*, 938 So.2d at 467. I would recede from those decisions for the same reasons articulated in *Daubert*, *Brown*, *Hawthorne* and *Kruse*.^{FN6}

FN5. The Fourth District subsequently affirmed its position that the Evidence Code contained a four-part test as outlined in *Kruse* for determining the admissibility of expert opinion evidence. See *CSX Transp., Inc. v. Whittler*, 584 So.2d 579, 584 (Fla. 4th DCA 1991).

FN6. A part of our *Frye* law that is particularly troubling is our direction to appellate courts that they are not only to conduct a de novo review of the general acceptance issue but they should also examine any extrajudicial materials available at the time of appeal to resolve the issue. *Hadden v. State*, 690 So.2d 573, 579 (Fla.1997). Of course, any such materials considered by the appellate court would not have been subject to cross-examination or other examination for reliability by the parties or the trial court. Such a novel procedure represents a significant break from our established law limiting appellate courts to a consideration of the trial record.

THIS CASE

There are courts that have addressed the exact question of expert testimony linking physical trauma to fibromyalgia and found it admissible pursuant to the rule announced in *Daubert*. For example, in *Reichert v. Phipps*, 84 P.3d 353 (Wyo.2004), the Wyoming Supreme Court reversed a trial court's order prohibiting the plaintiff from offering evidence that the car crash at issue in the case caused her fibromyalgia. *Id.* at 355. The court framed its analysis as follows:

We are not deciding whether trauma can cause [fibromyalgia], or even whether, as a general proposition, there is sufficient scientific foundation for the theory to allow juries to decide the issue as a question of fact.... The question before us is limited to whether this particular trial court, given the evidence and arguments at the time, reasonably could have concluded as it did.

Id. at 357. In finding that the trial court abused its discretion in excluding the evidence, the court found that, since some experts do believe that trauma can cause fibromyalgia, the proffered expert had reliable grounds for reaching such a conclusion and that therefore his *opinion* was admissible. *Id.* at 364 (emphasis added).

In the instant case, the proffered expert opinions were based on the petitioners self-reported symptoms, filtered through the two doctors' perceptions after years of experience with similar patients. The opinions were given in the overall context of a professional controversy over the link between physical trauma and FM, in which some experts take the position that there is, indeed, a causal connection. We conclude that, under these circumstances, the trial court abused its discretion in not allowing the jury to determine the weight to give the opinion testimony.

Id.

The Nebraska Supreme Court reached a similar conclusion in *Epp v. Lauby*, 271 Neb. 640, 715 N.W.2d 501, 504 (2006), involving an action for damages in which the plaintiff allegedly developed fibromyalgia after a car accident. The trial court conducted a *Daubert* hearing concerning Epp's expert testimony that the accident caused the fibromyalgia, and the trial court excluded the evidence, concluding that medical science was insufficient to link the trauma to the condition. *Id.* at 506. *559 Under an abuse of

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discretion standard, the supreme court overturned the trial court's ruling on the expert testimony after phrasing the question as follows: "[W]e are deciding whether there was sufficient evidence presented to allow Epp's experts, Handke and Bennett, to opine that physical trauma was the cause of Epp's fibromyalgia." *Id.* at 507. The court, noting the "professional controversy regarding the causal relationship between physical trauma and fibromyalgia," ultimately concluded that "general acceptance of the causal link ... is not determinative of the admissibility of expert testimony under *Daubert/Schafersman* [*Schafersman v. Agland Coop.*, 262 Neb. 215, 631 N.W.2d 862 (2001)] standards." *Id.* at 509-10. "So long as the expert's opinion is based on reliable methodology, his or her opinion is admissible, whether or not the court agrees with the expert's conclusion." *Id.* at 510. The court found that the experts' testimony was supported by sufficient medical and scientific literature supporting the theory that fibromyalgia may be caused by physical trauma. *Id.*

Although the issue is disputed, there is support in the medical literature for the theory that physical trauma can cause fibromyalgia. That support, while controverted, is the result of peer-reviewed research conducted pursuant to appropriate methods of scientific inquiry. While there is not a sufficient scientific consensus to say that the theory is generally accepted, nor has a rate of error been established, the theory that trauma can cause fibromyalgia has been the subject of empirical research, the results of which have been subjected to peer review and publication. See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, *supra*. We cannot conclude that Handke and Bennetts reliance on this research, instead of literature to the contrary, was methodologically unreliable. If proffered scientific evidence rests on sound scientific reasoning or methodology and properly can be applied to the facts in issue, it meets the *Daubert* requirements for admissibility, even if the conclusion is novel or controversial. See *State v. Dahood*[, 148 N.H. 723, 814 A.2d 159], *supra*. Despite the existence of spirited dissent, see *State v. Sampson*, 167 Or.App. at 503, 6 P.3d at 553, the lack of a scientific consensus on the link between trauma and fibromyalgia was not sufficient to render reliance upon that literature methodologically unreliable. We, therefore, conclude that the evidence was sufficient to support the theory of a causal relationship between physical trauma and fibromyalgia and that the trial court

abused its discretion in concluding otherwise.

Id. at 511. Accordingly, the supreme court remanded for a new trial on the issue of damages, since liability in the case was admitted. *Id.* at 512.

CONCLUSION

I would hold that *Frye* has been superseded by the adoption of Florida's Evidence Code, and that under the relevancy standard contained in the code the expert opinion evidence in question was admissible. Hence, I concur in the majority's decision.

PARIENTE, J., concurs.

CANTERO, J., dissenting.

I respectfully disagree with the majority's holding that testimony causally linking trauma to fibromyalgia is "pure opinion" testimony not subject to the *Frye* test. I also disagree that such testimony would satisfy *Frye*. I would approve the Fifth District's opinion in *Marsh v. Valyou*, 917 So.2d 313 (Fla. 5th DCA 2005), and disapprove the Second District's conflicting decision*560 in *State Farm Mutual Automobile Insurance Co. v. Johnson*, 880 So.2d 721 (Fla. 2d DCA 2004).

Below I demonstrate (I) why expert testimony causally linking trauma to fibromyalgia must satisfy *Frye*, and (II) that Petitioner, as the proponent of the evidence, has failed to demonstrate that it is generally accepted in the scientific community that trauma can cause fibromyalgia.

I. THE TESTIMONY IS SUBJECT TO *FRYE*

The *Frye* test is simple to state, if not always easy to apply: "[I]n order to introduce expert testimony deduced from a scientific principle or discovery, the principle or discovery 'must be sufficiently established to have gained general acceptance in the particular field in which it belongs.'" *Flanagan v. State*, 625 So.2d 827, 828 (Fla.1993) (quoting *Frye v. United States*, 293 F. 1013, 1014 (D.C.Cir.1923)). "This standard requires a determination, by the judge, that the basic underlying principles of scientific evidence have been sufficiently tested and accepted by the relevant scientific community." *Brim v. State*, 695 So.2d 268, 272 (Fla.1997); see also *Ramirez v. State*, 810 So.2d 836, 843 (Fla.2001) ("Evidence based on a

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novel scientific theory is inherently unreliable and inadmissible in a legal proceeding in Florida unless the theory has been adequately tested and accepted in the relevant scientific community.”). The underlying theory of *Frye* is that “a courtroom is not a laboratory, and as such it is not the place to conduct scientific experiments. If the scientific community considers a procedure or process unreliable for its own purposes, then the procedures must be considered less reliable for courtroom use.” *Stokes v. State*, 548 So.2d 188, 193-94 (Fla.1989).

A. Novel Scientific Testimony Versus “Pure Opinion”

Courts traditionally have exempted pure opinion testimony from the requirements of *Frye* on the theory that the testimony is based on the expert's personal experience and training. See, e.g., *Hadden v. State*, 690 So.2d 573, 580 (Fla.1997); *Flanagan*, 625 So.2d at 828; *State v. Demeniuk*, 888 So.2d 655, 659 (Fla. 5th DCA 2004). As we explained in *Flanagan*:

[P]ure opinion testimony, such as an expert's opinion that a defendant is incompetent, does not have to meet *Frye*, because this type of testimony is based on the expert's personal experience and training. While cloaked with the credibility of the expert, this testimony is analyzed by the jury as it analyzes any other personal opinion or factual testimony by a witness.

625 So.2d at 828. The majority holds that testimony causally linking trauma to fibromyalgia is just such “pure opinion” testimony. This conclusion broadens this supposedly narrow exception way beyond its limited purpose.

Testimony is “pure opinion” only when it is based solely on experience and training, and does not rely on a novel scientific principle, test, or methodology:

“Pure opinion” refers to expert opinion developed from inductive reasoning based on the experts' own experience, observation, or research, whereas the *Frye* test applies when an expert witness reaches a conclusion by deduction, from applying new and novel scientific principle, formula, or procedure developed by others.

Demeniuk, 888 So.2d at 659 (quoting *Holy Cross Hosp., Inc. v. Marrone*, 816 So.2d 1113, 1117 (Fla. 4th DCA 2001)). We first recognized that pure opinion testimony is not subject to *Frye* in *Flanagan*, 625 So.2d at 828. There, we recognized the distinction*561 between pure opinion testimony derived solely from “experience and training” and expert testimony that “necessarily relies on some scientific principle or test” and rejected labeling the pedophile/sex offender profile testimony at issue “pure opinion”:

Profile testimony ... by its nature necessarily relies on some scientific principle or test, which implies an infallibility not found in pure opinion testimony. The jury will naturally assume that the scientific principles underlying the expert's conclusion are valid. Accordingly, this type of testimony must meet the *Frye* test, designed to ensure that the jury will not be misled by experimental scientific methods which may ultimately prove to be unsound.

Id. Similarly, in *Hadden*, 690 So.2d at 581, we applied *Frye* to testimony that an alleged victim of sexual abuse exhibited symptoms consistent with those of a child who has been sexually abused. We explained that the *Frye* test “requires that the scientific principles undergirding this evidence be found by the trial court to be generally accepted by the relevant members of its particular field.” *Hadden*, 690 So.2d at 576. We rejected labeling the evidence “pure opinion”:

We differentiate pure opinion testimony based upon clinical experience from profile and syndrome evidence because profile and syndrome evidence rely on conclusions based upon studies and tests. Further, we find that *profile or syndrome evidence is not made admissible by combining such evidence with pure opinion testimony because such a combination is not pure opinion evidence based solely upon the expert's clinical experience.*

Id. at 580 (emphasis added).

Therefore, in both *Flanagan* and *Hadden* we recognized that pure opinion is not subject to *Frye*, but emphasized that the underlying scientific principles are. *Flanagan*, 625 So.2d at 828; *Hadden*, 690 So.2d at 576, 580; see also *Brim*, 695 So.2d at 272 (recognizing that under *Frye*, “the burden is on the proponent of the evidence to prove the general acceptance of both the underlying scientific principle and the

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testing procedures used to apply that principle to the facts at hand”) (quoting *Ramirez v. State*, 651 So.2d 1164, 1168 (Fla.1995)).

These cases dictate that where an expert's opinion is based on an underlying scientific principle, that underlying principle is subject to *Frye*. See also *Hildwin v. State*, 951 So.2d 784, 792 (Fla.2006) (“The principal inquiry under the *Frye* test is whether the scientific theory or discovery from which an expert derives an opinion is reliable.”) (quoting *Ramirez*, 651 So.2d at 1167).

In this case, the underlying scientific principle is that trauma *can* cause fibromyalgia. That principle must pass the *Frye* test. I agree that testimony that a particular patient, such as Marsh, suffers from fibromyalgia, if based on clinical experience, may constitute pure opinion not subject to *Frye*. In this case, however, the objection was not to testimony that Marsh suffers from fibromyalgia, but to testimony that it was caused by trauma. While the experts may assert that their testimony is based on their experience and training, it is also necessarily based on an underlying (and as yet unproven) scientific principle that trauma *can* cause fibromyalgia. *Marsh*, 917 So.2d at 327 (recognizing that the testimony requires “an underlying scientific assumption—that trauma can cause fibromyalgia—which is not involved in pure opinion cases”); see also *Kaelbel Wholesale, Inc. v. Soderstrom*, 785 So.2d 539, 547 (Fla. 4th DCA 2001) (rejecting the argument that causation testimony was *562 pure opinion, concluding that it “was not based upon personal experience or training” but instead “was based upon scientific principles to reach the opinions and conclusions drawn”). This theory of general causation does not become admissible simply because it is the opinion of some experts that trauma caused Marsh's fibromyalgia. See *Hadden*, 690 So.2d at 580 (recognizing that evidence is not made admissible by combining it with “pure opinion” testimony); *Marsh*, 917 So.2d at 327 (“[I]t is counterintuitive to permit an expert to ignore scientific literature accepted by the general scientific community in favor of the expert's personal experience to reach a conclusion not generally recognized in the scientific community and then allow testimony about that conclusion on the basis that it is ‘pure opinion.’”). As we recognized in *Hadden*:

Novel scientific evidence must also be shown to be

reliable on some basis other than simply that it is the opinion of the witness who seeks to offer the opinion. In sum, we will not permit factual issues to be resolved on the basis of opinions which have yet to achieve general acceptance in the relevant scientific community; to do otherwise would permit resolutions based upon evidence which has not been demonstrated to be sufficiently reliable and would thereby cast doubt on the reliability of the factual resolutions.

690 So.2d at 578; see also *Ramirez*, 810 So.2d at 844 (recognizing that *Frye* requires more than “[a] bald assertion by the expert that his deduction is premised upon well-recognized scientific principles”).

The majority's holding that an opinion about specific causation need not pass the *Frye* test, even where the underlying theory of general causation is not accepted, in effect renders specific causation testimony always admissible as the “pure opinion” of the expert. This constitutes a sea change in Florida law, as Florida courts have regularly applied *Frye* to causation testimony. See, e.g., *Shepard v. Barnard*, 949 So.2d 232, 233 (Fla. 5th DCA 2007) (applying *Frye* to testimony that the use of Verteporfin could cause permanent photoallergy); *Hawkins v. State*, 933 So.2d 1186, 1189 (Fla. 4th DCA 2006) (finding *Frye* applicable to an opinion about the cause of a silicone embolism), review dismissed, 950 So.2d 414 (Fla.2007); *Demeniuk*, 888 So.2d at 657, 659 (finding *Frye* applicable to testimony of a causal connection between selective serotonin reuptake inhibitors and suicide/involuntary alcohol consumption where the opinions “were based on a novel scientific theory”); *David v. Nat'l R.R. Passenger Corp.*, 801 So.2d 223, 226 (Fla. 2d DCA 2001) (remanding for a determination of whether the theory that repetitive motion can cause carpal tunnel syndrome was generally accepted); *Kaelbel Wholesale, Inc.*, 785 So.2d at 548-50 (rejecting testimony linking ciguatera poisoning to the development of Guillain-Barré Syndrome where the theory of causation was not generally accepted); *Poulin v. Fleming*, 782 So.2d 452, 452 (Fla. 5th DCA 2001) (applying *Frye* to testimony that prenatal exposure to radiation caused schizencephaly).

As I explain more fully below, we have approved, and have seemingly applied, this approach. See *U.S. Sugar Corp. v. Henson*, 787 So.2d 3, 5 (Fla. 1st DCA 2000) (applying *Frye* to testimony that the cumula-

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tive effect of pesticide exposure caused phrenetic nerve mononeuropathy and finding *both* the general causation theory and specific causation methodology to be generally accepted), *approved*, 823 So.2d at 109 (commending and approving “the thoughtful analysis performed by the district court below evaluating the general acceptance of the methodologies and scientific principles supporting Henson’s experts’ opinions”).

*563 Other courts recognize this proposition as well. As a federal appellate court has said,

The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur. Based on this predicate knowledge, it may then be possible to fasten legal liability for a person’s disease or injury.

Black v. Food Lion, Inc., 171 F.3d 308, 314 (5th Cir.1999); *cf. McClain v. Metabolife Int’l Inc.*, 401 F.3d 1233, 1239 (11th Cir.2005) (noting that in toxic tort cases where the medical community does not generally recognize an agent as both toxic and capable of causing the injury alleged, “the *Daubert* analysis covers not only the expert’s methodology for the plaintiff-specific questions about individual causation but also the general question of whether the drug or chemical *can* cause the harm plaintiff alleges”). Permitting an expert to testify that X caused Y in a specific case without requiring the general acceptance of the theory that X can *ever* cause Y expands the “pure opinion” exception to the point where it swallows the rule.

B. *U.S. Sugar* and *Castillo*

Two of our recent decisions confirm the applicability of *Frye* to general causation testimony. See *U.S. Sugar Corp. v. Henson*, 823 So.2d 104 (Fla.2002); *Castillo v. E.I. Du Pont De Nemours & Co.*, 854 So.2d 1264 (Fla.2003). *U.S. Sugar* involved a *Frye* challenge to an expert’s opinion that the cumulative effect of pesticide exposure caused the claimant’s phrenetic nerve mononeuropathy. 823 So.2d at 106. The First District applied *Frye* to conclude:

Because our *de novo* review establishes that there

is general acceptance in the relevant scientific community *both* (i) for claimant’s *general causation theory that certain pesticides to which he was repeatedly exposed over a long period of time can cause peripheral neuropathy*, and (ii) for the differential diagnosis methodology employed by claimant’s physicians, which they used to exclude other facts that might cause his condition and to determine that his pesticide exposure specifically caused his injury, we affirm.

U.S. Sugar Corp., 787 So.2d at 5 (emphasis added). On review, we agreed that it is “generally accepted in the scientific community that ‘organophosphates are neurotoxic’ ” and that “[b]ecause of this generally accepted scientific foundation, the ‘extrapolation’ method utilized by these experts in concluding that chronic exposure to these pesticides caused claimant’s condition is an acceptable scientific technique in this case.” *U.S. Sugar*, 823 So.2d at 109 (quoting *U.S. Sugar*, 787 So.2d at 16-17). We went on to “highlight” (referring to the Third District’s decision in *E.I. DuPont De Nemours & Co., Inc. v. Castillo*, 748 So.2d 1108 (Fla. 3d DCA 2000), *quashed*, 854 So.2d 1264 (Fla.2003)) that “under *Frye*, the inquiry must focus only on the general acceptance of the scientific principles and methodologies upon which an expert relies in rendering his or her opinion.” *U.S. Sugar*, 823 So.2d at 110.

The other case in which we confirmed *Frye*’s application to general causation was *Castillo*, 854 So.2d at 1264. That case involved expert testimony that fetal exposure to a fungicide (Benlate) caused a birth defect (microphthalmia). *Id.* at 1267. The *Frye* challenge related to the methodology for determining whether, and at what level, Benlate could cause birth defects in humans. *Id.* The defendants acknowledged that the *in vivo* tests (animal toxicology) and *in vitro* tests (analysis of the *564 effects of suspected substances on isolated cell systems) underlying the opinion were generally accepted methods for analyzing toxicology, but they argued that the expert’s extrapolation from the tests to conclude that Benlate is a human teratogen was not generally accepted. *Castillo*, 748 So.2d at 1116, 1118. The district court found that the expert’s extrapolation from the tests was subject to and failed to satisfy *Frye*. *Id.* at 1120-21 (“[W]here, as here, plaintiffs wish to establish a substance’s teratogenicity in human beings based on animal and *in vitro* studies, the methodology used in

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the studies, including the method of extrapolating from the achieved results, must be generally accepted in the relevant scientific community.”). On review, we disagreed, concluding that the expert conclusions reached through extrapolation fell outside of *Frye* consideration:

By considering the extrapolation of the data from the admittedly acceptable experiments, the Third District went beyond the requirements of *Frye*, which assesses only the validity of the underlying science. *Frye* does not require the court to assess the application of the expert's raw data in reaching his or her conclusion. We therefore conclude that the Third District erroneously assessed the Castillo's expert testimony under *Frye* by considering not just the underlying science, but the application of the data generated from that science in reaching the expert's ultimate conclusion.

Castillo, 854 So.2d at 1276 (emphasis added).

U.S. Sugar and *Castillo* confirm that while expert opinions deduced from generally accepted principles are not subject to *Frye*, the underlying principles are. *U.S. Sugar*, 823 So.2d at 109-10 (“[W]hen the expert's opinion is based on generally accepted scientific principles and methodology, it is not necessary that the expert's deductions based thereon and opinion also be generally accepted as well.”); *Castillo*, 854 So.2d at 1269, 1276 (“We must consider whether the scientific principles upon which the Castillo's experts based their opinions are generally accepted in the scientific community.”).

The majority characterizes the challenge in this case as one to the “experts' conclusions that trauma caused Marsh's fibromyalgia.” Majority op. at 549. But Respondents do not challenge the experts' conclusions. Rather, they challenge the premise behind them—the theory that trauma can ever cause fibromyalgia. If it were generally accepted in the scientific community that trauma can cause fibromyalgia, then I would agree that the experts' deduction from that principle to conclude that trauma caused Marsh's fibromyalgia would not be subject to *Frye*. See *Castillo*, 854 So.2d at 1276; *U.S. Sugar*, 823 So.2d at 110. It is that underlying principle, however, that is contested here.

I also disagree with the majority's conclusion that Marsh's experts' testimony is not subject to *Frye* sim-

ply because the methodology used—differential diagnosis—is generally accepted. Majority op. at 549. Differential diagnosis is certainly a generally accepted methodology for determining specific causation. The use of differential diagnosis alone, however, does not exempt causation testimony from *Frye*. Differential diagnosis is merely a “scientific methodology in which the expert eliminates possible causes of a medical condition to arrive at the conclusion as to the actual debilitating factor.” *U.S. Sugar*, 823 So.2d at 106. It is a process of elimination—the patient's condition, call it X, was not caused by A, B, or C; therefore, X must have been caused by D. But before causes A, B, and C can be scientifically *565 excluded as a specific cause (i.e., A did not cause X), they must first be scientifically included as a general cause (i.e., A can cause X). Experts cannot conclude, through a process of elimination, that trauma caused the plaintiff's fibromyalgia without first demonstrating the reliability of the theory that trauma can cause it.

To illustrate with an extreme example: a patient suffering from depression sees a doctor because her arm hurts. She does not know why her arm hurts. The doctor diagnoses a broken arm. The patient cannot tell the doctor how she broke her arm. The doctor may, through performing tests and interviewing the patient, conclude that it could not have been a car accident (the patient was not involved in an accident) and it could not have been playing sports (the patient does not play sports), but the doctor cannot then conclude that it must have been the depression that caused the broken arm—unless, of course, the doctor can show that the theory that depression can cause a broken arm is generally accepted in the scientific community. Similarly, only if it is generally accepted that trauma is a potential cause of fibromyalgia may an expert testify that, through differential diagnosis, she has concluded that trauma caused this plaintiff's fibromyalgia. See, e.g., *McClain*, 401 F.3d at 1253 (“[A]n 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.”); *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057-58 (9th Cir.2003) (“The first step in [a differential diagnosis] is to compile a comprehensive list of hypotheses.... The issue at this point in the process is which of the competing causes are generally capable of causing the patient's symptoms or mortality. Expert testimony that rules in a potential cause that is not so capable is unreliable.”) (citation

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omitted); *Food Lion*, 171 F.3d at 314 (recognizing that the causes of fibromyalgia are unknown and “[a]bsent these critical scientific predicates ... no scientifically reliable conclusion on causation can be drawn” such that the “use of a general methodology cannot vindicate a conclusion for which there is no underlying medical support”); *Maras v. Avis Rent A Car Sys., Inc.*, 393 F.Supp.2d 801, 809 (D.Minn.2005) (noting that the plaintiff failed to demonstrate a proper basis for “ruling in” an accident as the cause of fibromyalgia and thus, use of differential diagnosis did not render the testimony admissible). Differential diagnosis is not a wild card that can be used to introduce novel scientific theories into the courtroom. Any other logic would revert us to the science of the Salem Witch Trials. *See, e.g.*, Laurie Winn Carlson, *A Fever in Salem* xiv (1999) (“With the limited scientific and medical knowledge of the time, physicians who were consulted could only offer witchcraft as an explanation.”); *cf.* Carl Sagan, *The Demon-Haunted World* 26 (1995) (“Science is an attempt, largely successful, to understand the world, to get a grip on things, to get hold of ourselves, to steer a safe course. Microbiology and meteorology now explain what only a few centuries ago was considered sufficient cause to burn women to death.”).

II. THE TESTIMONY FAILS TO SATISFY *FRYE*

Having determined that testimony causally connecting trauma to fibromyalgia is subject to the *Frye* test, the next question I address is whether the evidence in this case satisfied the test. I conclude that the answer is “no.” *Frye* requires the proponent to show general acceptance by a “clear majority” of the members of the relevant scientific community. *See, e.g.*, *Brim*, 695 So.2d at 272; *Hadden*, 690 So.2d at 576 n. 2. The majority here concludes*566 that testimony causally linking trauma to fibromyalgia is admissible because some experts recognize an association between the two. Majority op. at 550. I cannot agree that such evidence satisfies *Frye*. As explained below, a review of the materials presented to the trial court, district court, and this Court, as well as opinions from other jurisdictions, demonstrate an ongoing debate on the issue of whether trauma can cause fibromyalgia. *See, e.g.*, *Ramirez*, 810 So.2d at 844 (recognizing that a court may consider “expert testimony, scientific and legal publications, and judicial opinions” in determining whether a theory has been “sufficiently tested

and accepted by the relevant scientific community’ ”) (quoting *Brim*, 695 So.2d at 272). No clear majority has emerged-either way. Therefore, Marsh, as the proponent of the evidence, has failed to meet her burden.

The record in this case contains a large amount of material. However, the parties focused on six documents-three “consensus reports”-Frederick Wolfe et al., *The Fibromyalgia Syndrome: A Consensus Report on Fibromyalgia and Disability*, 23 J. Rheumatology 534 (1996) [hereinafter *Consensus Report*]; Muhammad B. Yunus et al., *Fibromyalgia Consensus Report: Additional Comments*, 3 J. Clinical Rheumatology 324 (1997) [hereinafter *Additional Comments*]; and Anil Kumar Jain et al., *Fibromyalgia Syndrome: Canadian Clinical Working Case Definition, Diagnostic and Treatment Protocols-A Consensus Document*, 11 J. Musculoskeletal Pain 3 (2003) [hereinafter *2003 Consensus Document*]-and three studies (Dan Buskila et al., *Increased Rates of Fibromyalgia Following Cervical Spine Injury*, 40 Arthritis & Rheumatism 446 (1997) [hereinafter *Buskila study*]; A.W. Al-Allaf et al., *A Case-Control Study Examining the Role of Physical Trauma in the Onset of Fibromyalgia Syndrome*, 41 Rheumatology 450 (2002) [hereinafter *Al-Allaf study*]; and Moshe Tishler et al., *Neck Injury and Fibromyalgia-Are They Really Associated?*, 33 J. Rheumatology 1183 (2006) [hereinafter *Tishler study*]). I address these documents below, along with others.

The *Consensus Report*, *supra*, at 534, resulted from a 1994 conference of fibromyalgia experts. It specifically addresses the connection between trauma and fibromyalgia:

Evidence that trauma can cause FM, a potential (or It Can) causal proposition, comes from a few case series or case reports and is insufficient to establish causal relationships. That trauma might cause FM sometimes, a predictive (or It Will) causal proposition, can only be addressed by epidemiological studies that measure the risk of potential exposures on the development of FM. Epidemiologic studies of trauma and FM needed to address potential or predictive causality are currently not available....

Overall, then, data from the literature are insufficient to indicate whether causal relationships ex-

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ist between trauma and FM. The absence of evidence, however, does not mean that causality does not exist, rather that appropriate studies have not been performed.

Id. at 534-35 (footnotes omitted) (emphasis added). In response to the *Consensus Report*, another group published the *Additional Comments, supra*. The authors recognized that “[o]ur scientific understanding of FMS is still very limited.” *Id.* at 324. However, with regard to causality, they disagreed with the *Consensus Report*, stating, “[I]t seems more than 51% likely that trauma does play a causative role in some FMS patients.” *Id.* at 325. ^{FN7}

FN7. The focus of this statement is on the causal probability rather than the general acceptance of the causal theory—the relevant inquiry under *Frye*. However, the point seems to be that these experts believe trauma can cause fibromyalgia.

*567 Later, another group published the *2003 Consensus Document, supra*, which was primarily a summary of previous research. The *2003 Consensus Document* recognizes that no known cause of fibromyalgia exists, but reviews numerous studies to conclude that “[t]here is strong consistency in documentation that physical trauma such as a fall or motor vehicle accident, particularly a whiplash or spinal injury, can trigger FMS in some patients.” *Id.* at 44. The authors recognize, however, that further research on “[t]he etiology of FMS including genetic components and prodromal events such as physical trauma” is needed. *Id.* at 61.

Although not a “consensus” report, another recent document surveys physician opinions about the association between trauma and fibromyalgia. See Kevin P. White et al., *Perspectives on Posttraumatic Fibromyalgia: A Random Survey of Canadian General Practitioners, Orthopedists, Psychiatrists, and Rheumatologists*, 27 J. Rheumatology 790, 794 (2000) [hereinafter *White survey*]. The authors randomly surveyed Canadian physicians to determine which factors were deemed most important in an individual with widespread pain following a motor vehicle trauma. *Id.* at 791. They found that the physicians surveyed “were reluctant to ascribe primary responsibility for chronic widespread pain to the trauma itself.” *Id.* at 794.

If these documents demonstrate anything, it is the lack of consensus on the issue, and therefore the lack of general acceptance of the theory that trauma can cause fibromyalgia. The very fact that competing “consensus reports” exist, with experts on each side, demonstrates the lack of general acceptance by a “clear majority” of members of the community.

As the majority notes, *see majority op.* at 550, some articles do suggest an association between trauma and fibromyalgia. But most of them are case reports and anecdotal accounts. ^{FN8} I recognize that to satisfy *Frye* epidemiological studies confirming a causal theory are not always required, *see, e.g., Castillo*, 854 So.2d at 1270; *U.S. Sugar*, 823 So.2d at 110, but if a majority of experts agrees about anything, it is that (1) the cause of fibromyalgia is unknown, ^{FN9} and (2) to determine the *568 relationship between fibromyalgia and trauma, more studies are needed. ^{FN10}

FN8. *See, e.g., Samuel A. McLean et al., Fibromyalgia After Motor Vehicle Collision: Evidence and Implications*, 6 Traffic Injury Prevention 97, 97, 99 (2005) (recognizing a “plethora” of case reports and anecdotal accounts of fibromyalgia in close temporal association with trauma, but only one case-controlled study—the *Buskila* study—directly examining the relationship); Yoram Shir et al., *Whiplash and Fibromyalgia: An Ever-Widening Gap*, 33 J. of Rheumatology 1045, 1046 (2006) (noting that the link with trauma has been mostly based on patient report and retrospective studies); John B. Winfield, *Pain in Fibromyalgia*, 25 Pain Management in the Rheumatic Diseases 55, 63 (1999) (“The argument in favor of a connection between trauma and fibromyalgia is based on the experience of certain clinicians that trauma and fibromyalgia are associated....”).

FN9. *See, e.g., Dan Buskila & Lily Neumann, Musculoskeletal Injury as a Trigger for Fibromyalgia/Posttraumatic Fibromyalgia*, 2 Current Rheumatology Reports 104, 104 (2000) (“[T]he etiology and pathophysiology of FM are still unclear.”); *2003 Consensus Document, supra*, at 43-44 (recognizing that “[t]here is no known single

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initiating cause” of fibromyalgia); Roland Staud, *Fibromyalgia Pain: Do We Know the Source?*, 16 *Current Opinion in Rheumatology* 157, 157 (2004) (“Fibromyalgia syndrome is a chronic pain syndrome of unknown etiology....”); Tishler study, *supra*, at 1183 (“The etiology and pathophysiology of this disorder remain unclear....”); *Consensus Report, supra*, at 536 (“The cause(s) of FM are incompletely understood.”). The Petitioner likewise recognizes that “the precise etiology and exact pathological mechanisms are not fully understood.”

FN10. *See, e.g.*, Buskila & Neumann, *supra*, at 107 (“Future research needs to be directed to prospective longitudinal evaluation of patients who fall victim to motor vehicle or industrial accidents to determine the natural history of postaccident FM.”); *2003 Consensus Document, supra*, at 61 (recognizing that further research is “obviously needed” on the “etiology of FMS,” including the link to trauma); McLean et al., *supra*, at 99, 101 (stating that further case-control studies are needed to “more firmly establish causation”); Shir et al., *supra*, at 1046 (“The debate ... is not completely settled for an association of a triggering event and the onset of FM, but requires further study in order to reach a final conclusion.”); Staud, *supra*, at 159 (“Further prospective studies, however, are needed to confirm this association and to identify whether trauma plays a causal role for FMS pain.”); George W. Waylonis & Robert H. Perkins, *Post-Traumatic Fibromyalgia: A Long-Term Follow-Up*, 73 *Am. J. of Physical Med. & Rehabilitation* 403, 403 (1994) (recognizing that “literature investigating post-traumatic fibromyalgia is quite limited”); Kevin P. White et al., *Trauma and Fibromyalgia: Is There an Association and What Does It Mean?*, 29 *Seminars in Arthritis & Rheumatism* 200, 201, 209 (2000) (stating “there is limited evidence either to support or refute an association between trauma and FM” and that further studies are needed); *Consensus Report, supra*, at 534 (“Epidemiologic studies of trauma and FM needed to address potential or predictive causality are currently not available.”).

The parties primarily rely on three such studies: (1) the Buskila study; (2) the *Al-Allaf* study; and (3) the Tishler study. All three of these studies conclude that more research is needed to determine whether trauma causes fibromyalgia. The authors of the Buskila study, *supra* at 446, which was published in 1997, studied the relationship between cervical spine injury and the development of fibromyalgia. They recognized that to date the evidence that trauma can cause fibromyalgia had been “equivocal” and “from a few case series or case reports ... insufficient to establish causal relationships.” *Id.* (footnotes omitted). They studied two groups of Israeli patients who visited an occupational clinic: (1) those with neck injuries (102 patients); and (2) those with leg fractures (fifty-nine patients). *Id.* at 447. The researchers found that twenty-two of the patients with neck injuries, and only one of the patients with a leg fracture, developed fibromyalgia. *Id.* at 449. The article concludes that “[t]he present data in the literature are insufficient to indicate whether causal relationships exist between trauma and FMS. Our study, however, suggests that soft tissue trauma to the neck can result in an increased incidence of FMS compared with other injuries.” *Id.* at 451.

Despite this conclusion, a later article by two of the same authors states:

Traumatic incidents have been suggested as a possible etiologic factor relating to the onset of FM. However, evidence that musculoskeletal injury or trauma can cause FM comes from a few case series or anecdotal case reports. *Reviewing the current literature reveals that data are insufficient to indicate whether causal relationships exist between trauma and FM.*

Buskila & Neumann, *supra*, at 107 (emphasis added).

Another study examining “whether physical trauma precipitates the onset of fibromyalgia” is the *Al-Allaf* study, *supra*, at 451, a retrospective study based on patient recall. The researchers found that 39% of the fibromyalgia patients reported a history of trauma, compared with 24% of the control subjects, suggesting “that physical trauma was significantly associated with the onset of FMS.” *Id.* at 452. However, they cautioned:

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Our own results are, of course, retrospective and may be influenced by recall *569 bias, but if they are confirmed in a prospective study this would lead us to speculate on the mechanisms by which trauma might precipitate FMS.

....

In conclusion, our study suggests that physical trauma in the 6 months before the onset of symptoms is significantly associated with the onset of FMS in patients attending a rheumatology outpatient clinic. *Further prospective studies are needed to confirm this association and to determine whether trauma has a causal role or if there are more important factors in the development of FMS.*

Id. at 453 (emphasis added).

Thus, both the *Buskila* study and *Al-Allaf* study suggest an *association* between trauma and fibromyalgia. However, they also indicate that before a causal connection can be found, more research is needed. It has been noted that a call for further research does not necessarily indicate uncertainty, and that the purpose of a study is not to fix a cause but to “assess the existence and strength or absence of an association between an agent and a disease.” *Berry v. CSX Transp., Inc.*, 709 So.2d 552, 567, 568 n. 12 (Fla. 1st DCA 1998). In this case, however, despite finding an association between trauma and fibromyalgia, the authors specifically recognized that insufficient data existed to find a causal relationship.

The majority nevertheless deems the studies finding a mere association between trauma and fibromyalgia sufficient to satisfy *Frye*. Majority op. at 550. Yet a recent study, the *Tishler* study, *supra*, at 1183—a prospective study published in 2006—suggests the absence of even that. The *Tishler* study involved 153 car accident patients who had been discharged from the emergency room with a whiplash injury, and a control group of forty-eight car accident patients hospitalized because of severe trauma. *Id.* The researchers found:

The issue of trauma and FM remains controversial Several studies in the past, most of them retrospective, have reported that up to 50% of patients with FM can recall an event, most often

physical trauma, that immediately preceded their symptoms. An extensive review of the literature failed to yield solid conclusions concerning this issue. The only prospective study that found a causative link between trauma and FM is by *Buskila, et al.* In this study, which was not followed by others, the authors found that 21.6% of patients with neck injury developed FM shortly after a work accident. These data are impressive since in their control group of patients with leg fractures, the rate of FM was much lower.... *We could not confirm these earlier findings; after a mean followup of 14.5 months, only one out of 153 patients with whiplash injury developed FM.*

....

In conclusion, the results of our prospective study do not support earlier observations about a link between neck trauma and FM.

Id. at 1184-85 (footnotes omitted) (emphasis added); *see also*, *Shir et al., supra*, at 1046 (“We now have a single, but large and well designed prospective study with a surprising conclusion.... *Tishler's* conclusion should be upheld.”).

Let me be clear: I do not argue that these studies demonstrate that trauma does *not* cause fibromyalgia. My point is that no clear majority exists *either way*. Instead, the scientific community is in the middle of an ongoing and intense debate. *See, e.g., Shir et al., supra*, at 1045 (“Opinions regarding an association between trauma such as whiplash injury (WLI) and *570 subsequent FM are emotionally charged and highly polarized.”); *McLean et al., supra*, at 97 (“The ability of physical trauma ... to trigger the development of FM remains the subject of intense debate.”); *White survey, supra*, at 790 (“There may be no issue more contentious in FM than the causative role of trauma.”); *Winfield, supra*, at 62-63 (recognizing that “[t]rauma as a ‘trigger’ or cause of fibromyalgia is an important and contentious issue in modern American society” and that “[d]ebate, which actually has raged for much of this century, continues”) (footnotes omitted). The very existence of this debate precludes *Marsh* from satisfying the requirement that this novel scientific principle be generally accepted. *See, e.g., Castillo*, 854 So.2d at 1268 (“The proponent of the evidence bears the burden of establishing by a preponderance of the evidence the general acceptance of

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the underlying scientific principles and methodology.”).

My conclusion is consistent with cases from other jurisdictions considering this precise issue under both *Frye* and *Daubert* (or a *Daubert*-type analysis). See, e.g., *Vargas v. Lee*, 317 F.3d 498, 502-03 (5th Cir.2003) (applying *Daubert* and excluding testimony that a car accident caused fibromyalgia); *Food Lion*, 171 F.3d at 314 (applying *Daubert* and finding testimony linking a slip-and-fall to fibromyalgia inadmissible); *Maras*, 393 F.Supp.2d at 808-10 (finding testimony that motor vehicle accident caused fibromyalgia failed to meet the general acceptance factor, among other factors, of *Daubert*); *Hultberg v. Wal-Mart Stores, Inc.*, No. CIV. A. 97-2858, 1999 WL 244030, at *1 (E.D.La. Apr.22, 1999) (applying *Daubert* and excluding testimony that a slip-and-fall accident caused fibromyalgia); *Schofield v. Laboscam, Inc.*, No. CIV. A. CV-00-197, 2002 WL 1335867, at *3 (Me.Super.Ct. June 6, 2002) (granting motion in limine to exclude testimony that a vehicle accident caused fibromyalgia); *Jones v. Conrad*, No. CA2000-12-257, 2001 WL 1001083, at *3-4 (Ohio Ct.App. Sept. 4, 2001) (finding testimony linking work accident to fibromyalgia inadmissible and the theory that trauma can cause fibromyalgia not generally accepted); *Grant v. Boccia*, 133 Wash.App. 176, 137 P.3d 20, 24 (2006) (citing with approval the district court's decision in *Marsh* and holding inadmissible under *Frye* testimony linking a car accident to fibromyalgia where “[n]one of the authorities presented by either party has the effect of persuasively establishing acceptance in the relevant community as to the cause of fibromyalgia or the causal role of trauma in the development of fibromyalgia”), *review denied*, 159 Wash.2d 1014, 154 P.3d 919 (2007); cf. *Washburn v. Merck & Co.*, 213 F.3d 627, 2000 WL 528649, at *2 (2d Cir. May 1, 2000) (No. 99-9121) (affirming exclusion of testimony that vaccination caused fibromyalgia and other conditions under *Daubert* because it was based “on little more than temporal correlation” between the vaccination and onset of symptoms); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1321-22 (11th Cir.1999) (affirming exclusion of testimony that breast implants caused fibromyalgia); *Wynacht v. Beckman Instruments, Inc.*, 113 F.Supp.2d 1205, 1209 (E.D.Tenn.2000) (finding testimony linking a chemical spill to fibromyalgia and other conditions inadmissible under *Daubert*); *Gross v. King David Bistro, Inc.*, 83 F.Supp.2d 597, 602 (D.Md.2000) (granting motion in

limine to preclude testimony under *Daubert* that shigella infection caused fibromyalgia); *Bushore v. Dow Corning-Wright Corp.*, No. 92-344-CIV-T-26C, 1999 WL 1116920, at *1 (M.D.Fla. Nov.15, 1999) (applying *Daubert* and excluding testimony that breast implants caused fibromyalgia); *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826, 855 (Del.Super.Ct.2000) *571 (excluding evidence that a “sick building” caused fibromyalgia because “there appears to be a consensus that there is no known cause of FM”).

I recognize that a few courts applying *Daubert* have admitted testimony causally linking trauma to fibromyalgia. See, e.g., *Epp v. Lauby*, 271 Neb. 640, 715 N.W.2d 501, 509-11 (2006) (recognizing a “professional controversy regarding the causal relationship between physical trauma and fibromyalgia” and that “there is not a sufficient scientific consensus to say that the theory is generally accepted,” but noting that general acceptance is not determinative under *Daubert* and finding admissible testimony causally linking plaintiff's car accident to fibromyalgia); *Reichert v. Phipps*, 84 P.3d 353, 364-65 (Wyo.2004) (finding causation testimony admissible because differential diagnosis is an acceptable method of diagnosing fibromyalgia and because the proffered expert opinions “were given in the overall context of a professional controversy over the link between physical trauma and FM, in which some experts take the position that there is, indeed, a causal connection”); cf. *Alder v. Bayer Corp.*, 61 P.3d 1068, 1085 (Utah 2002) (holding admissible testimony linking chemical fumes to fibromyalgia where it was based on differential diagnosis). These are in the minority, however, and they apply a different test. Other than the Second District's recent decision in *Johnson*, 880 So.2d at 721, however, I have found only one case applying a *Frye*-type test to testimony linking trauma to fibromyalgia that has found the testimony admissible. See *Byrum v. Superior Court of Los Angeles County*, No. B153001, 2002 WL 243565, at *2 (Cal.Ct.App. Feb.20, 2002). Even that case seems to conflict with another case within the same appellate district. See *Pflum v. Sears, Roebuck & Co.*, No. B161862, 2004 WL 348783, at *2 (Cal.Ct.App. Feb.25, 2004) (concluding the issue was not preserved, but addressing the merits and finding a lack of “a reasonable degree of medical certainty that trauma can exacerbate fibromyalgia”).

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III. CONCLUSION

For the reasons stated, I would hold that expert testimony causally linking trauma to fibromyalgia is subject to, and fails, the *Frye* test. Our precedent dictates that this underlying scientific principle of causation is subject to the *Frye* test. Whether trauma can ever cause fibromyalgia is a subject of much debate, and therefore the view that it can has not been generally accepted. I cannot agree with the majority that the jury should be left to sort out contentious and complex disputes about medical causation where experts in the relevant scientific community have been unable to agree. See *Brim*, 695 So.2d at 272 (“[W]e have expressly held that the trial judge must treat new or novel scientific evidence as a matter of admissibility (for the judge) rather than a matter of weight (for the jury.)”); *Ramirez*, 651 So.2d at 1168 (recognizing that “[t]he trial judge has the sole responsibility to determine” “the general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts at hand”). Contrary to our admonition in *Stokes*, 548 So.2d at 193-94 (“[A] courtroom is not a laboratory.... If the scientific community considers a procedure or process unreliable for its own purposes, then the procedures must be considered less reliable for courtroom use.”), the majority decision turns the courtroom into a laboratory. For these reasons, I respectfully dissent.

WELLS and BELL, JJ., concur.
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United States Court of Appeals,
Eleventh Circuit.
Johnny C. McClain, Annie McClain, Plaintiffs-
Appellees,
Shirley Franks, wife, Wilmer Hudson, husband, et al.,
Plaintiffs-Appellees, Cross-Appellants,
v.
METABOLIFE INTERNATIONAL, INC., a corpo-
ration, Defendant-Appellant, Cross-Appellee.
No. 03-12776.

March 2, 2005.

Background: Users of herbal weight-loss supplement containing ephedrine and caffeine sued supplement manufacturer alleging that manufacturer marketed and sold an unreasonably dangerous diet drug, resulting in ischemic strokes in three of the users and a heart attack in the other. Following a jury verdict, the United States District Court for the Northern District of Alabama, No. 01-01801-CV-AR-S, William M. Acker Jr., J., entered judgment for users, and manufacturer appealed.

Holding: The Court of Appeals, Royal, District Judge, sitting by designation, held that expert testimony was insufficiently reliable to be admissible under *Daubert*.

Reversed and remanded.

West Headnotes

[1] Federal Courts 170B  823

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk823 k. Reception of Evidence.
Most Cited Cases
The court of appeals reviews a trial court's *Daubert* rulings under an abuse of discretion standard.

[2] Federal Courts 170B  823

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk823 k. Reception of Evidence.

Most Cited Cases

When applying the abuse of discretion standard to a district court's *Daubert* rulings, an appellate court must affirm unless it at least determines that the district court has made a clear error of judgment, or has applied an incorrect legal standard. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[3] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  557

157 Evidence

157XII Opinion Evidence
157XII(D) Examination of Experts
157k557 k. Experiments and Results
Thereof. Most Cited Cases

Proffered testimony by expert in pharmacology that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, was insufficiently reliable under *Daubert* to be admissible in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; expert drew speculative conclusions about the supplement's toxicity from questionable principles of pharmacology, while at the same time, neglected the hallmark of the science of toxic torts, the dose-response relationship, drew unsubstantiated analogies between ephedrine and phenylpropanolamine, a drug from the same class as ephedrine, inferred conclusions from studies and reports that the papers did not authorize, and unjustifiably relied on government public health reports

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and consumer complaints. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[4] Evidence 157  **555.10**

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Pharmacology expert's application of scientific principles in reaching his conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, was insufficiently specific to reach reliable opinion on causation under *Daubert* in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; expert's testimony was ambiguous and offered nothing specific about how the supplement affected individuals, did not say how much it might elevate blood pressure, and offered no testimony about the dose of the supplement required to injure a user, and failed to take into account background risk for strokes and heart attacks. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Negligence 272  **1661**

272 Negligence

272XVIII Actions

272XVIII(C) Evidence

272XVIII(C)5 Weight and Sufficiency

272k1661 k. Dangerous Situations and Substances; Strict Liability. Most Cited Cases

Products Liability 313A  **380**

313A Products Liability

313AIV Actions

313AIV(C) Evidence

313AIV(C)4 Weight and Sufficiency of Evidence

313Ak380 k. In General. Most Cited

Cases

(Formerly 313Ak82.1)

In toxic tort cases, scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are

minimal facts necessary to sustain the plaintiff's burden.

[6] Negligence 272  **306**

272 Negligence

272VIII Dangerous Situations and Strict Liability

272k306 k. Dangerous Substances. Most Cited

Cases

Products Liability 313A  **147**

313A Products Liability

313AII Elements and Concepts

313Ak146 Proximate Cause

313Ak147 k. In General. Most Cited Cases

(Formerly 313Ak43)

Products Liability 313A  **217**

313A Products Liability

313AIII Particular Products

313Ak217 k. Chemicals in General. Most

Cited Cases

(Formerly 313Ak43)

To carry the burden in a toxic tort case, a plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.

[7] Evidence 157  **555.10**

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  **557**

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

Pharmacology expert's reliance on an analogy between ephedrine and phenylpropanolamine (PPA) in

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reaching his conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, rendered expert's analysis unreliable under *Daubert*, in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; studies relied upon by the author in making the analogy drew no conclusions about ephedrine and did not say that ephedrine was analogous to PPA, and expert failed to show that the differences in the chemical structures of the drugs made no difference. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[8] Evidence 157 555.2

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

The *Daubert* requirement that the expert testify to scientific knowledge, conclusions supported by good grounds for each step in the analysis, means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[9] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157 557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

Pharmacology expert's reliance on certain studies and reports in reaching his conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine

made it more toxic, rendered expert's analysis unreliable under *Daubert*, in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; authors of one report admitted their studies did not offer a basis to prove causation between ephedrine and caffeine, and authors of another report indicated that their report demonstrated only a temporal, not a causal, relationship between ephedrine and adverse cardiovascular events. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[10] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Pharmacology expert's reliance on Food and Drug Administration's (FDA) proposed rules to severely restrict the sale of herbal supplements containing ephedrine in reaching his conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, rendered expert's analysis unreliable to prove causation under *Daubert*, in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; a regulatory agency may choose to err on the side of caution and employs a risk-utility analysis that involves a much lower standard than demanded by a court of law. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[11] Evidence 157 555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Pharmacology expert's reliance on Food and Drug Administration's (FDA) adverse events reports and other consumer complaints in reaching his conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, rendered expert's analysis unreliable under *Daubert*, in toxic tort action

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brought by users of the supplement who subsequently suffered either ischemic strokes or heart attacks. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[12] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Methodology used by pharmacology expert in reaching conclusion that weight-loss supplement containing ephedrine and caffeine caused vasospasm and vasculitis, which in turn caused strokes and heart attacks and that adding caffeine made it more toxic, was insufficiently reliable to be admissible under *Daubert* to show general causation in toxic tort action brought by users of the supplement who suffered either ischemic strokes or heart attacks; expert offered no evidence of any testing of his theory, failed to present evidence of any peer review of his opinions, submitted no publication linking ephedrine and caffeine to strokes and heart attacks beyond the general incident rate or background risk, and offered no clinical trials or long-term studies about the toxicity of the ephedrine/caffeine combination on humans. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[13] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

Neurologist's use of differential diagnosis approach to rule out all causes for injuries, except herbal weight-loss supplement containing ephedrine and caffeine, in toxic tort action brought by user of the

supplement who suffered either ischemic strokes or heart attacks was insufficiently reliable to serve as a reliable basis for an expert opinion on causation, where neurologist did not offer a reliable explanation for the physiological process by which the supplement caused heart attacks or strokes. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[14] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  556

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k556 k. References to Authorities on

Subject. Most Cited Cases

Neurologist's reliance on anecdotal case reports found in medical literature in reaching conclusion that herbal weight-loss supplement containing ephedrine and caffeine caused each of user's injuries, in toxic tort action brought by user of the supplement who suffered either ischemic strokes or heart attacks, was insufficiently reliable under *Daubert* to serve as a basis for an expert opinion on causation. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[15] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157  557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

401 F.3d 1233, 66 Fed. R. Evid. Serv. 753, Prod.Liab.Rep. (CCH) P 17,126, Prod.Liab.Rep. (CCH) P 17,329, 18 Fla. L. Weekly Fed. C 281
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Neurologist's use of "challenge/de-challenge/re-challenge" methodology in reaching his conclusion that herbal weight-loss supplement containing ephedrine and caffeine caused each of user's injuries, in toxic tort action brought by user of the supplement who suffered either ischemic strokes or heart attacks, was insufficiently reliable under *Daubert* to serve as a reliable basis for an expert opinion on causation, given that there were insufficient controls employed by the neurologist and neurologist testified that one user suffered ischemic events even when she was not taking the supplement. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

*1236 John Patrick Kavanagh, Jr., Edward G. Bowron, Bowron, Latta & Wasden, P.C., Mobile, AL, Cavender Crosby Kimble, Balch & Bingham, LLP, Birmingham, AL, for Metabolife Intern., Inc.

A. David Fawal, Archie C. Lamb, Jr., Law Offices of Archie Lamb, LLC, Robert B. Roden, Shelby & Car-tee, Birmingham, AL, for Plaintiffs-Appellees and Plaintiffs-Appellants, Cross-Appellants.

Evan M. Tager, Mayer, Brown, Rowe & Maw LLP, Washington, DC, for Chamber of Commerce of the U.S., Amicus Curiae.

Appeals from the United States District Court for the Northern District of Alabama.

Before ANDERSON and BIRCH, Circuit Judges, and ROYAL^{FN*}, District Judge.

FN* Honorable C. Ashley Royal, United States District Judge for the Middle District of Georgia, sitting by designation.

ROYAL, District Judge:

This is an appeal of a jury verdict in a products liability action against Metabolife International, Inc. At trial Plaintiffs claimed that they suffered serious medical problems after taking Metabolife 356, an herbal weight-loss supplement, manufactured, marketed, and sold by Metabolife. After hearing the evidence, a jury returned a verdict in Plaintiffs' favor. Metabolife now appeals that verdict on the ground that the trial court erred in admitting the testimony of Plaintiffs' experts on the issue of causation. For the reasons discussed below, we find that the trial court

erroneously admitted Plaintiffs' experts' testimony. Accordingly, we REVERSE and REMAND for proceedings below consistent with these rulings.

I. Background Information

Annie McClain, Shirley Franks, Connie Thornburg and Wilmer Hudson contend that they suffered serious injuries after taking Metabolife 356, an herbal appetite suppressant containing ephedrine and caffeine. Ephedrine occurs naturally in a plant called ma huang and has been used for decades for treating adults and children, especially in over-the-counter medicines.

Plaintiffs brought this action against Defendant Metabolife International, Inc., charging that Metabolife manufactured, marketed, and sold an unreasonably dangerous diet drug. Plaintiffs further contend that Metabolife knew that its product could cause heart attacks and strokes, but nonetheless, continued to sell the drug without adequate warning. All four Plaintiffs took the dietary aid. Plaintiffs Thornburg, Franks, and McCain suffered ischemic cerebral events (strokes), and Plaintiff Hudson suffered an acute myocardial infarction (heart attack).

*1237 Before trial Metabolife moved to exclude Plaintiffs' experts' testimony on medical causation asserting that Plaintiffs' experts' opinions lacked a reliable foundation for admission under the standards of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The trial court held a *Daubert* hearing, and Plaintiffs offered two expert witnesses to prove causation: James O'Donnell, Pharm. D., and Hashim Hakim, M.D., a neurologist. Dr. O'Donnell primarily offered opinions on general causation. Dr. Hakim offered testimony on both general and individual causation.

In its brief written order on the motion, the district court acknowledged its role as a gatekeeper under FED.R.EVID. 702, but concluded that it lacked sufficient knowledge on the scientific subject matter to exclude the testimony presented and that Defendant had not produced competing testimony for it to determine that, as a matter of law, testimony from Plaintiffs' experts was inadmissible. Metabolife later filed a motion for reconsideration on the issue, and it was denied. The two experts testified at trial on the

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issues covered by Defendant's motion, and the jury returned a verdict for Plaintiffs. Defendant appealed contending that the district court abused its discretion in admitting Plaintiffs' experts' testimony on medical causation.

II. Legal Standard

This is a toxic tort case. Plaintiffs contend that the toxic combination of ephedrine and caffeine in the Metabolife 356 that they ingested harmed them. To prove their toxic tort claims, Plaintiffs must prove the toxicity of the ephedrine/caffeine combination and that it had a toxic effect on them causing the injuries that they suffered—ischemic strokes in three Plaintiffs and a heart attack in the other.

This type of proof requires expert testimony, and when a party offers expert testimony and the opposing party raises a *Daubert* challenge, the trial court must “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). This requirement for proof of the reliability of the expert's method comes from FED.R.EVID. 702, which authorizes the admission of expert opinion testimony “if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” Rule 702 lays the foundation for the trial court's *Daubert* analysis. 509 U.S. at 590, 113 S.Ct. 2786.

Daubert requires the trial court to act as a gatekeeper to insure that speculative and unreliable opinions do not reach the jury. *Id.* at 589 n.7, 597, 113 S.Ct. 2786. As a gatekeeper the court must do “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Id.* at 593-94, 113 S.Ct. 2786. The proposed testimony must derive from the scientific method; good grounds and appropriate validation must support it.^{FN1} *Id.* at 590, 113 S.Ct. *1238 2786. “In short, the requirement that an expert's testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Id.*

The court must consider the testimony with the understanding that “[t]he burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion....” *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir.2004).^{FN2}

FN1. While this opinion focuses upon the scientific methodology of an expert, it should be remembered that “experience in a field may offer another path to expert status.” *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir.2004). “In fact, the plain language of Rule 702 makes this clear: expert status may be based on ‘knowledge, skill, experience, training, or education.’ ” *Id.* (emphasis omitted).

FN2. In its order following the *Daubert* hearing, the court below indicated that it was unclear who bore the burden of proof as to the reliability of a proffered expert's opinions. That burden clearly rests with the proponent of that expert, *see Frazier*, 387 F.3d at 1260, and thus in this case Plaintiffs bore the burden of establishing the reliability of their experts' opinions.

[1][2] The court of appeals reviews a trial court's *Daubert* rulings under an abuse of discretion standard. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 140, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). A “district court enjoys ‘considerable leeway’ in making [reliability] determinations” under *Daubert*. *Kumho*, 526 U.S. at 152, 119 S.Ct. 1167. Thus, “[w]hen applying [the] abuse of discretion standard, we must affirm unless we at least determine that the district court has made a ‘clear error of judgment,’ or has applied an incorrect legal standard.” *See Piamba Cortes v. Am. Airlines, Inc.*, 177 F.3d 1272, 1306 (11th Cir.1999) (quoting *SunAmerica Corp. v. Sun Life Assurance Co. of Canada*, 77 F.3d 1325, 1333 (11th Cir.1996)).

A trial court, however, abuses its discretion by failing to act as a gatekeeper. In this case the trial court essentially abdicated its gatekeeping role. Although the trial court conducted a *Daubert* hearing, and both witnesses were subject to a thorough and extensive examination, the court ultimately disavowed its ability to handle the *Daubert* issues.^{FN3} This abdication was in itself an abuse of discretion.^{FN4}

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FN3. In ruling on the *Daubert* motion, the trial court stated:

Trying to cope in this case without a pharmacological, or a medical, or a chemical, or a scientific background, the court cannot fully and fairly appreciate and evaluate the methodology employed by either of these witnesses as they reached the conclusions they reached, conclusions that a jury could not reach without some expert opinion testimony. Neither can the court fully appreciate or evaluate the criticisms made by defendant of the proposed testimony of these witnesses, especially when the criticisms do not come from competing proposed experts. This court does not pretend to know enough to formulate a logical basis for a preclusionary order that would necessarily find, as a matter of law, that these witnesses cannot express to a jury the opinions they articulated to the court.

FN4. See *Kumho*, 526 U.S. at 158-59, 119 S.Ct. 1167 (Scalia, J. concurring) (“[T]rial-court discretion in choosing the manner of testing expert reliability-is not discretion to abandon the gatekeeping function. I think it worth adding that it is not discretion to perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is *junky*.”); *Joiner*, 522 U.S. at 148, 118 S.Ct. 512. (Breyer J. concurring) (“Of course, neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the ‘gatekeeper’ duties that the Federal Rules of Evidence impose....”).

Yet, even had the trial court fully accepted its role, it would have abused its discretion by admitting the experts' testimony. The record of their testimony in the pretrial hearing demonstrates that their testimony failed to satisfy the standards of reliability required under *Daubert* and its progeny. The admission of their testimony on medical causation in this toxic tort case substantially prejudiced Metabolife and authorizes reversal of the judgment. See *Piamba Cortes*, 177 F.3d at 1305.

*1239 In analyzing the experts' testimony, we note that toxic tort cases usually come in two broad categories: first, those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue, and second, those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges. Examples of the first type include toxins like asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; and cigarette smoke, which causes cancer. This case, involving Metabolife's combination of ephedrine and caffeine, falls into the second category. The medical community does not generally recognize the toxicity of this drug combination or ephedrine alone as causing the injuries Plaintiffs allege.

The court need not undertake an extensive *Daubert* analysis on the general toxicity question when the medical community recognizes that the agent causes the type of harm a plaintiff alleges. The battleground in this first category of cases focuses on plaintiff-specific questions: was plaintiff exposed to the toxin, was plaintiff exposed to enough of the toxin to cause the alleged injury, and did the toxin in fact cause the injury? A *Daubert* analysis in the first type of case deals with questions of individual causation to plaintiff.

In the second category of toxic tort cases, the *Daubert* analysis covers not only the expert's methodology for the plaintiff-specific questions about individual causation but also the general question of whether the drug or chemical *can* cause the harm plaintiff alleges.^{FN5} This is called general causation. “General causation is concerned with whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease.” Michael D. Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 392 (Federal Judicial Center, 2d ed.2000). Thus, in this case, Plaintiffs' experts must offer reliable opinions about Metabolife's general toxicity for the harm Plaintiffs allege and that it in fact harmed them. The court will consider, therefore, the reliability of Plaintiffs' experts' opinions on the question of general causation and also the question of individual causation.

FN5. This is not an effort to resurrect the

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test first announced in *Frye v. United States*, 293 F. 1013, 1014 (D.C.Cir.1923), and later applied by the Ninth Circuit Court of Appeals in its ruling on *Daubert* stating that “expert opinion based on a scientific technique is inadmissible unless the technique is ‘generally accepted’ as reliable in the relevant scientific community.” *Daubert*, 951 F.2d 1128, 1129-1130, *vacated*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) (overruling *Frye*). This two-part designation for toxic tort cases is devised to further the interests of judicial economy. There is rarely a reason for a court to consider opinions that medical doctors routinely and widely recognize as true, like cigarette smoking causes lung cancer and heart disease, too much alcohol causes cirrhosis of the liver, and that the ingestion of sufficient amounts of arsenic causes death. This two-part division follows a point made in *Kumho* that the trial court does not need to waste time with a *Daubert* hearing “where the reliability of an expert’s methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert’s reliability arises.” *Kumho*, 526 U.S. at 152, 119 S.Ct. 1167.

III. James O'Donnell, Pharm. D.

[3] Dr. O'Donnell, Pharm. D., testified as an expert in pharmacy, pharmacology and nutrition; he is not a toxicologist or a medical doctor. He based his opinions about Metabolife's toxicity and its ability to cause heart attacks and strokes in substantial part on ephedrine's classification as a sympathomimetic drug. He testified that drugs in the sympathomimetic family, *1240 including ephedrine, cause constriction of blood vessels that leads to increased pulse rate and increased blood pressure. The long-term use of ephedrine can cause narrowing of blood vessels, called vasospasm, a transitory constriction of a blood vessel, and also vasculitis, an inflammation or irritation of blood vessels. Vasospasm and vasculitis caused by extended use of ephedrine can lead to heart attacks and strokes. That Metabolife causes vasospasm and vasculitis, which in turn causes strokes and heart attacks, is O'Donnell's ultimate opinion that the court must analyze under *Daubert*.

O'Donnell also testified that adding caffeine to ephedrine in Metabolife 356 makes ephedrine more toxic, so any amount of caffeine added to ephedrine is too much. This combination of drugs poses an “imminent risk of death.”

O'Donnell's opinions lack the indicia of reliability necessary to survive a *Daubert* inquiry and challenge under Rule 702. He draws speculative conclusions about Metabolife's toxicity from questionable principles of pharmacology, while at the same time, neglecting the hallmark of the science of toxic torts—the dose-response relationship. He also draws unsubstantiated analogies between ephedrine and phenylpropylamine, infers conclusions from studies and reports that the papers do not authorize, and unjustifiably relies on government public health reports and consumer complaints to establish medical causation. In short, O'Donnell does not support his opinions with sufficient data or reliable principles, as identified by the *Daubert* rubric, and fails to follow the basic methodology that experts should follow in toxic tort cases.

A. Application of Broad Scientific Principles

[4] O'Donnell testified that ephedrine belongs to a family of drugs called the sympathomimetics. These drugs stimulate the cardiovascular system by raising heart rate and blood pressure. He drew key conclusions about ephedrine's toxicity from its classification as a sympathomimetic. A close examination of his testimony, however, shows that he dramatically dilutes the value of these conclusions, which in turn, impugns his methodology. About ephedrine's family or drug class connection and effects, he left a trail of equivocation by making the following statements at various points in his testimony: Sympathomimetics *can* constrict blood vessels. And *when* you constrict blood vessels, you *may* raise blood pressure. Sympathomimetics stimulate the heart and increase the pulse, increase the heart rate. *If* you stimulate the heart, you *may* cause an abnormal heart rate or an abnormal heart rhythm. *If* you constrict blood vessels, *if* it happens in a cerebral vessel in the brain, it *may* cause vasospasm which *may* lead to a stroke. *If* you stimulate or cause a constriction in the coronary blood vessel that *can* cause vasospasm and it *may* lead to chest pain, angina, arrhythmia, or myocardial infarction. He also testified that “aggravation of

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blood pressure is something that the ephedrine and caffeine in Metabolife or any product containing those drugs *can do*.” He further explained that the ephedrine/caffeine combination “*can* elevate blood pressure and stimulate the heart, and it *has been reported to be associated* with strokes and heart attacks.” Or as O'Donnell stated: “*this may be dangerous for some patients*.” O'Donnell's equivocation about the effects of sympathomimetics exposes a tenuous basis for his opinions about Metabolife's profound toxicity—that *any* level of caffeine combined with ephedrine poses “an unreasonable risk of harm.”

O'Donnell likewise offered nothing specific about how Metabolife affects individuals. When asked how one tablet of Metabolife might increase heart rate, he could *1241 not give an answer and explained that it would vary from patient to patient. He also could not say how much it might elevate a patient's blood pressure. He agreed that effect would vary from patient to patient and admitted that it might not raise a person's blood pressure at all. He further said that aerobic exercise impacts blood pressure and heart rate more than the maximum recommended dosage of Metabolife.

Although he agreed that a drug's effect is dose-driven, he offered no testimony about the dose of Metabolife required to injure Plaintiffs or anyone else. He could not say how much is too much. In explaining his opinion about the extreme danger of Metabolife, while at the same time offering no opinions about dose, he said: “[t]hat's why I always answer with potential, may, or could.” On the other hand, he admitted that the amount of ephedrine in Metabolife 356 does not exceed the amount of ephedrine in the hundreds of over-the-counter products available to the public. Likewise, he conceded that many people take drugs containing ephedrine at the same time they ingest large amounts of caffeine from coffee, and that the recommended dose of Metabolife 356 contains 72 milligrams of ephedrine, roughly half the FDA allowable limits on ephedrine. His lack of testimony about the dose-response relationship combined with his vague testimony about significant individual variations leaves a muddle of ambiguity that undermines his opinions.

[5][6] Because of this ambiguity, O'Donnell laid no reliable groundwork for determining the dose-response relationship for either ephedrine or ephed-

rine and caffeine. This signals a methodology problem. In toxic tort cases, “[s]cientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden....” *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir.1996). Or, as the Court of Appeals for the Tenth Circuit explained in *Mitchell v. Gen-corp*, 165 F.3d 778, 781 (10th Cir.1999), to carry the burden in a toxic tort case, “a plaintiff must demonstrate ‘the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.’ ” (quoting *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106 (8th Cir.1996)); see also *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir.1998) (excluding expert testimony which “offered no scientific support for his general theory that exposure to toluene solution at any level would cause RADS.”)^{FN6}

FN6. One should not conclude from this analysis that to pass *Daubert* muster an expert must give precise numbers about a dose-response relationship. Some ambiguity about individual responses is expected. However, the link between an expert's opinions and the dose-response relationship is a key element of reliability in toxic tort cases.

Although Plaintiffs can testify about how much Metabolife 356 they took, O'Donnell could not provide any opinions about the general dose-response levels for Metabolife's toxicity, i.e., the dose or level of exposure at which it causes harm. O'Donnell opined that any level is too much, but this statement conflicts with the importance of individual responses to toxins— “[b]ecause of individual variation, a toxic agent generally will not cause disease in every person exposed.” *Green, supra*, at 392.

When analyzing an expert's methodology in toxic tort cases, the court should pay careful attention to the expert's testimony about the dose-response relationship. The dose-response relationship is “[a] relationship in which a change in amount, intensity, or duration of exposure to an agent is *1242 associated with a change—either an increase or decrease—in risk of disease.” *Id.* at 390. The expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology.

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To help federal judges deal with *Daubert* issues in toxic tort cases, the Federal Judicial Center published several articles in the *Journal of Law and Policy* under the title "Science for Judges I: Papers on Toxicology and Epidemiology." 12 J.L. & POL'Y 1 (2003).^{FN7} The article entitled "Scientific Judgment and Toxic Torts-A Primer in Toxicology for Judges and Lawyers" by Dr. David Eaton provides valuable insight for understanding how to assess *Daubert* issues in these cases. *Id.* at 5. Dr. Eaton, Ph.D., is a toxicologist and Professor of Environmental and Occupational Health Sciences at the University of Washington. *Id.* He also serves as Associate Dean for Research, School of Public Health and Community Medicine at the University. *Id.*

FN7. The FJC collaborated on this work with the Brooklyn Law School's Center for Health Law and Policy and the Panel on Science, Law and Technology of the National Academy of Sciences. 12 J.L. & POL'Y 1 (2003).

In his article 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." *Id.* at 9. Foremost among these principles is the dose-response relationship.

Dr. Eaton explains that "the relationship between dose and effect (dose-response relationship) is the hallmark of basic toxicology." *Id.* at 15. "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." *Id.* at 11. Often "low dose exposures—even for many years—will have no consequence at all, since the body is often able to completely detoxify low doses before they do any damage." *Id.* at 13. Furthermore, "for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual." *Id.* at 16.

These essential principles of toxicology directly contradict several of what O'Donnell calls "the broad principles of pharmacology" upon which he bases his opinions. But more importantly, it shows something about O'Donnell's methodology: he does not follow

the basic methodology that scientists use to determine causation—the dose-response relationship.

Beyond explaining the importance of the dose-response 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." *Id.* at 38. This focuses on the issue of general causation. O'Donnell has failed to show that Metabolife 356 causes either strokes or heart attacks. Furthermore, the medical literature does not support this opinion. O'Donnell has simply substituted his own *ipse dixit* for scientific proof on this essential issue.

Second, "the individual must have been exposed to a sufficient amount of the substance in question to elicit the health effect in question." *Id.* at 39. 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.

As already shown, O'Donnell offers no opinion about the dose of Metabolife that *1243 caused ischemic strokes in three Plaintiffs and a heart attack in the other. He only said that any amount of Metabolife is too much, which clearly contradicts the principles of reliable methodology delineated by Eaton.^{FN8}

FN8. Although the court understands that *Daubert* focuses on the methodology used to derive opinions rather than on the accuracy of the opinion, when the opinions clearly demonstrate something about the expert's methodology, as in this case, the court can draw inferences about the methodology from the opinions. As the Supreme Court said in *Joiner*: "Conclusions and methodology are not entirely distinct from one another." 522 U.S. at 147, 118 S.Ct. 512.

Third, "the chronological relationship between exposure and effect must be biologically plausible." *Id.* 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-

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existing condition or disease." *Id.* at 39-40. This also focuses on individual causation.

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 then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the *post hoc ergo propter hoc* fallacy.

The *post hoc ergo propter hoc* fallacy assumes causality from temporal sequence. It literally means "after this, because of this." BLACK'S LAW DICTIONARY 1186 (7th ed.1999). It is called a fallacy because it makes an assumption based on the false inference that a temporal relationship proves a causal relationship. As the Court of Appeals for the District of Columbia explained in a similar context: "[i]n essence, the requirement of 'adequate documentation in scientific literature' ensures that decision makers will not be misled by the *post hoc ergo propter hoc* fallacy-the fallacy of assuming that because a biological injury occurred after a spill, it must have been caused by the spill." *Ohio v. U.S. Dept. of the Interior*, 880 F.2d 432, 473 (D.C.Cir.1989).

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." Eaton, *supra*, at 40. This refers to the background risk of a specific disease-the risk that everyone faces of suffering the same malady that a plaintiff claims without having exposure to the same toxin.

A reliable methodology should take into account the background risk. The background risk is not the risk posed by the chemical or drug at issue in the case. It is the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical in question. The background risks include all those causes of a disease, whether known or unknown, excluding the drug or chemical in question. So, the background risk for heart attack is very high because heart disease is the leading cause of morbidity and mortality in America. See *Heart Attacks*, Nat'l Heart, Lung, & Blood Inst., at <http://www.nhlbi.nih.gov> (last visited Dec. 27, 2004).

Likewise, stroke is the third leading cause of death in America and the leading cause of disability. See Jeffrey L. Arnold, *Ischemic Stroke*, emedicine, at <http://www.emedicine.com> (last visited Dec. 27, 2004). Ischemic strokes, like three Plaintiffs suffered in this case, account for 80% of all stroke cases. *Id.*

*1244 Thus, in evaluating the reliability of the experts' opinions on general causation, it would help to know how much additional risk for heart attack or ischemic stroke Metabolife consumers have over the risks the general population faces. If ephedrine or an ephedrine/caffeine combination do not increase the incidence of heart attack and ischemic stroke in persons who ingest it, as opposed to all those who do not and still have heart attacks and strokes, that fact would reduce the likelihood that Metabolife harmed Plaintiffs. Likewise, if Plaintiffs could show that taking Metabolife increases the risk of heart attack and ischemic stroke beyond the usual incidence of these common diseases, that would support their methodology in this case. O'Donnell offered no evidence of additional risk. The court must assume that it does not exist. (Indeed, O'Donnell testified that he did not know the background risk for stroke and heart attack.)

Toxicologists and medical doctors doing research commonly assess risks posed by drugs, chemicals and other agents. A quick internet search of TOXNET for "risk assessment" or "background risks" will show thousands of articles about risks for various drugs and chemicals-Plaintiffs' experts offered no such evidence. See generally, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 816 (5th Cir.1992); *Norfolk & W. Ry. Co. v. Ayers*, 538 U.S. 135, 156, 123 S.Ct. 1210, 155 L.Ed.2d 261 (2003).

Now as to these four criteria for proving causation, O'Donnell failed to demonstrate a link between Metabolife and the types of injuries Plaintiffs suffered as required by the first criteria. He also failed to show that Plaintiffs had sufficient individual exposure to Metabolife to cause the medical problems as required by the second criteria, and he further failed to show evidence of an increased incidence of strokes and heart attacks from Metabolife 356 over the background risk as required by the fourth criteria. There is evidence in the case supporting the third criteria, the chronological relationship between exposure and effect, but this does not overcome the failure of proof

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on the other three propositions.

Finally, on the speculative nature of his testimony, O'Donnell attempts to anoint his opinions by claiming that he based them on the "broad principles of pharmacology." In the *Daubert* context, such phrases have little value. They are not shibboleths that distinguish those experts that offer reliable science from those who foist junk science on the court. "The expert's assurances that he has utilized generally accepted scientific methodology [are] insufficient." See *Moore*, 151 F.3d at 276. Such statements can spring just as quickly from the *ipse dixit* of the expert as some ultimate opinion about causation or toxicity. As the Supreme Court explained in *Joiner*: "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." 522 U.S. at 147, 118 S.Ct. 512. Moreover, "[t]he trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" FED.R.EVID. 702 advisory committee's note (2000).

B. The PPA Analogy

[7][8] In reaching his opinions about general causation, O'Donnell relies heavily on an analogy between ephedrine and phenylpropanolamine (PPA). PPA is a sympathomimetic drug that has been used widely in over-the-counter cough and cold medications and weight loss products. RALPH I. HOROWITZ ET AL., PHENYLPROPANOLAMINE & RISK OF HEMORRHAGIC STROKE: FINAL REPORT OF THE HEMORRHAGIC STROKE PROJECT (2000). The conclusions that O'Donnell*1245 draws about ephedrine by analogy from PPA are very important to his opinions, but he did not show the reliability of each of his steps in deducing Metabolife's toxicity from this analogy. This is a fatal defect under *Daubert*. "The *Daubert* 'requirement that the expert testify to scientific knowledge-conclusions supported by good grounds for each step in the analysis-means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible.'" *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2002) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3rd Cir.1994)).

When O'Donnell described how ephedrine damages blood vessels based on the PPA analogy, he stated

that the longer one has exposure to a chemical, the more rigid a blood vessel becomes, and it takes time for the body to release a chemical even after the person stops taking the medicine. Thus, the drug can cause vasospasm or vasculitis and continue to cause these problems even after someone stops taking the drug. These steps are essential to his analysis of Metabolife's toxicity in general and for Plaintiffs' specific injuries. But he admitted that this theory has only been proven with PPA, not ephedrine.

O'Donnell cannot show that Metabolife causes vasospasm and vasculitis, which in turn causes ischemic strokes and heart attacks, except by a leap of faith. He also cannot show that Metabolife stays in the body for prolonged periods after someone stops taking it or that its effects linger. The medical articles do not support these conclusions. Speculation replaces science in this unreliable analogy between ephedrine and phenylpropanolamine. "Subjective speculation that masquerades as scientific knowledge" does not provide good grounds for the admissibility of expert opinions. *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir.2001).

According to O'Donnell, studies have shown that PPA causes vasospasm and vasculitis that lead to stroke and heart attack, and the studies also show that long-term use of the drug can cause a continuation of symptoms even after a person stops taking it. For these conclusions he relied primarily on the Hemorrhagic Stroke Project (HSP) that showed a 15-fold increase in the risk of hemorrhagic strokes in patients who took PPA as a diet supplement rather than as a cough and cold remedy. Horowitz, *supra*, at 2. These results, he said, should be reasonably analogized to ephedrine and especially ephedrine with caffeine. This analogy authorizes him to conclude that not only will ephedrine cause the hemorrhagic strokes demonstrated in the HSP from taking PPA, but also ischemic strokes and heart attacks. (None of the Plaintiffs in this case had hemorrhagic strokes.) Yet, he admitted that while the FDA banned PPA because of the risk of strokes, it authorized *ephedrine* to replace PPA in over-the-counter medications. But more importantly, the plain reading of the HSP article does not authorize O'Donnell's conclusions.

In 2000, the New England Journal of Medicine published the report on the Hemorrhagic Stroke Project. The report shows that the investigators devised and

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implemented a scientific approach to evaluate the toxicity of PPA. *Id.* The authors concluded that “the results of the HSP suggest that PPA increases the risk for hemorrhagic strokes. For both individuals considering use of PPA and for policy-makers, the HSP provides important data for a contemporary assessment of risks associated with the use of PPA.” *Id.* at 3. The authors draw no conclusions about ephedrine and nowhere say that ephedrine is analogous to PPA in any respect.

The authors likewise do not say that PPA is associated with ischemic stroke or *1246 heart attack or that one can analogize that because PPA may cause hemorrhagic strokes, it also causes ischemic strokes and heart attacks. Furthermore, the authors do not attempt to explain the physiological mechanism by which PPA causes strokes. Although O'Donnell contends that the PPA analogy supports his opinions that ephedrine causes vasospasm or vasculitis, nowhere in the HSP study do the authors assert this about PPA, much less about the ephedrine/caffeine combination. This study offers no support for O'Donnell's opinions.

But another methodological problem undermines O'Donnell's analogical approach. As Dr. Eaton explains: “even small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced.” See Eaton, *supra*, at 10-11. Likewise, as this court noted in *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir.2002), “[e]ven minor deviations in chemical structure can radically change a particular substance's properties and propensities.” *Id.* at 1201 (citing *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir.2001)). O'Donnell failed to show that the PPA analogy is valid or that the differences in chemical structure between PPA and ephedrine make no difference. He simply assumes its validity without offering any scientific evidence. As he said, one *presumes* the same effect by drugs in the same class until proven otherwise. Such presumptions do not make for reliable opinions in toxic tort cases. (As Dr. Hakim admitted, if one product had the same effect as another product, it would be the same product.)

The court addressed drug analogies in detail in *Rider* where plaintiffs sued Sandoz claiming that they suffered postpartum hemorrhagic strokes from ingesting Parlodel to suppress lactation after childbirth. *Id.* at 1196. Plaintiffs' experts in that case followed an ana-

logical approach similar to O'Donnell's. They testified that Parlodel (bromocriptine) is a member of a class of drugs known as ergot alkaloids, and that ergot alkaloids can cause vasoconstriction, which suggests that Parlodel causes vasoconstriction. *Id.* at 1198. Animal studies also suggest that Parlodel causes vasoconstriction. *Id.* Vasoconstriction can cause high blood pressure and ischemic stroke. *Id.* Because Parlodel can cause vasoconstriction, which causes high blood pressure resulting in ischemic stroke, it can also cause hemorrhagic stroke. *Id.* Thus, Parlodel caused plaintiffs' hemorrhagic strokes, according to Plaintiffs' experts. *Id.*

This drug analogy is stronger than O'Donnell's because in *Rider* the experts analogized from the same drug and also had some partial support for their theory from animal studies. 295 F.3d at 1200-02. O'Donnell, on the other hand, compares one drug, PPA, to a different drug, ephedrine, to reach his opinions that not only does ephedrine cause hemorrhagic stroke, as reported about PPA, it also causes ischemic stroke and heart attack. (Hemorrhagic stroke occurs when a blood vessel ruptures. Ischemic stroke occurs because of decreased blood flow to the brain.) The court in *Rider* properly rejected the testimony because of the unreliable analogy. *Id.* As the court stated, “[e]vidence suggest[ing] that [a chemical] may cause ischemic stroke does not apply to situations involving hemorrhagic stroke. This is ‘a leap of faith’ supported by little more than the fact that both conditions are commonly called strokes.” *Id.* at 1202.

Finally, on O'Donnell's analogy methodology, he agreed that: “[t]here is a tendency in the literature, particularly in government monographs, to lump together all ephedrine alkaloids. Doing so is both foolish and misleading as it implies that the *1247 toxicity of all enantiomers is equivalent, which is clearly not the case.” After agreeing with this statement, he went on to say that “it's not predictable.”

This lack of predictability, O'Donnell's use of an unreliable analogy and his inclination to draw overreaching conclusions from self-limiting medical articles, show the speculative nature of his opinions. As Judge Posner explained: “the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir.1996).

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C. Reliance on Other Studies and Reports

[9] O'Donnell also relied on several other studies to support his opinions about the toxicity of ephedrine and caffeine. A close analysis of the studies, however, shows that they do not authorize his opinions. The authors of the articles limit the application of their studies consistent with the principles of good science; O'Donnell expands the application beyond good science.

O'Donnell relied heavily on a report by Haller and Benowitz published in the *New England Journal of Medicine* that concluded that the ephedrine/caffeine combination "in some patients may cause toxicity." Christine A. Haller & Neal Benowitz, "Adverse Cardiovascular and Central Nervous System Events Associated with Dietary Supplements Containing Ephedra Alkaloids," 343 *NEW ENG. J. MED.* 3-38 (2000) (emphasis supplied). The authors studied 140 adverse incident reports from persons who took dietary supplements containing ephedra alkaloids. *Id.* The authors said that "these interactions between phenylpropanolamine and caffeine support the idea that the combination of ephedrine and caffeine could increase the risk of adverse effects." *Id.* (emphasis supplied). The authors, however, admit that their study does not offer a basis to determine the incidence of serious adverse effects of ephedrine alkaloids, and they recognize the necessity for study of "the determinants of individual susceptibility to serious adverse effects of dietary supplements containing ephedra alkaloids so that the appropriate guidelines and warnings can be devised." *Id.* Moreover, O'Donnell agreed that Haller and Benowitz concluded from this study that "the use of dietary supplements that contained ephedra alkaloids may pose health risks to some persons." *Id.* (emphasis supplied). He further conceded that the authors sent a letter to the editor explaining that the study did not prove causation.

In the same volume of the *New England Journal of Medicine*, Dr. G. Alexander Fleming published an editorial entitled "The FDA, Regulation, and the Risk of Stroke," in which he discusses the Haller and Benowitz study that O'Donnell considers so important. 343 *NEW ENG. J. MED.* 1886-87 (2000). About that study Fleming stated: "the study by Haller and Benowitz represents only an early step in the process of pharmacologic vigilance. Data from spontaneous reports usually provide only preliminary evidence of

risk and not proof of risk." *Id.* Fleming reviewed the eleven cases of sudden catastrophic cardiovascular and cerebrovascular events that Haller and Benowitz attributed as definitely or probably caused by ephedra alkaloids. *Id.* He concluded that only one of the cases should be attributed to supplements containing ephedra alkaloids. *Id.* He reached this conclusion in substantial part because of the *background risk* of subarachnoid hemorrhage and myocardial infarction. As he explained, "subarachnoid hemorrhage and myocardial infarction are too common, even among young and middle-aged people to be pathognomonic of complications of the use of products containing ephedra alkaloids." *Id.* He acknowledges*1248 the importance of background risks in reaching conclusions about toxicity and individual injury. *Id.*

Fleming went on to explain that

it is much less clear whether the FDA should take steps to ban or even restrict the use of products containing ephedra alkaloids. The risks of such products, when they are used as directed, have not been adequately established. A large body of data suggests that products containing ephedra alkaloids and ephedrine as an over-the-counter drug have a low risk of adverse effects at the recommended levels of consumption. The report by Haller and Benowitz provides information that justifies the initiation of the same kind of study that was conducted by the Hemorrhagic Stroke Project.

Id.

Fleming neither exonerates nor indicts ephedra alkaloids, but he does explain the limitations of the Haller and Benowitz study which, in turn, shows that O'Donnell does not follow the conservative approach of scientists in this field. Dr. Fleming exemplifies this approach by limiting conclusions about causation from insufficient evidence. Indeed, Haller and Benowitz limit the conclusions authorized from their study by saying that it does not prove causation. The comments of Fleming and Haller and Benowitz demonstrate the intellectual rigor in this field of science, an intellectual rigor that is conservative and does not leap to specific conclusions about causation or toxicity from incomplete evidence or broad principles. But the record offers yet more evidence of O'Donnell's willingness to exceed the limits of the conservative scientific methodology.

401 F.3d 1233, 66 Fed. R. Evid. Serv. 753, Prod.Liab.Rep. (CCH) P 17,126, Prod.Liab.Rep. (CCH) P 17,329, 18 Fla. L. Weekly Fed. C 281
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He also relies on an article called "*Adverse Cardiovascular Events Temporally Associated with Ma Huang, an Herbal Source of Ephedrine*" published in the Mayo Clinic Proceedings. David Samenuk et al., 77 MAYO CLIN PROC. 12-16 (2002). The author studied adverse reaction reports filed with the FDA by consumers of ma huang, a natural source of ephedrine. The study focused on the safety of ma huang for adverse cardiovascular effects. *Id.* Of the 926 complaints studied, 37 involved serious cardiovascular events. *Id.* at 15. But the authors of the study explained that their report "must be interpreted as demonstrating only a temporal, *not a causal*, relationship between ma huang (ephedrine) and the adverse cardiovascular events." *Id.* at 13. The authors further explained that "[o]ur report has the limitation of being an observational study and as such does not definitively establish the relationship between ma huang use and the risk of adverse cardiovascular events." But this shows again O'Donnell's lack of scientific rigor in that he draws unauthorized conclusions from limited data—conclusions the authors of the study do not make.

D. Reliance on FDA Reports and Recommendations

[10] O'Donnell also placed great weight on a Food & Drug Administration (FDA) proposal to severely restrict the sale and distribution of herbal supplements containing ephedrine. But the FDA did not publish those rules because the General Accounting Office (GAO) reviewed the FDA data and found a need for further study.

The GAO determined that the FDA's methodology relied heavily on adverse incident reports without sufficient scientific controls. In other words, the FDA employed a flawed methodology to reach its proposal to restrict ephedrine in herbal supplements. In response to this criticism, the FDA withdrew the proposed rules.

*1249 But 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.

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. Consequently, risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not.

Margaret A. Berger, *The Supreme Court's Trilogy on the Admissibility of Expert Testimony*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 33 (Federal Judicial Center, 2d. ed.2000). 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.

As Dr. Eaton explains:

[i]t is important to recognize that the procedures commonly used in "risk assessment" for the purpose of establishing public health guidelines that represent "acceptable" exposure levels for large populations are often, in this author's opinion, of marginal relevance to estimating "causation" in an individual—e.g., whether a particular chemical caused or contributed to a particular disease or illness in a given person. Although toxicological data—and the basic principles of toxicology outlined above—are useful for both (establishing guidelines for protection of public health and establishing "causation"), there are substantial differences in approach.

Eaton, *supra*, at 34.

He then gives a helpful explanation of this difference. "Public health guidelines, however, should not be interpreted as predicting exact levels at which effects would occur in a given individual." *Id.*

Because a number of protective, often "worst-case"

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assumptions ... are made in estimating allowable exposures for large populations, these criteria and the resulting regulatory levels ... generally overestimate potential toxicity levels for nearly all individuals. Furthermore, because these guidelines are intended to be protective of all individuals in a population, including the very young, the very old, and other potentially "sensitive" individuals, the theoretical risks from exposure at the guideline range level is likely to be substantially overestimated for the large majority of individuals in the population.

Id. at 34-35.

Understanding how government agencies establish rules for public health is important in this case for two reasons. First, in trying to determine the reliability of an expert's opinions based on agency rules, it is important to know both what the agency intended by setting the guidelines and how the expert uses the guidelines to support his opinions. The court is not rejecting public health rules from consideration in a *Daubert* analysis. Rather, in ruling on methodology issues, the trial court should understand what the rule really means about causation for the specific plaintiff, not simply about protecting the public-at-large from risk of harm based on a risk-utility analysis of the drug.

As this court explained in *Rider*:

*1250 [the] risk-utility analysis involves a much lower standard than that which is demanded by a court of law. A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required under the *Daubert* trilogy to engage in objective review of evidence to determine whether it has sufficient scientific basis to be considered reliable.

295 F.3d at 1201.

The Court of Appeals for the Eighth Circuit further explained the difference between a public agency approach and a courtroom causation approach in a case involving Parlodel.

The FDA's approach differs from ours in another critical aspect. The FDA will remove drugs from

the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or the more-like-than-not standard used to assess tort liability. "The methodology employed by a government agency 'results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances....'" The FDA's 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (*vis-a-vis* tort liability) for gauging causation when it decides to rescind drug approval.

Glastetter, 252 F.3d at 991 (internal cites omitted).

Consideration of the risk-utility or the cost-benefit approach versus the expert-causation approach is important in this case for a second reason. O'Donnell testified at the *Daubert* hearing in a way more adjusted to agency-risk analysis than courtroom-causation analysis. For example, he said: "[s]o the issue of risk benefit is, what is the benefit? If there is no proven benefit, it's all risk. So the risk benefit analysis is lopsided on the risk side." Also, when asked about how much Metabolife is too much, he said: "I don't have a number. I've said I think it's unreasonable to combine caffeine because it adds to the toxicity. I don't see a beneficial effect in using this in the population." This implies a risk-benefit analysis, which does not directly focus on the question of causation in these four Plaintiffs-the heart of this toxic tort case.

E. Reliance on Anecdotal Consumer Complaints

[11] The FDA's adverse events reports (AERs) and other consumer complaints also provided another important source for O'Donnell's opinions. But these FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment. Under the adverse events reporting system, consumers call in to describe medical problems that they think they are experiencing from taking a product. These complaints provide the basis for the AERs. O'Donnell also considered the same type of complaints called into the "Metabolife health-line." Yet, both O'Donnell and Hakim testified that such anecdotal reports do not prove causation.

Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both

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general and individual causation. The GAO found that the FDA's heavy reliance on the AERs without sufficient scientific controls undermined the FDA's analysis, yet O'Donnell relies on them in a significant way. This again implies that O'Donnell follows more of a federal agency risk analysis approach, rather than a courtroom causation analysis. It also shows that he relied on data that lacks the indicia of scientific reliability.

***1251 F. O'Donnell's Methodology Ultimately Fails to Satisfy the Requirements of the *Daubert* Rubric or to Otherwise Comport with the Basic Methodology which should be Utilized by Experts in Toxic Tort Cases**

[12] While we have addressed certain types of unreliable evidence used by O'Donnell in reaching his opinions in this case, we find it necessary to also note that O'Donnell's methodology would have failed to survive the *Daubert* inquiry using those guidelines set forth in *Daubert* itself. The Supreme Court in *Daubert* identified four nonexclusive factors for trial courts to use in determining the reliability of scientific opinions; i.e.: (1) whether the theory can and has been tested; (2) whether it has been subjected to peer review; (3) the known or expected rate of error; and (4) whether the theory and methodology employed is generally accepted in the relevant scientific community. *Daubert*, 509 U.S. at 593-94, 113 S.Ct. 2786.

There is no doubt that O'Donnell's theory of the toxicity of the ephedrine/caffeine combination can be tested, as can most theories; but, he has offered no evidence of any testing of his theory, and therefore, he has shown no proof for support of his opinions by the scientific community. General acceptance of his theory would offer important support for the reliability of his opinion. As the United States Supreme Court has explained:

Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community" Widespread acceptance can be an important factor in ruling particular evidence admissible, and "a known technique which has been able to attract only minimal support within the community" ... may properly be

viewed with skepticism.

Id. at 594, 113 S.Ct. 2786 (internal citations omitted).

O'Donnell has also failed to present evidence of any peer review of his opinions about the extreme toxicity of ephedrine and caffeine or that their use can cause strokes and heart attacks. He submitted no publication linking ephedrine and caffeine to strokes and heart attacks beyond the general incident rate or background risk for these two very common ailments. He likewise failed to offer any testimony about the known or expected rate of error of his theories, and although he has provided unsupported testimony about the general acceptance within the relevant scientific community of his "broad principles of pharmacology," he has offered no testimony about the acceptance of his specific opinions. In fact, his own sources say that their studies cannot be used to show causation.

It is also important to consider what other evidence O'Donnell failed to present that might have supported the reliability of his opinions in this case. He offered no epidemiological data. He offered no clinical trials. He offered no animal studies to support his opinions. O'Donnell also offered no long-term studies about the toxicity of the ephedrine/caffeine combination on humans. As even O'Donnell explained: "[l]ong term studies are used for chronic use to determine safety;" still, he offered opinions about the safety of Metabolife in absence of such long-term studies.

Ultimately, O'Donnell failed to show the trial court either that his opinions were based upon reliable sources and data or that his methodology comported with that criteria listed in *Daubert* or with those standards otherwise utilized by experts in the field of toxicology. It was therefore ***1252** error to admit his testimony to establish general causation at trial.

IV. Hashim Hakim, M.D.

Dr. Hakim is a medical doctor specializing in the practice of neurology; he is a clinician and not a medical researcher. He treated Plaintiff Thornburg and then saw the other three Plaintiffs on referral from Plaintiffs' counsel. He offered opinions at the *Daubert* hearing about the general toxicity of Metabolife and about its effects on the individual Plaintiffs, including that Metabolife caused ischemic

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strokes in three Plaintiffs and a heart attack in the other.

Hakim followed a methodology similar to O'Donnell's in determining the general toxicity of Metabolife. He relied in significant part on ephedrine's classification as a sympathomimetic, the PPA analogy, the Haller and Benowitz study, and the Hemorrhagic Stroke Project. To the degree to which Hakim and O'Donnell shared the same methodology about the general toxicity of Metabolife, their opinions share the same fate. Their opinions lack sufficient reliability to satisfy *Daubert*. Furthermore, like O'Donnell, Hakim failed to offer the type of evidence that could support his methodology, so his opinions are subject to the same conclusions that the court made about O'Donnell's opinions. The only question then about Hakim's testimony is whether the additional bases for his opinions, which O'Donnell's did not have, can overcome the defects in the methods they shared. The answer is no.

A. The Differential Diagnosis Method

[13] Hakim used the "differential diagnosis" approach to rule out all causes for Plaintiffs' injuries, except Metabolife 356. Under certain circumstances, circumstances that ensure reliability, this approach may offer an important component of a valid methodology. This approach, however, will not 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.

Differential diagnosis involves "the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings." *DORLAND'S ILLUSTRATED MEDICAL DICTIONARY* 240, (Douglas M. Anderson et al. ed., 29th ed.2000). This leads to the diagnosis of the patient's condition, not necessarily the cause of that condition. The more precise but rarely used term is differential etiology, which is "a term used on occasion by expert witnesses or courts to describe the investigation and reasoning that leads to the determination of external causation, sometimes more specifically described by the witness or court as a process of identifying external causes by a process of elimination." See Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, in *REFERENCE MANUAL*

ON SCIENTIFIC EVIDENCE 439, 481 (Federal Judicial Center, 2d ed.2000). The etiology of a disease is the cause or origin of the disease, and in this case Plaintiffs allege that Metabolife is the etiology of their medical problems.^{FN9}

FN9. Hakim's differential diagnosis primarily involved determining the etiology of Plaintiffs' diseases rather than the diagnoses of three ischemic strokes and a heart attack. Although defendants often dispute the injuries that plaintiffs allege in toxic tort cases, Defendant does not dispute the nature of Plaintiffs' injuries, only that Metabolife caused the injuries.

To support this theory, Hakim testified that he employed the differential diagnosis method. He took medical histories from Plaintiffs, examined them, and did some tests. After taking these steps, he concluded that he could rule out all the usual *1253 causes for Plaintiffs' injuries and therefore inferred that Metabolife caused the injuries. He *assumed* that Metabolife could cause these injuries using the same evidence offered by O'Donnell, the deficiencies of which the court has demonstrated at length.

A valid differential diagnosis, however, only satisfies a *Daubert* analysis if the expert can show the general toxicity of the drug by reliable methods. As the Court of Appeals for the Ninth Circuit explained:

The first step in the diagnostic process is to 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 or mortality. Expert testimony that rules in a potential cause that is *not* so capable is unreliable.... "It is important to realize that a fundamental assumption underlying [differential diagnosis] is that the final, suspected 'cause' ... must actually be capable of causing the injury."

Clausen v. M/V NEW CARISSA, 339 F.3d 1049, 1057-58 (9th Cir.2003) (internal citations omitted). Thus, 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. As the Court of Appeals for the

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Fifth Circuit has explained:

No one doubts the utility of medical histories in general or the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. But such general rules must ... be applied fact-specifically in each case. *The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur.* Based on such predicate knowledge, it may then be possible to fasten legal liability for a person's disease or injury.

Black v. Food Lion, Inc., 171 F.3d 308, 314 (5th Cir.1999) (emphasis added).

Here, neither O'Donnell nor Hakim have offered a reliable explanation of the physiological process by which Metabolife causes heart attacks and ischemic strokes, i.e., establish general causation. Their PPA analogy does not show it. The medical articles do not explain it. In the absence of such a foundation for a differential diagnosis analysis, a differential diagnosis generally may not serve as a reliable basis for an expert opinion on causation in a toxic tort case.

B. Reliance on Anecdotal Case Reports

[14] In defending his methodology, Hakim also testified about case reports that he found in the medical literature. The case studies involve reports by doctors about patients whom the doctor suspects suffered a serious adverse reaction to ephedrine. These reports are anecdotal, meaning that they are "based on descriptions of unmatched individual cases rather than on controlled studies." DORLAND'S, *supra*, at 76. Because they are anecdotal, "case studies lack controls and thus do not provide as much information as controlled epidemiological studies do.... Causal attribution based on case studies must be regarded with caution." Henifin, *supra*, at 475.

We in fact discussed the value of case reports in *Rider*, explaining that:

Much of the plaintiffs' expert testimony relied on case reports in which patients suffered injuries subsequent to the ingestion of Parlodel. Although the court may rely on anecdotal evidence such as case reports, ... courts must consider *1254 that case re-

ports are merely accounts of medical events. They reflect only reported data, not scientific methodology.... Some case reports do contain details of the treatment and differential diagnosis. Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context. They may rule out other potential causes of the effect, but they do not rule out the possibility that the effect manifested in the reported patient's case is simply idiosyncratic or the result of unknown confounding factors. As such, while they may support other proof of causation, case reports alone ordinarily cannot prove causation.

295 F.3d at 1199 (internal citations omitted). Simply stated, case reports raise questions; they do not answer them.

This analysis of the value and limitations of case reports is important in this case for two reasons. First, it explains something about Hakim's differential diagnosis method. If he had taken his findings and opinions about these four Plaintiffs and submitted them to a medical journal for publication, they would simply be case reports-anecdotal information, nothing more. Second, in light of all the other failures of proof on the reliability of their methods, Plaintiffs' experts cannot now redeem their opinions with this type of anecdotal evidence. They do not offer the underlying toxicological data in a scientifically reliable form to satisfy *Daubert*. Anecdotal evidence will not cure that failure.

C. Challenge/De-challenge/Re-challenge Methodology

[15] Finally, in reaching his opinions that Metabolife 356 in fact caused each of the Plaintiff's injuries, Hakim claims to have used a "challenge/de-challenge/re-challenge" methodology. To explain this methodology during the *Daubert* hearing, Hakim testified that while treating Plaintiff Thornburg he noticed a pattern. When she took Metabolife 356, she had strokes, but when she did not take it, she did not have strokes until she started it again. In essence, the stroke occurred during the challenge stage when she took the drug. The de-challenge occurred when she came off the drug and did not have a stroke, and the

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re-challenge occurred when she started taking the drug again and had another ischemic event. But this theory has a serious flaw.

In April of 2000, Hakim decided that Metabolife had caused Thornburg's strokes and told her to stop taking it. In June of 2000, after being off Metabolife for two months, she had another ischemic event. In other words, according to his challenge/de-challenge/re-challenge theory, she had another ischemic event during the de-challenge phase. During the hearing, Hakim attempted to explain away that inconsistency by saying that the ischemic event during the de-challenge phase occurred because of the lingering effects of ephedrine. To bolster this opinion he resorted to another medical analogy—the analogy of alcohol causing liver damage. Nothing in the evidence, however, supports the dubious analogy that the ephedrine causes strokes and heart attacks like alcohol causes cirrhosis of the liver.

Furthermore, “[t]he temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation.” *Moore*, 151 F.3d at 278. It is also subject to the problem of assuming what the witness is trying to prove. This pitfall will most likely arise when, as here, there are not scientific controls in place.

As this court explained in *Rider*, “de-challenge/re-challenge tests are still case *1255 reports and do not purport to offer definitive conclusions as to causation.” 295 F.3d at 1200. Their value is directly related to the degree of scientific control used in the testing. Because there were insufficient controls employed in Hakim's crude challenge/de-challenge/re-challenge methodology, and Hakim's own testimony established that Thornburg suffered ischemic events when she was not taking Metabolife 356, this methodology does not provide the necessary indicia of reliability to his final opinions on causation.

D. Hakim's Overall Methodology

Again, like O'Donnell, Hakim failed to offer the type of evidence that could support the methodology he employed in reaching his opinions. Even considering the three additional methodologies he used, we must conclude that Hakim failed to rely upon reliable sources and data and that his overall methodology

falls short of those standards otherwise utilized by experts testifying as to causation in a toxic tort case. It was therefore error to admit his testimony to establish general or individual causation at trial.

V. Conclusion

At the outset, we noted that the primary purpose of any *Daubert* inquiry is for the district court to determine whether that expert, “whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho*, 526 U.S. at 152, 119 S.Ct. 1167. As shown in this case, however, neither O'Donnell nor Hakim utilized a reliable methodology to prove that use of Metabolife 356 actually causes strokes or heart attacks, either generally or in these Plaintiffs. The medical literature does not support such opinions. Plaintiffs' experts took leaps of faith and substituted their own *ipse dixit* for scientific proof on essential points. Here, “there is simply too great an analytical gap between the data and the opinion proffered.” *See Joiner*, 522 U.S. at 146, 118 S.Ct. 512.

Thus, in the end, we must find that there was no basis for the court below to conclude that Plaintiffs' experts employed the same level of intellectual rigor that characterizes the practice of an expert testifying about causation in a toxic tort case. Plaintiffs' expert testimony did not satisfy the foundational requirements of Rule 702, because their opinions were not based on sufficient data and were not the product of reliable methods. Because they did not establish the requisite scientific reliability *Daubert* demands, the trial court abused its discretion both by abdicating its gatekeeper responsibilities and by admitting the expert testimony at trial. We reverse.

REVERSED and REMANDED.

C.A.11 (Ala.),2005.

McClain v. Metabolife Intern., Inc.

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Appellate Court of Illinois,
 First District, First Division.
 Carol McWILLIAMS and Robert McWilliams,
 Plaintiffs-Appellants,

v.

Donald DETTORE, Christopher D. Joyce, and Sub-
 urban Surgical Associates, a Partnership or Corpora-
 tion, Defendants-Appellees.

No. 1-07-0678.

Jan. 20, 2009.

Background: Patient brought medical malpractice action against surgeon, alleging surgeon negligently failed to diagnose her with non-Hodgkins lymphoma. The Circuit Court, Cook County, Carol P. McCarthy, J., entered order finding patient's proposed expert was not qualified to give standard-of-care testimony, and denying her motion to voluntarily dismiss. Patient appealed.

Holding: The Appellate Court, Garcia, J., held that oncologist was not qualified to offer expert testimony.

Affirmed.

Wolfson, J., filed specially concurring opinion.

Robert E. Gordon, P.J., filed dissenting opinion.

West Headnotes

[1] Health 198H  611

198H Health
 198HV Malpractice, Negligence, or Breach of
 Duty

198HV(B) Duties and Liabilities in General
 198Hk611 k. Elements of Malpractice or
 Negligence in General. Most Cited Cases

Health 198H  821(2)

198H Health

198HV Malpractice, Negligence, or Breach of
 Duty

198HV(G) Actions and Proceedings

198Hk815 Evidence

198Hk821 Necessity of Expert Testi-
 mony

198Hk821(2) k. Standard of Practice
 and Departure Therefrom. Most Cited Cases

Health 198H  821(3)

198H Health

198HV Malpractice, Negligence, or Breach of
 Duty

198HV(G) Actions and Proceedings

198Hk815 Evidence

198Hk821 Necessity of Expert Testi-
 mony

198Hk821(3) k. Proximate Cause.
 Most Cited Cases

In medical negligence cases, a plaintiff generally must establish by expert testimony the applicable standard of care against which the defendant health care professional's conduct is measured, a deviation from that standard, and an injury proximately caused by that deviation.

[2] Evidence 157  538

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

157k538 k. Due Care and Proper Conduct
 in General. Most Cited Cases

To render standard of care testimony against a medi-
 cal practitioner, a proffered expert must be a licensed
 member of the school of medicine about which he or
 she proposes to opine, and must be familiar with the
 methods, procedures, and treatments that similarly
 situated physicians as the defendant would ordinarily
 observe.

[3] Evidence 157  538

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

901 N.E.2d 1023
 387 Ill.App.3d 833, 901 N.E.2d 1023, 327 Ill.Dec. 290
 (Cite as: 387 Ill.App.3d 833, 901 N.E.2d 1023, 327 Ill.Dec. 290)

157k538 k. Due Care and Proper Conduct in General. Most Cited Cases
 If the threshold determination that a proffered expert is medically qualified to render standard of care testimony is not met, the analysis ends and the trial court must disallow the expert's testimony.

[4] Evidence 157 ↪ 538

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

157k538 k. Due Care and Proper Conduct in General. Most Cited Cases

To determine whether a proffered expert is qualified to give an opinion on a medical standard of care, there is a three-step analysis: the two foundational requirements of licensure in the school of medicine about which the expert proposes to opine and familiarity with the methods, procedures, and treatments that similarly situated physicians would ordinarily observe, and the discretionary requirement of competency.

[5] Health 198H ↪ 821(2)

198H Health

198HV Malpractice, Negligence, or Breach of Duty

198HV(G) Actions and Proceedings

198Hk815 Evidence

198Hk821 Necessity of Expert Testimony

198Hk821(2) k. Standard of Practice and Departure Therefrom. Most Cited Cases
 Generally, expert testimony is required in a medical negligence case to assist a jury to determine any lack of necessary scientific skill on the part of the physician.

[6] Evidence 157 ↪ 538

157 Evidence

157XII Opinion Evidence

157XII(C) Competency of Experts

157k538 k. Due Care and Proper Conduct in General. Most Cited Cases

Oncologist was not qualified to offer expert testimony on standard of care or skill required to determine whether surgeon should have performed biopsy

after mammogram and CT scan revealed two swollen lymph nodes near patient's armpit, in patient's medical malpractice action against surgeon alleging surgeon negligently failed to diagnose her with non-Hodgkins lymphoma; oncologist failed to demonstrate his expertise with the methods, procedures, and treatments pertaining to when a biopsy should be performed.

[7] Pretrial Procedure 307A ↪ 509

307A Pretrial Procedure

307AIII Dismissal

307AIII(A) Voluntary Dismissal

307Ak506 Time for Dismissal; Condition of Cause

307Ak509 k. Trial, Dismissal During.

Most Cited Cases

Patient was not entitled to voluntarily dismiss her medical malpractice action following determination that her expert witness was unqualified to offer standard of care testimony, where jury had been selected and trial had commenced at insistence of patient prior to her motion to dismiss. S.H.A. 735 ILCS 5/2-1009(a).

**1024 Ronald S. Fishman, Fishman & Fishman, Ltd., Chicago, IL, for Plaintiffs-Appellants.

Mark J. Smith, Joan M. Kublanza, Scott R. Wolfe, and Mehreen S. Sherwani, Lewis & Gellen, LLP, Chicago, IL, for Defendant-Appellee Donald Dettore, M.D.

Krista R. Frick, Luisa R. Frick, Luisa F. Trujillo, Bollinger, Ruberry & Garvey, Chicago, IL, for Defendants-Appellees Christopher D. Joyce, M.D. and Suburban Surgical Associates.

**1025 Justice GARCIA delivered the opinion of the court.

***292 *835 In this medical negligence case, Carol and Robert McWilliams appeal the circuit court's orders finding their expert, Dr. Hector Gomez, a hematologist/oncologist, not qualified to give standard of care testimony against Dr. Christopher D. Joyce, a surgeon. The plaintiffs also contend the circuit court abused its discretion in denying their motion to voluntarily dismiss their case against both Dr. Joyce and the primary care physician, Dr. Donald Dettore, after the circuit court granted Dr. Joyce's motion *in limine*,

when the jury had already been selected and sworn. We affirm.

BACKGROUND

The suit against Dr. Dettore and Dr. Joyce, individually and as an agent for Suburban Surgical Associates (SSA)^{FN1}, alleged they negligently failed to diagnose Mrs. Carol McWilliams with non-Hodgkins lymphoma. Dr. Dettore was Mrs. McWilliams' primary care physician. Dr. Joyce is a surgeon to whom Dr. Dettore referred Mrs. McWilliams.

FN1. Dr. Joyce and SSA will collectively be referred to as "Dr. Joyce," unless otherwise noted.

I. Pleadings and Other Background

A September 28, 1998, mammogram of Mrs. McWilliams' left breast revealed a six-centimeter mass in her left axilla (armpit). The radiologist who performed the mammogram recommended a surgical consultation and, according to the plaintiffs, "strongly recommended" a biopsy, followed by tissue samples. Dr. Dettore, consistent with the recommendation from the radiologist, referred Mrs. McWilliams to Dr. Joyce, a surgeon. Dr. Joyce ordered a CT scan. The October 8, 1998, CT scan revealed two lymph nodes each swollen to two centimeters.

*836 Dr. Joyce did not biopsy the lymph nodes. Dr. Dettore was informed about the CT scan findings but did not refer Mrs. McWilliams for further treatment. Dr. Joyce saw Mrs. McWilliams again on October 13, 1998, and in February 1999. Mrs. McWilliams remained under Dr. Dettore's care through September 2000.

In 2001, Mr. and Mrs. McWilliams moved to Wisconsin. Sometime thereafter, Mrs. McWilliams was diagnosed with stage IV B-Cell non-Hodgkin's lymphoma. While stage I non-Hodgkins lymphoma may be treated with radiation and may be cured, stage IV requires chemotherapy and cannot be cured. From February 2002 through August 2003, Mrs. McWilliams underwent intensive chemotherapy. Her lymphoma went into remission.

In 2004 or 2005, Mrs. McWilliams was diagnosed with ovarian cancer. The parties agreed Mrs. McWilliams was likely to die from ovarian cancer.

On May 8, 2003, prior to Mrs. McWilliams' ovarian cancer diagnosis, and while she was undergoing chemotherapy for lymphoma, the plaintiffs filed an amended medical malpractice complaint. The complaint alleged Dr. Dettore breached the standard of care by failing to order a biopsy and that Dr. Joyce breached the standard of care by failing to perform a biopsy. The plaintiffs alleged that had a timely biopsy been performed, Mrs. McWilliams would have been diagnosed with stage I non-Hodgkins lymphoma. According to the plaintiffs, "the Defendants kn[ew] or should have known that [Mrs. McWilliams] might be suffering from lymphoma, but negligently failed to do a biopsy to confirm that diagnosis. Instead, ***293 **1026 the Defendants told [Mrs. McWilliams] not to worry, and that she was all right." The plaintiffs' negligence theory is that Mrs. McWilliams suffered from stage I non-Hodgkins lymphoma at the time her mammogram revealed the six-centimeter mass that prompted her referral to Dr. Joyce.

In the course of discovery, the plaintiffs made clear their intention to present evidence at trial that the ovarian cancer was caused by the heavy doses of chemotherapy Mrs. McWilliams received in the course of her stage IV lymphoma treatment. The plaintiffs theorized that had Mrs. McWilliams' lymphoma been diagnosed and treated at stage I there would have been no need for the subsequent heavy doses of chemotherapy and the ovarian cancer would not have occurred. The plaintiffs did not amend their complaint to assert this claim.

II. Expert Witness

A. Rule 213 Disclosures

The plaintiffs retained Dr. Hector Gomez, a hematologist/oncologist, as their sole expert witness. In the plaintiffs' Supreme Court *837 Rule 213 (210 Ill.2d R. 213) disclosure filed October 25, 2005, Dr. Gomez set forth three medical opinions: (1) the standard of care required Drs. Dettore and Joyce to order a biopsy in 1998, and had a biopsy been performed, Mrs. McWilliams would have been diagnosed with stage I lymphoma; (2) to a reasonable degree of medical

certainty, had Mrs. McWilliams been diagnosed with lymphoma at stage I, and had she been treated with surgical intervention and radiation, and possibly chemotherapy, her lymphoma could have been cured or alleviated; and (3) to a reasonable degree of medical certainty, Mrs. McWilliams' ovarian cancer "could be" the result of the failure to properly treat the stage I lymphoma.

B. Deposition

Dr. Gomez was deposed on November 3, 2005. He testified he attended medical school in Peru and completed a medical residency and fellowship in hematology and oncology in the United States. He is board-eligible in hematology and oncology, but not board-certified.

Ten percent of Dr. Gomez's case load is devoted to internal medicine, while ninety percent is devoted to oncology/hematology. About 65% of that 90% is devoted to oncology. Seventy percent of those patients are referred to Dr. Gomez with a cancer diagnosis. He diagnoses the remaining 30%. He has treated between 80 and 100 non-Hodgkins lymphoma patients in his career.

Dr. Gomez is the chair of the oncology department at Thorek Hospital in Chicago and is on staff at several other community hospitals. He is an associate professor of clinical medicine at Northwestern University and instructs general residents at St. Joseph Hospital.

In his deposition, Dr. Gomez opined that the standard of care required Dr. Joyce "to do something," such as a biopsy or follow-up with additional CT scans. Dr. Gomez emphasized a biopsy should have been performed. Apparently believing Dr. Joyce was a general practitioner instead of a surgeon, Dr. Gomez also criticized Dr. Joyce for failing to obtain a surgical consult.

When asked to state the basis for his opinion that Dr. Joyce deviated from the standard of care, Dr. Gomez answered:

"The standard of care would have been if the patient had these suspicious nodes more than 2 centimeters and it was not an obvious cause to dismiss the patient for such a long time, I would persist and

do the biopsy of this patient. If there would have been an early diagnosis,***294 **1027 in retrospect, the patient would have had the best chance for a better life, if not cure."

Dr. Gomez stated the standard of care to be, "What I just said, that if a physician sees someone with such a node, the size of the node mainly, *838 you've got to do something about it, or else chances are you're going to make a mistake." Dr. Gomez agreed with the statement made by Dr. Joyce's counsel that the standard of care is the conduct that a reasonably well-qualified physician would do under similar circumstances.

Dr. Gomez acknowledged he is not board-certified or board-eligible in surgery. He did not complete a surgical residency and has never practiced as a surgeon. He holds no surgical privileges and does not teach surgical residents. He has never performed a biopsy. Dr. Gomez conceded the "ultimate" determination to perform a biopsy is made between the surgeon and the patient. However, a surgeon will generally do a biopsy at the clinician's request. According to Dr. Gomez, no surgeon had ever rejected his biopsy order. Dr. Gomez admitted that where a surgeon, in the course of a consult, declined to perform a biopsy, he would make a second referral to another surgeon.

Dr. Gomez opined that had Mrs. McWilliams been diagnosed with lymphoma in 1998, the lymphoma could have been treated with surgical excision, radiation, and possibly chemotherapy. Dr. Gomez testified that the chemotherapy Mrs. McWilliams would have received in 1998 would have been 95% of the chemotherapy she received to treat her stage IV lymphoma. According to Dr. Gomez, had Mrs. McWilliams been diagnosed in 1998, her life expectancy would have been 15 years.

Dr. Gomez also testified that in his opinion Mrs. McWilliams' lymphoma and the high-dose chemotherapy she received to treat it "greatly enhanced" the likelihood she would suffer from ovarian cancer, but did not "cause" it. When asked to give the basis for his opinion that there was a link between chemotherapy and ovarian cancer, Dr. Gomez explained, couched in reasonable degree of medical certainty language, lymphoma suppresses a patient's immune system and 5% to 10% of immunosuppressed patients receiving high-dose chemotherapy develop a second

malignancy, such as leukemia or ovarian cancer. When asked to identify any medical textbooks that supported his position that there is a link between chemotherapy-induced immunosuppression and a secondary malignancy, Dr. Gomez answered, "Based on my experience, it's my opinion because I've read so much that after 30 years I cannot precisely say what-I've read it somewhere."

III. Pretrial Motions

In October 2006, on the eve of trial, Dr. Dettore and Dr. Joyce filed numerous motions challenging Dr. Gomez's anticipated testimony at trial.

A. Causation

Dr. Dettore and Dr. Joyce each filed a motion *in limine* seeking to *839 bar Dr. Gomez from opining the chemotherapy Mrs. McWilliams received to treat the stage IV lymphoma caused the ovarian cancer. Drs. Dettore and Joyce argued there was no scientific basis for Dr. Gomez's causation opinion. The circuit court agreed and barred that testimony. Based on the barring of that testimony, Dr. Joyce moved for summary judgment, arguing the plaintiffs were unable to establish proximate cause between Dr. Joyce's alleged negligence and the damages or injuries claimed by Mrs. McWilliams based on her ovarian cancer. The court denied the motion because the plaintiffs were not given notice and an opportunity to respond.

1028 *295 Dr. Dettore also sought to bar Dr. Gomez from testifying that had Dr. Dettore referred Mrs. McWilliams to a second surgeon, the second surgeon would have performed a biopsy, and Mrs. McWilliams would have been diagnosed with lymphoma, treated, and cured. The court reserved ruling on this motion.

B. Standard of Care

Dr. Dettore also sought to bar Dr. Gomez's expert opinion on the standard of care on the ground that Dr. Gomez, an oncologist, was not competent to render expert testimony against Dr. Dettore, a family practitioner. The plaintiffs argued Dr. Gomez's specialty did not preclude his testimony as to the general "standard of care [of] what doctors do in treating a patient with a swollen lymph node." The plaintiffs

argued Dr. Gomez's standard of care testimony did not concern the treatment of cancer, but "what every doctor out of medical school should probably know" about treating a patient with swollen lymph nodes.

Dr. Joyce also filed a motion to bar Dr. Gomez from testifying as to the standard of care that applied to his medical treatment. Dr. Joyce argued Dr. Gomez was not qualified to give standard of care opinions because Dr. Gomez was not a surgeon, was not trained in surgery, and held no surgical privileges. The plaintiffs argued that their contention was not that Dr. Joyce deviated from the standard of care in performing surgery, as it was undisputed a biopsy was never performed. Rather, they claimed that Dr. Joyce breached the standard of care in failing to perform the biopsy in light of the mammogram results and the CT scan. According to the plaintiffs, "Dr. Gomez [was] clearly competent to testify that based upon the findings in the mammogram and in the CT scan, that a biopsy should have been performed." In other words, although Dr. Gomez did not perform biopsies, he "kn[ew] when a biopsy should be performed."

At the hearing on October 10, 2006, to address the motions *in limine*, the trial judge noted her doubts as to Dr. Gomez's qualifications*840 to testify against Dr. Joyce based on her review of Dr. Gomez's *curriculum vitae* and his discovery deposition. The plaintiffs responded that Dr. Gomez had not been asked the appropriate questions to establish his qualifications during his deposition. Rather than rule on Dr. Gomez's qualifications on the record as it stood before her, the trial judge provided the plaintiffs with an opportunity to *voir dire* Dr. Gomez before addressing the defendants' motions *in limine*. Counsel for the defendants and the court suggested postponing jury selection until after the *voir dire*. The plaintiffs' attorney saw no reason to delay jury selection. On October 13, 2006, a jury was selected and sworn. The *voir dire* of Dr. Gomez was scheduled for the following day.

IV. Voir Dire of Dr. Gomez

The *voir dire* of Dr. Gomez took place on Saturday, October 14, 2006. Dr. Gomez testified he went to medical school in Peru, where he learned about normal and abnormal lymph nodes. He described abnormal lymph nodes as "basic medicine" known "throughout the medical community." He also par-

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ticipated in a one-year rotating Peruvian internship in medicine, surgery, obstetrics/gynecology, and pediatrics similar to internships done in the United States. During his internship, Dr. Gomez was taught about abnormal axillary lymph nodes.

Dr. Gomez came to the United States in 1973 and did a yearlong internship at Columbus-Cuneo-Cabrini Medical Center in Chicago specializing in medicine, surgery, obstetrics/gynecology, and pediatrics. Doctors who would ultimately become primary care physicians and ***296 **1029 surgeons participated in the internship. During the internship, Dr. Gomez learned about abnormal lymph nodes and the lymphatic system.

From 1974 through 1977, Dr. Gomez participated in an internal medicine residency program at Columbus-Cuneo-Cabrini Medical Center. The lymphatic system was taught and discussed. Primary physicians and surgeons participated in the residency program. From 1977 through 1979, Dr. Gomez participated in a hematology/oncology fellowship at Northwestern University.

Dr. Gomez testified he had daily contact with surgeons and primary care physicians. He claimed ability to criticize a primary care physician regarding his or her treatment of an abnormal lymph node based on his training. When asked to explain why he thought he could criticize both primary care physicians and surgeons, Dr. Gomez answered:

“Well, multiple years and throughout my career, which included my training and my 20 years of practice-25 years of practice of medicine, I have been in touch with them.

*841 And I'm still in touch with them in training, and also as a practicing physician. So the answer is, yes, I am very well familiarized with their thinking and training.”

V. Trial Court Rulings

On October 16, 2006, the circuit court reviewed Dr. Gomez's *voir dire* testimony and heard arguments from the parties regarding his qualifications to testify as to the standards of care. The court concluded that Dr. Gomez was qualified to testify against Dr. Det-

tore, but not qualified to testify against Dr. Joyce. The court found Dr. Gomez failed to “demonstrate his familiarity with the methods, procedures and treatments ordinarily observed by similarly situated physicians such as Dr. Joyce.” The court also granted Dr. Dettore's motion *in limine*, on which it had reserved ruling, barring Dr. Gomez's testimony that had Dr. Dettore referred Mrs. McWilliams to a second surgeon, her lymphoma would have been timely diagnosed.

Based on the absence of expert testimony against Dr. Joyce, Dr. Joyce moved for dismissal with prejudice under section 2-619(a)(9) of the Code of Civil Procedure (735 ILCS 5/2-619 (a)(9) (West 2006)). Counsel for the plaintiffs responded that barring Dr. Gomez from testifying against Dr. Joyce was “the end of the case” because he was “not going to try this case * * * against one doctor when both doctors were guilty of negligence.” Counsel indicated he “would rather go to the Appellate Court now than try[] this case.” Counsel moved for a voluntarily dismissal. The court denied the motion because the jury had been sworn.

The record indicates the parties and the court attempted to devise a means for the plaintiffs to end the entire case, while preserving the plaintiffs' claim against Dr. Dettore, which could have gone forward before the jury. After much discussion on and off the record, the court granted Dr. Joyce's and Dr. Dettore's dismissal motions and dismissed the jury. Written orders to this effect were entered on October 17, 2006, one pertaining to Dr. Joyce, the other to Dr. Dettore.

VI. Postjudgment Proceedings

In their posttrial motion filed November 13, 2006, the plaintiffs asserted the circuit court erred in barring Dr. Gomez from testifying against Dr. Joyce and in dismissing their case against Dr. Joyce. The plaintiffs argued the *voir dire* of Dr. Gomez established he was competent to testify as to the standard of care that applied to Dr. Joyce in this case. The plaintiffs ***297 **1030 also argued Dr. Joyce's motion *in limine* was, in effect, an untimely motion for summary judgment without proper notice.

On November 21, 2006, the plaintiffs filed an affidavit by Dr. Gomez,*842 to supplement their posttrial motion. In the affidavit, Dr. Gomez averred (1) he

had “acquired considerable experience with the standard of care, methods, procedures and treatments relevant to allegations of negligence and the medical condition of Carol McWilliams, as presented in October, 1998, by general or primary physicians and surgeons”; (2) he had “acquired considerable experience with the standard of care, methods, procedures and care and treatment relevant to the allegations against Defendants, Dr. Donald Dettore and Dr. Christopher Joyce concerning a patient in the medical condition presented by Carol McWilliams in 1998”; (3) he “[had] experience with the standard of care, methods, procedures and treatments relevant to the allegations against Dr. Donald Dettore, a general physician” and “against Dr. Christopher Joyce a surgeon”; and (4) he was “knowledgeable with the general medical standard of care with respect to an individual suffering from two (2) two (2) centimeter lymph nodes in the axilla.”

Dr. Joyce filed a motion to strike Dr. Gomez's affidavit as untimely.

On November 29, 2006, the circuit court entered an “Agreed Amended Order * * * Nunc Pro Tunc” to October 17, 2006, the date the dismissal orders were entered. The *nunc pro tunc* order made clear that the plaintiffs' aim in not responding to the motions by Dr. Dettore was to “receive a single final and appealable order.”^{FN2} On February 15, 2007, the circuit court granted Dr. Joyce's motion to strike the affidavit and denied the plaintiffs' posttrial motion. This timely appeal followed.

FN2. For a different approach, see *Somers v. Quinn*, 373 Ill.App.3d 87, 310 Ill.Dec. 848, 867 N.E.2d 539 (2007). On the eve of trial, the circuit court barred the plaintiff's expert witness. “The parties stipulated that, in the absence of [the expert witness's] testimony, plaintiff would present no evidence on the standard of care. Defendant then moved for a directed verdict, which the trial court granted.” *Somers*, 373 Ill.App.3d at 90, 310 Ill.Dec. 848, 867 N.E.2d 539.

ANALYSIS

The plaintiffs assert that as to their case against Dr. Joyce, the circuit court committed four reversible errors: (1) finding Dr. Gomez unqualified to render a

standard of care opinion against Dr. Joyce; (2) striking Dr. Gomez's postjudgment affidavit; (3) granting Dr. Joyce's motion *in limine* to bar Dr. Gomez's testimony; and (4) barring Dr. Gomez from testifying to a casual connection between the alleged failure to diagnose stage I lymphoma and Mrs. McWilliams' ovarian cancer. The plaintiffs also assert that the circuit court abused its discretion in not granting their motion to voluntarily dismiss their case once Dr. Gomez was barred from testifying against Dr. Joyce.

*843 I. Dr. Gomez's Qualifications

[1] Generally, in medical negligence cases, a plaintiff must establish, with expert testimony, the applicable standard of care against which the defendant health-care professional's conduct is measured, a deviation from that standard, and an injury proximately caused by that deviation. *Sullivan v. Edward Hospital*, 209 Ill.2d 100, 114-15, 282 Ill.Dec. 348, 806 N.E.2d 645 (2004).

[2][3] To render standard of care testimony against a medical practitioner, a proffered expert must be scientifically or medically qualified. To be medically qualified, a two-prong showing must be made. First, the expert must be a licensed member***298 **1031 of the school of medicine about which he or she proposes to opine, the “licensure” prong. See *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. Second, the expert must be familiar with the methods, procedures, and treatments that similarly situated physicians as the defendant would ordinarily observe, the “familiarity” prong. See *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. The showings regarding scientific qualifications are “foundational requirements and form a threshold determination.” *Alm v. Loyola University Medical Center*, 373 Ill.App.3d 1, 5, 310 Ill.Dec. 641, 866 N.E.2d 1243 (2007), citing *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. “If this threshold determination is not met, the analysis ends and the trial court must disallow the expert's testimony.” *Alm*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243.

As both Dr. Gomez and Dr. Joyce are medically licensed physicians, this case hinges on the familiarity prong. The circuit court determined Dr. Gomez failed to “demonstrate his familiarity with the methods, procedures and treatments ordinarily observed by similarly situated physicians such as Dr. Joyce.” As a

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consequence, the circuit court granted the dismissal motion by Dr. Joyce.

A. Standard of Review

[4] Our supreme court made clear in *Sullivan* that the scientific qualifications of the proffered expert are “foundational requirements.” *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. A plaintiff’s failure to make this threshold showing compels the trial court to “disallow the expert’s testimony” and the “analysis ends.” *Alm*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243. This language in *Alm* suggests that whether the threshold requirements have been met presents a legal question. This language is based on *Sullivan*. To determine whether an expert is qualified to give an opinion on the standard of care, there is a “three-step analysis: the two foundational requirements of licensure and familiarity, and the *discretionary requirement of competency*.” (Emphasis added). *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. As the supreme court previously made clear in *Jones v. O’Young*, 154 Ill.2d 39, 180 Ill.Dec. 330, 607 N.E.2d 224 (1992), the trial court’s exercise of *844 discretion applies *only after* the legal requirements have been met. “Once the foundational requirements have been met, the trial court has discretion to determine whether a physician is qualified and competent to state his opinion as an expert regarding the standard of care.” *Jones*, 154 Ill.2d at 43, 180 Ill.Dec. 330, 607 N.E.2d 224.

The circuit court expressed doubts regarding Dr. Gomez’s qualifications based on its review of his *curriculum vitae* and his deposition testimony. The plaintiffs attributed the deficiency to Dr. Gomez not being asked the right questions, leading to the *voir dire* examination on his qualifications outside the presence of the trial judge. Upon the trial judge’s review of the transcript, she determined that the *voir dire* testimony did not establish Dr. Gomez’s qualifications and barred his opinion testimony. Because we find no basis to conclude that the circuit court’s review of the deposition and *voir dire* transcripts involved an exercise of discretion, we owe no deference to the circuit court’s determination that the familiarity-prong requirement has not been met. See *Redmond v. Socha*, 216 Ill.2d 622, 634, 297 Ill.Dec. 432, 837 N.E.2d 883 (2005) (an issue “is reviewed under an abuse of discretion standard only when the trial court actually engages in an exercise of discre-

tion”). “The circuit court did not hold an evidentiary hearing, weigh the testimony or assess***299 **1032 the credibility of [Dr. Gomez].” *Townsend v. Sears, Roebuck & Co.*, 227 Ill.2d 147, 154, 316 Ill.Dec. 505, 879 N.E.2d 893 (2007). The record consists solely of the transcripts of the examinations of Dr. Gomez and his *curriculum vitae*. “When a trial judge bases [her] decision solely on the same ‘cold’ record that is before the court of review, it is difficult to see why any deference should be afforded to that decision.” *Toland v. Davis*, 295 Ill.App.3d 652, 654, 230 Ill.Dec. 445, 693 N.E.2d 1196 (1998).

Because the ruling by the circuit court deprived the plaintiffs, pretrial, of presenting their case before a jury, much as a grant of summary judgment or a grant of a motion to dismiss would, both of which are reviewed *de novo*, we decline to review the circuit court’s determination that the familiarity-prong of the foundation requirements has not been met here as lying within its discretion. We review the circuit court’s determination *de novo*.

B. Familiarity Prong

We first note that in their main brief, the plaintiffs take the position that a single standard of care under the circumstances present in this case applies to both Dr. Dettore, a family practitioner, and Dr. Joyce, a board-certified surgeon. It is against this backdrop that we examine whether a sufficient showing of the familiarity prong was made by the plaintiffs to qualify Dr. Gomez to testify against Dr. Joyce.

[5] *845 “The foundational requirements provide the trial court with the information necessary to determine whether an expert has expertise in dealing with the plaintiff’s medical problem and treatment.” *Jones*, 154 Ill.2d at 43, 180 Ill.Dec. 330, 607 N.E.2d 224. It is insufficient for a plaintiff to merely present that “another physician * * * would have acted differently from the defendant, since medicine is not an exact science. It is rather a profession which involves the exercise of individual judgment within the framework of established procedures. Differences in opinion are consistent with the exercise of due care.” *Walski v. Tiesenga*, 72 Ill.2d 249, 261, 21 Ill.Dec. 201, 381 N.E.2d 279 (1978). Generally, expert testimony is required to assist a jury to determine “any lack of necessary scientific skill on the part of the physician.” *Walski*, 72 Ill.2d at 256, 21 Ill.Dec. 201,

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381 N.E.2d 279. Before a medical negligence case requiring expert testimony can reach a jury, a plaintiff must present an expert familiar with the methods, procedures, and treatments that make up the standard of care against which the conduct of the defendant doctor may be measured. *Walski*, 72 Ill.2d. at 255, 21 Ill.Dec. 201, 381 N.E.2d 279. Only with the presentation of such expert testimony can a plaintiff "prove that, judged in the light of these standards, the doctor was unskillful or negligent and that his want of skill or care caused the injury to the plaintiff." *Walski*, 72 Ill.2d. at 256, 21 Ill.Dec. 201, 381 N.E.2d 279.

[6] To satisfy the familiarity prong, the plaintiffs had to demonstrate that Dr. Gomez, an oncologist that orders biopsies of swollen lymph nodes and treats cancer patients, had familiarity with the generally accepted standard of care or skill required to determine when a biopsy, a surgical procedure, under the circumstances presented by Mrs. McWilliams, should be performed.

The plaintiffs were given two opportunities to demonstrate Dr. Gomez's familiarity with the standard of care applicable to Dr. Joyce. At the pretrial motions hearing, the plaintiffs acknowledged that Dr. Gomez had not been asked the appropriate questions to establish his qualifications during his deposition. The trial judge provided ***300 **1033 the plaintiffs with an opportunity to *voir dire* Dr. Gomez. In their main brief, the plaintiffs do not include an excerpt from the *voir dire* examination of Dr. Gomez that they claim satisfied the familiarity prong regarding the standard of care applicable to Dr. Joyce. Rather, the plaintiffs, in concluding their argument on this issue, assert "the standard of care regarding the care, treatment and management of [the plaintiff's] condition is the same for all physicians involved, keeping in mind that the radiologist at [the hospital where the mammogram was taken] warned both doctors that in his opinion a biopsy was necessary."

We look to the cases that address the familiarity prong to determine whether the plaintiffs made a sufficient showing to qualify *846 Dr. Gomez to allow the case to go forward before a jury. In *Northern Trust Co. v. Upjohn Co.*, 213 Ill.App.3d 390, 157 Ill.Dec. 566, 572 N.E.2d 1030 (1991), *Hubbard v. Sherman Hospital*, 292 Ill.App.3d 148, 153, 226 Ill.Dec. 393, 685 N.E.2d 648 (1997), and *Alm*, the familiarity prong was not established. In *Silverstein v.*

Brander, 317 Ill.App.3d 1000, 251 Ill.Dec. 276, 740 N.E.2d 357 (2000), we found the opposite. We begin with the principal case the plaintiffs contend supports their position.

In *Silverstein*, we reversed the circuit court's ruling that the plaintiff's expert, an internist, was unqualified to criticize the defendant physiatrist. The case involved the treatment of the plaintiff with the drug Indocin after hip surgery. The proffered expert's testimony averred that the defendant doctor "should have recognized problems from the use of Indocin for a patient with a history of peptic ulcers complaining of nausea." *Silverstein*, 317 Ill.App.3d at 1002, 251 Ill.Dec. 276, 740 N.E.2d 357. It was alleged that "[t]he continued use of Indocin caused plaintiff's [new] ulcer." *Silverstein*, 317 Ill.App.3d at 1002, 251 Ill.Dec. 276, 740 N.E.2d 357. The plaintiff's expert did not offer any criticism of the physical therapy rendered by the defendant. The expert criticized the medical management of the plaintiff regarding the continued administration of Indocin once the plaintiff complained of nausea. *Silverstein*, 317 Ill.App.3d at 1002, 251 Ill.Dec. 276, 740 N.E.2d 357. While the defense attorneys sought to bar testimony of the plaintiff's expert as to the alleged violation of the standard of care, based on the trial judge's ruling, it is clear that the challenge was directed at the plaintiff's expert's alleged lack of "familiarity with the standard of care for physiatrists." *Silverstein*, 317 Ill.App.3d at 1003, 251 Ill.Dec. 276, 740 N.E.2d 357. In reversing, we noted the plaintiff's expert "had considerable experience with Indocin, and he testified that all physicians, including physiatrists, know of Indocin's effects" on a patient with peptic ulcers. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357. We found the plaintiff's expert sufficiently familiar with the adverse effects of Indocin and the medical management standard of care for the administration of Indocin, which required "all physicians, including physiatrists" to recognize "that a patient with a history of peptic ulcers is especially vulnerable to those effects." *Silverstein*, 317 Ill.App.3d at 1007-08, 251 Ill.Dec. 276, 740 N.E.2d 357.

Relying on the medical management reference in *Silverstein*, the plaintiffs contend in their main brief that "Dr. Gomez did not criticize Dr. Joyce for surgical procedure, but disapprove[d] of [Dr. Joyce] for [his] medical management." According to the plaintiffs, Dr. Gomez opined "[Dr. Joyce] should know

that [a] lymph node over one-centimeter in the axilla is abnormal. Therefore since [Dr. Joyce] knew [Mrs. McWilliams] suffered from two very abnormal lymph nodes, [Dr. Joyce was] required to administer appropriate medical ***301 **1034 care, consisting of telling her of her ailment, recommend biopsy, and further medical care."

*847 While *Silverstein* may fall under the rubric of "medical management," the role medical management played in the case turned on the claim of negligence tied to the patient's care. In *Silverstein*, the claim was the psychiatrist was negligent in failing to recognize symptoms connected to the administration of Indocin to a patient that had peptic ulcers. The plaintiff's expert testimony was that "all physicians, including psychiatrists" know of, and are expected to recognize such symptoms. Thus, the proffered expert in *Silverstein* testified to sufficient familiarity with the controlling standard of care to which "all physicians, including psychiatrists" would be held on the claim of negligence regarding the administration of Indocin to the plaintiff.

Here, the plaintiffs' negligence claim against Dr. Joyce is that he failed to perform a biopsy on Mrs. McWilliams in light of her abnormal lymph nodes disclosed in the mammogram and the CT scan. However, it is beyond contention that Dr. Gomez has never performed a biopsy, holds no surgical privileges and does not teach surgical residents. Dr. Gomez conceded in his discovery deposition that disagreements with surgeons may arise on whether to perform a biopsy.

"Q. If the surgeon disagrees with you, then you go out and get another surgeon?"

A. I get another opinion, and you know, until I get this done."

In fact, during his discovery deposition, Dr. Gomez wrongly criticized Dr. Joyce for not having referred Mrs. McWilliams to a surgeon.

Dr. Gomez's admission that he and the surgeon to whom he might refer a patient presenting abnormal lymph nodes, like Mrs. McWilliams here, might disagree, leads us to conclude that the decision whether to perform a biopsy is inherently tied to a surgeon's training. The plaintiffs' claim is that Dr. Joyce should

have performed a biopsy. It is simply not accurate to state that because no biopsy was performed, Dr. Gomez's criticism of Dr. Joyce is not based on factors that a surgeon would consider in deciding whether to perform surgery. Whether to perform a biopsy (to cut or not to cut) is not a decision that "all physicians, including [oncologists]," know as counsel for the plaintiffs argues. Nor did Dr. Gomez ever testify to such a claim. In fact, such a claim may be foreclosed to Dr. Gomez when he acknowledged that his own practice is to refer patients with abnormal lymph nodes to surgeons and conceded that the "ultimate" decision whether to perform a biopsy is made between the surgeon and the patient. We reject the plaintiffs' argument that the case against Dr. Joyce concerned "what every doctor out of medical school should probably know."

More to the point, nowhere do we find any testimony by Dr. Gomez*848 as to the standard of care to which Dr. Joyce, a surgeon, was bound to adhere. Although Dr. Gomez's *voir dire* testimony established his expertise with abnormal lymph nodes, his testimony did not link this expertise to the performance of a biopsy. Dr. Gomez's testimony, as it stands before us, is indistinguishable from the testimony of the plaintiff's expert found insufficient in *Walski*. The plaintiff's expert "at no time testified that there was a generally accepted medical standard of care or skill which required the [medical procedure] under the circumstances. * * * Absent is any statement of a standard [the defendant doctor] was required to follow in this case." *Walski*, 72 Ill.2d at 259-60, 21 Ill.Dec.***302 **1035 201, 381 N.E.2d 279. Our conclusion is the same here.

It was incumbent upon the plaintiffs to demonstrate the standard of care or skill that would dictate when a biopsy would be medically necessary. On the record before us, we are compelled to conclude Dr. Gomez was not qualified to testify against Dr. Joyce, a board-certified surgeon, as to his decision not to perform a biopsy.^{FN3}

FN3. Though not a part of our analysis, Dr. Joyce's discovery responses indicate that because he could not "palpate the mass," the mammogram results and the CT scan were insufficient to justify the surgical procedure a biopsy would entail, a conclusion supported by his own lineup of experts.

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Our conclusion is supported by the three cases, referenced above, where the familiarity prong was found not to have been satisfied. In *Northern Trust*, we concluded the plaintiff's expert, board-certified in internal medicine and emergency medicine and the director of emergency services at Northwestern Memorial Hospital, was unqualified to testify to the standard of care that applied to the use of the drug Prostin in the context of an abortion procedure, which, according to the complaint, caused the patient to suffer cardiac arrest, resulting in brain injury. The plaintiff's expert had never worked in an obstetrics or gynecology ward, had never performed an abortion, had never used Prostin, had never seen Prostin used, and had never observed a patient's reaction to Prostin. Based on these facts, we concluded the expert "was not qualified to give an opinion on [the standard of care] since he could not know what was customary practice" for someone in the defendant's position. *Northern Trust*, 213 Ill.App.3d at 407, 157 Ill.Dec. 566, 572 N.E.2d 1030.

In *Hubbard*, the pertinent appellate review concerned the disallowance of testimony by the plaintiff's expert that was critical of the defendant surgeon's "performance of the actual surgery." *Hubbard*, 292 Ill.App.3d at 153, 226 Ill.Dec. 393, 685 N.E.2d 648. The *Hubbard* court agreed with the trial court that the plaintiff's expert was not qualified to testify against the emergency room surgeon. We noted that the plaintiff's expert "provided no information that he had ever actually performed an appendectomy*849 himself or that he holds or held surgical privileges at any hospitals. Accordingly, the trial court properly precluded his testimony concerning surgery and related topics, such as the time of the surgery and presurgical testing." *Hubbard*, 292 Ill.App.3d at 155, 226 Ill.Dec. 393, 685 N.E.2d 648.

In *Alm*, a two-month-old infant died the day after receiving plastic surgery to fix a cleft lip and palate. The parents sued the plastic surgeons and anesthesiologist, alleging they failed to properly monitor the infant during surgery and improperly discharged her following surgery. The circuit court barred the plaintiffs' proposed expert, a pathologist. In affirming, we found the expert's deposition testimony failed to establish he had any experience with the methods, procedures, and treatments at issue—those pertaining to the postoperative care of infants and "discharge deci-

sionmaking." *Alm*, 373 Ill.App.3d at 6, 310 Ill.Dec. 641, 866 N.E.2d 1243. The expert's training and experience involved the examination of tissue samples from the living and the deceased; he had not evaluated a live patient in about 20 years and had not treated a pediatric patient for even longer. The expert testified he "deals with" plastic surgeons but he did not consider himself an expert in plastic surgery. *Alm*, 373 Ill.App.3d at 6, 310 Ill.Dec. 641, 866 N.E.2d 1243. His only training in anesthesiology was part of a rotation while a resident approximately 25 ***303 **1036 years earlier. He was unable to recall ever discharging a patient and could not identify the applicable standard of care.

As in *Alm*, Dr. Joyce's decisionmaking is central to the plaintiffs' negligence claim. The plaintiffs' claim against Dr. Joyce is based on his decision not to perform a biopsy. Before Dr. Gomez could be allowed to criticize Dr. Joyce's medical judgment before a jury, Dr. Gomez first had to demonstrate his experience with the methods, procedures and treatments at issue—those pertaining to when a biopsy should be performed. Dr. Gomez had no experience in such decisionmaking. As in *Northern Trust* and *Hubbard*, Dr. Gomez did not know the customary practice for a surgeon regarding the decision whether to perform the surgical procedure of a biopsy. While we do not read *Hubbard* to hold that only a surgeon can provide critical testimony against another surgeon, it is clear that before critical testimony based on professional standards may be allowed, a plaintiff's proffered expert must be familiar with the matters that a reasonably qualified surgeon would consider in the course of carrying out his medical duties.

We emphasize that our holding does not rest on Dr. Gomez not being a surgeon. We agree with the plaintiffs' repeated contention that one need not be a surgeon to criticize a surgeon. See *Jones*, 154 Ill.2d at 43, 180 Ill.Dec. 330, 607 N.E.2d 224 ("Whether the expert is qualified to testify is not dependent on whether he is a member of the same specialty or subspecialty as the defendant"). *Silverstein* demonstrates this as well. Nonetheless, before *850 a plaintiff's expert may step into the shoes of a defendant doctor to assess his medical skills, the plaintiff's expert must demonstrate he is familiar with the medical standard against which the defendant doctor's medical judgment must be measured. While it is not beyond the realm of possibility that an oncologist may be capa-

ble of criticizing a surgeon's decision to forego a biopsy, Dr. Gomez's testimony did not demonstrate the necessary expertise.

As a matter of law, the plaintiffs failed to meet the familiarity-prong threshold of the foundational requirements. *Sullivan*, 209 Ill.2d at 115, 282 Ill.Dec. 348, 806 N.E.2d 645. The plaintiffs having failed to meet this threshold determination, our "analysis ends and the trial court [was correct to] disallow the expert's testimony." *Alm*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243. Accordingly, the circuit court did not err in barring Dr. Gomez from testifying as an expert against Dr. Joyce.^{FN4}

FN4. While the dissent contends the familiarity prong showing was established, unlike in *Silverstein*, neither the plaintiffs nor the dissent quotes Dr. Gomez's "precise testimony" that in their judgment qualifies Dr. Gomez "as an expert in the kind of treatment criticized." *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357.

II. Remaining Claims of Reversible Error

Because the remaining three claims of reversible error as to the plaintiffs' case against Dr. Joyce turn on Dr. Gomez's anticipated court testimony against Dr. Joyce and we find Dr. Gomez was properly barred from rendering expert testimony against Dr. Joyce, our resolution of the first issue is dispositive to the other three as well. Nonetheless, we briefly address the remaining three claims of reversible error pertaining to the case against Dr. Joyce.

A. Motion in Limine

We are unpersuaded that the motion *in limine* filed by Dr. Joyce somehow came as a surprise to the plaintiffs. The plaintiffs were given two opportunities to establish the foundational requirements to qualify***304 **1037 Dr. Gomez. The second opportunity came after Dr. Joyce's motion *in limine* challenging Dr. Gomez's qualifications was filed. That the grant of the motion *in limine* laid the basis for the section 2-619(a)(9) motion to dismiss does not make the motion *in limine* or the motion to dismiss the equivalent of a motion for summary judgment, for notice purposes. "If we accepted plaintiffs' argument that the motion to dismiss was an untimely motion

for summary judgment and reversed the trial court, plaintiffs would ultimately find themselves in the same position they are in now. With no expert witness to prove [standard of care], the court would grant a directed verdict for [Dr. Joyce], after having had to waste both its time and the parties' time, *851 money and energy on an unnecessary proceeding. "[T]he law does not require the doing of a useless act." *Seef v. Ingalls Memorial Hospital*, 311 Ill.App.3d 7, 20, 243 Ill.Dec. 806, 724 N.E.2d 115 (1999), quoting *Stone v. La Salle National Bank*, 118 Ill.App.3d 39, 45, 73 Ill.Dec. 811, 454 N.E.2d 1060, 1065 (1983).

B. Affidavit

The plaintiffs argue the circuit court had discretion to consider the affidavit, which they assert "certainly established Dr. Gomez's qualifications and familiarity with the standard of care concerning both physicians."^{FN5}

FN5. No party disputes the trial court's finding that Dr. Gomez was qualified to testify against Dr. Dettore.

While we do not disagree that the circuit court may have had discretion to consider the affidavit, we find the affidavit adds nothing to Dr. Gomez's deposition and *voir dire* testimony. The postjudgment affidavit fails to set forth any specific facts to demonstrate Dr. Gomez's expertise to criticize a surgeon for failing to perform a biopsy. Dr. Gomez's affidavit contains nothing more than conclusory statements. Accordingly, it was properly rejected by the circuit court.

C. Causal Connection to Ovarian Cancer

The plaintiffs' final contention involving the case against Dr. Joyce is that under the "loss-of-chance doctrine," the circuit court erred when it barred Dr. Gomez from testifying to a causal connection between the defendants' alleged failure to timely diagnose Mrs. McWilliams' non-Hodgkins lymphoma and her development of ovarian cancer. The plaintiffs' loss-of-chance argument is not clear. The loss-of-chance doctrine is related to the cause-in-fact component of the proximate cause element of a negligence case. See, e.g., *Scardina v. Nam*, 333 Ill.App.3d 260, 269, 266 Ill.Dec. 454, 775 N.E.2d 16 (2002).

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Drs. Joyce and Dettore assert that a loss-of-chance theory was never raised below and was never ruled upon by the circuit court. Our review of the record confirms this and, thus, this contention is waived. See, e.g., *Haudrich v. Howmedica, Inc.*, 169 Ill.2d 525, 536, 215 Ill.Dec. 108, 662 N.E.2d 1248 (1996) (issues not raised below are forfeited on appeal).

Waiver aside, we agree with the circuit court that more was required than a Rule 213 disclosure to support this claim. The circuit court ruled that Dr. Gomez's causation theory—that Mrs. McWilliams' ovarian cancer “could be” the result of her treatment for stage IV lymphoma—was not generally accepted under *Frye v. United States*, 293 F. 1013 (D.C.Cir.1923). On appeal, the plaintiffs do not contend this ruling was erroneous, which comes as no surprise given that Dr. Gomez cited no scientific support for his position. See, ***305 **1038 e.g., *Ruffin v. *852 Boler*, 384 Ill.App.3d 7, 322 Ill.Dec. 255, 890 N.E.2d 1174, 1188 (2008) (reliability and general acceptance may be established under *Frye* where the theory has been published in scientific literature).

Finally, there is no reason to reach the proximate cause issue of the loss-of-chance doctrine when the plaintiffs failed to establish the applicable standard of care. See *Alm*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243 (if threshold requirements have not been met, expert testimony must be disallowed).

III. Voluntary Dismissal

[7] Finally, the plaintiffs argue the circuit court abused its discretion in not granting their motion to voluntarily dismiss their action once Dr. Gomez was found unqualified and that notions of equity require us to reverse the circuit court's order. Upon meeting statutory requirements, a plaintiff has the nearly unfettered right to voluntarily dismiss his or her case any time prior to the commencement of trial. 735 ILCS 5/2-1009(a) (West 2006); *Valdovinos v. Luna-Manalac Medical Center, Ltd.*, 328 Ill.App.3d 255, 265, 262 Ill.Dec. 147, 764 N.E.2d 1264 (2002).

Here, trial commenced when the jury was selected, which occurred prior to the plaintiffs' motion for voluntary dismissal. *Kahle v. John Deere Co.*, 104 Ill.2d 302, 308, 84 Ill.Dec. 650, 472 N.E.2d 787 (1984), citing *Wilhite v. Agbayani*, 2 Ill.App.2d 29, 33, 118

N.E.2d 440 (1954) (trial commenced when the jurors were examined and sworn). Notions of equity do not persuade us to overturn the lower court's order where the record shows it was the plaintiffs' counsel who insisted on impaneling the jury prior to Dr. Gomez's *voir dire*. The circuit court and defense counsel urged putting off jury selection until after Dr. Gomez was reexamined. The plaintiffs' counsel, as master of his case, saw no reason to delay jury selection. As the plaintiffs' position was acceded to, we see no basis to overturn the circuit court's denial of the request for a voluntary dismissal. The plaintiffs have made no showing of an abuse of discretion by the circuit court in denying their motion for a voluntary dismissal.

CONCLUSION

As a matter of law, the circuit court correctly ruled that Dr. Gomez was not qualified to render a standard of care opinion against Dr. Joyce and, therefore, the circuit court properly granted Dr. Joyce's motion *in limine*. The circuit court did not abuse its discretion in striking Dr. Gomez's postjudgment affidavit and barring Dr. Gomez from testifying to any purported link between stage I lymphoma and ovarian cancer. Finally, the circuit court acted within its discretion in *853 denying the plaintiffs' motion to voluntarily dismiss their case. The judgment of the circuit court is affirmed.

Affirmed.

WOLFSON, J., specially concurs.

R. GORDON, P.J., dissents. Justice WOLFSON, specially concurring:

I write this special concurrence only to express my disagreement with a small portion of the majority opinion.

We should apply an abuse of discretion standard to the trial court's decision to bar Dr. Gomez' testimony against Dr. Joyce. To reach the conclusion that Dr. Gomez was not qualified to testify the trial court had to review Dr. Gomez' deposition and *voir dire* testimony. The trial court weighed the testimony and made an evidentiary ruling. It was not a ruling based on “documentary evidence,” as it was in *Townsend v. Sears, Roebuck & Co.*, 227 ***306 **1039 Ill.2d 147, 154, 316 Ill.Dec. 505, 879 N.E.2d 893 (2007).

Presiding Justice ROBERT E. GORDON dissenting.

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I respectfully dissent.

The trial judge in this case made two incorrect rulings that would require this court to reverse the trial court. First, when the trial court denied Dr. Detorre's motion *in limine* to bar plaintiff's expert, Dr. Gomez, from testifying against him on standard of care, the trial court abused its discretion in granting Dr. Detorre's motion to dismiss the case with prejudice,^{FN6} when plaintiff did not want to proceed further. "If a trial judge dismisses a plaintiff's cause of action as a result of a refusal to proceed with trial due to the unavailability of a necessary witness, the proper order of dismissal is one for want of prosecution." *Farrar v. Jacobazzi*, 245 Ill.App.3d 26, 33, 185 Ill.Dec. 125, 614 N.E.2d 259 (1993).

FN6. Plaintiff's failure to satisfy the statutory requirements of notice and costs was not an absolute bar to a voluntary dismissal. See 387 Ill.App.3d at 852, 327 Ill.Dec. at 305, 901 N.E.2d at 1038, citing *Valdovinos*, 328 Ill.App.3d at 265, 262 Ill.Dec. 147, 764 N.E.2d 1264. In *Valdovinos*, this court held that we would excuse "plaintiffs' failure to strictly comply with the requirements of section 2-1009" where no prejudice resulted. *Valdovinos*, 328 Ill.App.3d at 267-68, 262 Ill.Dec. 147, 764 N.E.2d 1264. In *Valdovinos*, we held that no prejudice resulted, where defendants "were given an opportunity to respond to the plaintiffs' motion despite the lack of notice," and where the court's dismissal order directed plaintiffs to subsequently "pay costs and expenses to the defendants." *Valdovinos*, 328 Ill.App.3d at 267-68, 262 Ill.Dec. 147, 764 N.E.2d 1264.

Plaintiff complains in his brief and oral argument that it is unfair for the defense to file motions *in limine* to bar her sole expert witness on the day the case is assigned for immediate trial. Yet, not only is there no rule of law that prohibits that practice, lawyers normally file their motions to bar at that time, and the trial bar is well aware of *854 that process. If a lawyer feels that he or she needs that disposition to occur earlier, a motion judge in Cook County could require a party to file such motions earlier on plaintiff's motion to do so. Plaintiff in this case made no motion to do so.

However, in a medical negligence case, when a plaintiff's sole expert witness is barred from testifying against a defendant physician at the last moment, the plaintiff has no expert to proceed in order to make a *prima facie* case and the circumstances are the same as the unavailability of a necessary witness.^{FN7} Thus, the dismissal in the case at bar should have been "for want of prosecution." It is established law in Illinois that a trial judge does not have the power to dismiss a cause of action for want of prosecution with prejudice." *Farrar v. Jacobazzi*, 245 Ill.App.3d at 34, 185 Ill.Dec. 125, 614 N.E.2d 259; see also *Kraus v. Metropolitan Two Illinois Center*, 146 Ill.App.3d 210, 212, 100 Ill.Dec. 15, 496 N.E.2d 1080 (1986) ("a dismissal for want of prosecution * * * is not an adjudication on the merits, does not prejudice the case of the party against whom it is entered, and does not bar a subsequent suit on the same issues"). Thus, the order should have been entered, without prejudice.

FN7. The majority is at a loss about how to properly characterize the trial court's order regarding the motion *in limine*. On the one hand, the majority opinion states that our review of this order should be *de novo*, because the order was tantamount to a summary judgment order. 387 Ill.App.3d at 844, 327 Ill.Dec. at 299, 901 N.E.2d at 1032. On the other hand, the majority opinion states later that the motion *in limine* was not "the equivalent of a motion for summary judgment," for which proper notice would have been required. 387 Ill.App.3d at 850, 327 Ill.Dec. at 304, 901 N.E.2d at 1037.

1040 *307 Second, the trial court erred in barring Dr. Gomez from testifying against Dr. Joyce, both as to standard of care^{FN8} and to causation. The trial court first determined that Dr. Gomez failed to "demonstrate his familiarity 'with the methods, procedures and treatments ordinarily observed by' similarly situated physicians such as Dr. Joyce." *McWilliams v. Detorre*, No. 02-L-12242 (Cook Co. Cir.Ct. October 17, 2006), quoting *Alm v. Loyola*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243. I agree with the majority that to satisfy the familiarity prong, the plaintiff had to demonstrate that Dr. Gomez, an oncologist, had familiarity with the generally accepted standard of care required to determine when a cancer biopsy should be performed.

However, this court's decision in *Silverstein*-*855 and the long line of cases like it-directs the outcome in the case at bar. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357 (“The cases instruct us to look to the expert's precise testimony and determine whether he qualifies as an expert in the kind of treatment criticized”); *Rosenberg v. Miller*, 247 Ill.App.3d 1023, 1029, 1030-31, 187 Ill.Dec. 285, 617 N.E.2d 493 (1993) (a dentist was qualified to testify against a periodontist, where the deviation concerned something that “all dentists” should know); *Gorman v. Shu-Fang Chen, M.D., Ltd.*, 231 Ill.App.3d 982, 983-85, 988, 173 Ill.Dec. 471, 596 N.E.2d 1350 (1992) (a plastic surgeon was qualified to testify against an orthopedic surgeon concerning his failure, in light of plaintiff's swollen jaw, to x-ray and hence diagnose a jaw fracture); *Rock v. Pickleman*, 214 Ill.App.3d 368, 370, 374, 158 Ill.Dec. 569, 574 N.E.2d 682 (1991) (an internist was qualified to testify against a surgeon concerning the surgeon's post-operative management of the patient, because proper management did not require knowledge of surgical procedures); *Smock v. Hale*, 197 Ill.App.3d 732, 739-40, 144 Ill.Dec. 177, 555 N.E.2d 74 (1990) (a doctor who was an expert in Crohn's disease was qualified to testify against a family practitioner who supervised the pregnancy of a patient with Crohn's disease); *Petkus v. Girzadas*, 177 Ill.App.3d 323, 328, 126 Ill.Dec. 648, 532 N.E.2d 333 (1988) (a cardiologist was qualified to testify against an orthopedic surgeon concerning “the minimum standards applicable to any physician rendering post-operative care” to a patient with a heart condition).

FN8. The majority stated: “In their main brief, the plaintiffs do not include an excerpt from the *voir dire* examination of Dr. Gomez that they claim satisfied the familiarity prong regarding the standard of care applicable to Dr. Joyce.” 387 Ill.App.3d at 845, 327 Ill.Dec. at 300, 901 N.E.2d at 1033. That statement is factually wrong. Plaintiffs include an extensive excerpt from the *voir dire* examination of Dr. Gomez on page 14 of their brief, which they state shows that Dr. Gomez was “familiar” with the standard of care required of surgeons.

In *Silverstein*, we reversed the trial court's determination that plaintiff's expert, an internist, was unqualified to criticize the defendant physiatrist concerning

her care and treatment of plaintiff, with the medication Indocin, after plaintiff's hip replacement surgery. *Silverstein*, 317 Ill.App.3d at 1007-08, 251 Ill.Dec. 276, 740 N.E.2d 357. The expert's testimony concerned defendant's medical management of plaintiff after surgery, and defendant's prescription of the drug Indocin-areas in which the expert had considerable experience. *Silverstein*, 317 Ill.App.3d at 1007-08, 251 Ill.Dec. 276, 740 N.E.2d 357. The negligence claim turned on whether the defendant physiatrist should have recognized that plaintiff had symptoms of an ulcer after taking Indocin. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357. We found the expert sufficiently familiar with the adverse effects of the medication-symptoms which “all physicians,***308 **1041 including physiatrists” knew of, and were expected to recognize. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357.

The majority attempts to distinguish *Silverstein* from this case, claiming that a biopsy is a surgical procedure and that only another surgeon can testify about whether a surgeon breached the standard of care: (1) by failing to perform a biopsy, in light of plaintiff's abnormal lymph nodes, disclosed in both the mammogram*856 and the CT scan; (2) by failing to inform the patient about the findings of both her mammogram and her CT scan; and (3) by failing to suggest to plaintiff that she should obtain a second opinion concerning the biopsy. It is well established that an expert does not have to be in the same specialized field, in order to render an opinion about the appropriate standard of care. *Alm*, 373 Ill.App.3d at 5, 310 Ill.Dec. 641, 866 N.E.2d 1243 (“a plaintiff's medical expert need not have the same specialty or subspecialty as the defendant doctors”), citing *Jones v. O'Y-oung*, 154 Ill.2d 39, 43, 180 Ill.Dec. 330, 607 N.E.2d 224 (1992); see also 735 ILCS 5/8-2501(a) (West 2006) (board certification in the same specialty is only one factor for a trial court to consider). Even the radiologist at the hospital where the mammogram was taken warned both defendant physicians that a biopsy was necessary. In *Silverstein*, plaintiff's expert was not in the same specialized field as the defendant physician, but had “considerable” experience with the medication that was prescribed. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357. In the case at bar, plaintiff's expert was not in the same specialty field as the surgeon, but he is a cancer specialist (oncologist), and knew from his training and daily dealings with surgeons that a biopsy was

required under the applicable standard of care for *all* physicians. *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357 (“all physicians” are expected to know certain things). The majority states that “neither the plaintiffs nor the dissent quotes the ‘expert’s precise testimony’ that in their judgment qualifies Dr. Gomez ‘as an expert in the kind of treatment criticized.’ ” 387 Ill.App.3d at 850 n. 4, 327 Ill.Dec. at 303 n. 4, 901 N.E.2d at 1036 n. 4, quoting *Silverstein*, 317 Ill.App.3d at 1007, 251 Ill.Dec. 276, 740 N.E.2d 357. The precise testimony, quoted by plaintiffs in their briefs, is Dr. Gomez’s description of his training and experience, as well as his almost daily dealings with surgeons, concerning questions just like the one at issue here, namely when to do a biopsy. In addition, Dr. Gomez took two rotating internships that included surgery, and it is common knowledge that surgeons confer with oncologists on cancer matters. It is common knowledge in today’s world that the only sure way to determine whether tissue is cancerous is to take a biopsy. Anything less is no more than Russian roulette. *Somers*, 373 Ill.App.3d at 90, 310 Ill.Dec. 848, 867 N.E.2d 539 (if “the physician’s negligence is so grossly apparent or the treatment so common as to be within the everyday knowledge of a lay person,” expert medical testimony is not required to establish either the standard of care or a deviation from it), quoting *Sullivan*, 209 Ill.2d at 112, 282 Ill.Dec. 348, 806 N.E.2d 645. But even more important, one does not need an expert to inform a jury that a patient has a right to be advised of a physician’s findings, especially abnormal lymph nodes. The fact that this oncologist did not perform biopsies does not make him unqualified as an expert; it only goes to the weight of his testimony.

The majority based its opinion on Dr. Gomez “concession” that *857 surgeons may disagree with him and that the surgeon, with the patient, is the “ultimate” decisionmaker. 387 Ill.App.3d at 838, 847, 327 ***309 **1042 Ill.Dec. at 294, 301, 901 N.E.2d at 1027, 1034. This description distorts Dr. Gomez’s actual testimony.^{FN9} *Rock*, 214 Ill.App.3d at 373, 158 Ill.Dec. 569, 574 N.E.2d 682 (a doctor’s statements must be read “in context”). Dr. Gomez testified *repeatedly* that no surgeon had ever disagreed with his assessment about the need to do a biopsy. When opposing counsel asked “[a]nd sometimes the surgeons do not do the biopsy,” Dr. Gomez replied emphatically “[n]ot in any case [where] I’ve been present.” When opposing counsel asked what Dr. Gomez

would do if, in a hypothetical case, some surgeon in the future did disagree, Dr. Gonzalez testified that, in that event, he would obtain a second opinion. The “ultimate” language quoted by the majority originally came from opposing counsel. Counsel asked: “The ultimate decision-maker between whether to perform a biopsy or not, that’s between the surgeon and the patient, correct?” Dr. Gomez answered: “The ultimate, yeah, supposed to.” Dr. Gomez subsequently clarified his answer, explaining that the patient was the ultimate decision-maker. Dr. Gomez stated: “I want to add to the last statement about the biopsy, the patient in this situation has to be agreeable to have the biopsy, approved by him. You know, I would never make a decision for my patient.”

FN9. The majority also stated that “Dr. Gomez cited no scientific support for his position” concerning causation. 387 Ill.App.3d at 851, 327 Ill.Dec. at 304, 901 N.E.2d at 1037. However, what Dr. Gomez actually stated during his discovery deposition was this his opinion was based on his extensive reading and experience over the last 30 years, and that he could not then recall precisely the names of texts. His opinion to a reasonable degree of medical certainty was that there was no question that the patient’s immune system had been compromised and that the immunosuppression enhanced her chances for developing a secondary malignancy.

The majority then concluded that, since Dr. Gomez “conceded” in his discovery deposition that the “ultimate” determination to perform a biopsy is made between the surgeon and the patient, Dr. Gomez cannot opine that the failure to perform a biopsy is a breach of the standard of care, because he is not a surgeon. The majority and the trial court apparently believe that there is some “magic” in the decision-making process of a surgeon that only another surgeon can testify to. A biopsy is no more than a cutting and taking of a sample of tissue to discern cancer and its severity. When Dr. Gomez testified that the “ultimate” determination to perform a biopsy is made between the surgeon and the patient, he was referring to the fact that the patient must consent to the process; and in order to consent, the patient must be made aware of the findings that suggest a biopsy-findings that *858 this patient was never told, according to

plaintiff's account of what occurred in this case.

Since the trial court erred in granting the motion *in limine*, we must vacate the dismissal order, which resulted from this error. *Rock*, 214 Ill.App.3d at 377, 158 Ill.Dec. 569, 574 N.E.2d 682 (since the summary judgment order resulted from the trial court's error in striking plaintiff's medical expert, the summary judgment order had to be reversed)

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United States Court of Appeals,
Tenth Circuit.
Dee NORRIS, Plaintiff-Appellant,

v.
BAXTER HEALTHCARE CORPORATION, De-
fendant-Appellee.
No. 03-1471.

Feb. 8, 2005.

Background: Recipient of silicone gel breast implants brought state-court action against implant manufacturer, alleging both systemic autoimmune disease and local injury from implants, and asserting claims including negligence, strict liability, and breach of warranty. Manufacturer removed action. The United States District Court for the District of Colorado, Daniel B. Sparr, J., granted summary judgment for manufacturer, and recipient appealed.

Holdings: The Court of Appeals, McKay, Circuit Judge, held that:

- (1) recipient had to counter manufacturer's epidemiological evidence in order to satisfy general causation requirement for claim of systemic injury;
- (2) recipient's proffered expert testimony was insufficiently reliable as to causation of systemic injury and thus inadmissible; and
- (3) limitations period for claim of local injury began to run when recipient had implants replaced and became aware of scarring of her breasts.

Affirmed.

West Headnotes

[1] Products Liability 313A 147

313A Products Liability
313AII Elements and Concepts
313Ak146 Proximate Cause
313Ak147 k. In General. Most Cited Cases
(Formerly 313Ak46.1)

Products Liability 313A 227

313A Products Liability
313AIII Particular Products
313Ak223 Health Care and Medical Products
313Ak227 k. Implants and Prosthetic De-
vices. Most Cited Cases
(Formerly 313Ak46.1)
Recipient of silicone breast implants who brought products liability action against implant manufacturer alleging systemic autoimmune disease caused by implant had to prove both general causation, i.e. that implant was capable of causing disease in question, and specific causation, i.e. that implant had caused recipient's individual injury.

[2] Products Liability 313A 227

313A Products Liability
313AIII Particular Products
313Ak223 Health Care and Medical Products
313Ak227 k. Implants and Prosthetic De-
vices. Most Cited Cases
(Formerly 313Ak83)

Products Liability 313A 390

313A Products Liability
313AIV Actions
313AIV(C) Evidence
313AIV(C)4 Weight and Sufficiency of
Evidence
313Ak389 Proximate Cause
313Ak390 k. In General. Most Cited
Cases
(Formerly 313Ak83)

Recipient of silicone breast implants who brought products liability action against implant manufacturer alleging systemic autoimmune disease caused by implant had to counter manufacturer's proffered epidemiological studies, finding no proven link between silicone implants and systemic disease, in order to satisfy general causation requirement; non-epidemiological evidence alone was insufficient.

[3] Federal Courts 170B 776

170B Federal Courts

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170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)1 In General
170Bk776 k. Trial De Novo. Most Cited
Cases

Federal Courts 170B ↪823

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk823 k. Reception of Evidence.

Most Cited Cases

Court of Appeals reviews de novo whether district court applied proper standard in determining whether to admit or exclude expert testimony, and reviews for abuse of discretion manner in which district court exercised its *Daubert* "gatekeeping" role in making decision. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[4] Evidence 157 ↪508

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k508 k. Matters Involving Scientific or Other Special Knowledge in General. Most Cited Cases

Evidence 157 ↪555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

In ruling on admissibility of proffered expert testimony, federal district court determines: (1) if expert's proffered testimony has reliable basis in knowledge and experience of his discipline, and (2) whether proposed testimony is sufficiently relevant to task at hand. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Evidence 157 ↪555.2

157 Evidence
157XII Opinion Evidence
157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.2 k. Necessity and Sufficiency.

Most Cited Cases

Factors in evaluating reliability prong of test for admissibility of proffered expert testimony include whether: (1) theory has been or can be tested or falsified; (2) theory or technique has been subject to peer review and publication; (3) there are known or potential rates of error with regard to specific techniques; and (4) theory or approach has general acceptance. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[6] Evidence 157 ↪555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Evidence 157 ↪557

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k557 k. Experiments and Results

Thereof. Most Cited Cases

Silicone breast implant recipient's proposed expert testimony was insufficiently reliable as to both general and specific causation and thus inadmissible, in her products liability action against implant manufacturer alleging systemic autoimmune disease due to implant; experts ignored or discounted without explanation epidemiological studies finding no proven link between silicone implants and systemic disease, and instead relied on clinical case studies and differential diagnosis. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[7] Limitation of Actions 241 ↪95(3)

241 Limitation of Actions

241II Computation of Period of Limitation

241II(F) Ignorance, Mistake, Trust, Fraud, and Concealment or Discovery of Cause of Action

241k95 Ignorance of Cause of Action

241k95(3) k. Nature of Harm or Dam-

age, in General. Most Cited Cases

Under discovery rule of Colorado law, products li-

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ability action accrues when plaintiff is aware or should be aware, in exercise of reasonable diligence, of all elements of cause of action. West's C.R.S.A. § 13-80-108(1).

[8] Limitation of Actions 241 ↪95(3)

241 Limitation of Actions

241II Computation of Period of Limitation

241II(F) Ignorance, Mistake, Trust, Fraud, and Concealment or Discovery of Cause of Action

241k95 Ignorance of Cause of Action

241k95(3) k. Nature of Harm or Damage, in General. Most Cited Cases

Under discovery rule of Colorado law, once products liability plaintiff has suspicion of wrongdoing, she is under duty to attempt to find facts; uncertainty as to full extent of damage does not stop accrual of cause of action. West's C.R.S.A. § 13-80-108(1).

[9] Limitation of Actions 241 ↪95(4.1)

241 Limitation of Actions

241II Computation of Period of Limitation

241II(F) Ignorance, Mistake, Trust, Fraud, and Concealment or Discovery of Cause of Action

241k95 Ignorance of Cause of Action

241k95(4) Injuries to the Person

241k95(4.1) k. In General. Most

Cited Cases

Under Colorado law, silicone breast implant recipient came under duty to investigate problems with implants, commencing limitations period for recipient's products liability action against implant manufacturer alleging localized injuries to breasts, when recipient sensed some abnormalcy in one breast, was told by her physician that he believed implants were causing problem, had both implants removed and replaced, and became aware of scarring of breasts at time of replacement surgery. West's C.R.S.A. § 13-80-108(1).

*879 Derek Regensburger (Stephen H. Cook on the brief) of The Law Firm of Stephen H. Cook, P.C., Boulder, CO, for Plaintiff-Appellant.

Mary A. Wells (Suanne M. Dell of Wells, Anderson & Race, LLC, Denver, CO; Debra E. Pole and Roger K. Smith of Sidley, Austin, Brown & Wood, LLP, Los Angeles, CA, with her on the brief), Wells, Anderson & Race, LLC, Denver, CO, for Defendant-Appellee.

Before SEYMOUR, McKAY, and MURPHY, Circuit Judges.

McKAY, Circuit Judge.

This case involves Plaintiff's claims of systemic disease allegedly caused by a silicone gel breast implant Plaintiff received in 1974. The implant at issue was manufactured by Defendant's predecessor. In 1970, Plaintiff underwent bilateral breast augmentation surgery and received her first set of silicone gel and saline filled breast implants manufactured by a division of Dow Corning Corporation. Four years *880 later, due to problems with her left implant, Plaintiff had the left implant removed and replaced with another silicone gel and saline filled breast implant manufactured by Defendant's predecessor corporation. This implant is the sole focus of this appeal. In 1978, because of a rupture of her right implant, Plaintiff had both implants replaced with another set of implants manufactured by Dow Corning. Plaintiff points to no specific evidence in the record that the left implant which was manufactured by Defendant had leaked prior to the time of removal.

Beginning in 1987, Plaintiff began to suffer from a variety of ailments including pain in her right shoulder and foot and pain and swelling in her right knee, hip, and other joints. On October 23, 1989, Plaintiff had both implants removed because her doctor believed that she had silicone-induced lupus. The diagnosis was subsequently changed by Dr. Vasey, one of Plaintiff's proffered experts, to silicone-associated connective tissue disease-autoimmune disease caused by silicone which leaked from breast implants. This disease allegedly caused Plaintiff to suffer tenderness in the muscles of her mid and low back in addition to joint swelling in her upper extremities.

In 1991, Plaintiff filed suit in Colorado state court against several Defendants, including Defendant Baxter as the corporate successor to Heyer-Schulte, seeking compensatory and punitive damages based on claims of negligence, strict liability, breach of implied warranties, and breach of express warranties/misrepresentation. Plaintiff alleged two types of injuries as a result of her silicone breast implants: (1) systemic autoimmune disease and (2) local injuries such as pain suffered as a result of scarring and leakage. Plaintiff further alleged that Defendants knew

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that there was evidence linking silicone breast implants to various serious diseases. The action was removed to federal court and transferred to the Northern District of Alabama for consolidated proceedings. Dow Corning, the manufacturer of all but one of Plaintiff's breast implants, filed for bankruptcy. Plaintiff's claims against Baxter regarding the 1974 left implant were remanded back to the United States District Court for the District of Colorado.

After remand, Baxter moved for summary judgment on Plaintiff's systemic injury claims. Baxter argued that there was no epidemiological evidence showing an association between silicone breast implants and autoimmune disorders; therefore, Plaintiff could not meet her burden of proof with respect to general causation. Baxter further argued that the statute of limitations barred Plaintiff's local injury claims. In her opposition to Baxter's motion for summary judgment, Plaintiff primarily relied on the expert testimony of two physicians, Dr. Vasey and Dr. Espinoza. The district court granted Baxter's motion for summary judgment on Plaintiff's systemic and local injury claims.

The issue on appeal is whether the district court erred in granting Baxter summary judgment on (1) Plaintiff's claim of systemic autoimmune disease because she failed to meet her burden of establishing a triable issue of fact that silicone breast implants are capable of causing systemic injuries^{FN1} and (2) Plaintiff's claims for breach of warranty, negligence, and products liability on the basis that the applicable statute of limitations had expired.

FN1. We need not specifically discuss Plaintiff's other contentions of error because they all fall within the umbrella of whether she raised a genuine issue of material fact that silicone breast implants caused her alleged systemic injuries. See Aplt. Br. at 2. Therefore, all of Plaintiff's claims are within the scope of this opinion.

*881 We review *de novo* a district court's grant of summary judgment, applying the same legal standard employed by the district court, to determine whether there is a genuine issue as to any material fact and whether a party is entitled to judgment as a matter of law. *Gossett v. Oklahoma ex rel. Bd. of Regents for Langston Univ.*, 245 F.3d 1172, 1175 (10th

Cir.2001). Plaintiff's main assertion on appeal is that the district court erred in finding that she failed to meet her burden of establishing a triable issue of fact that her 1974 silicone breast implant was a factor in the development of her alleged systemic injuries. To support her theory of causation, Plaintiff presented expert testimony from two doctors. That evidence was excluded by the district court.

Before specifically addressing Plaintiff's proffer of expert testimony relating to her alleged silicone-associated connective tissue disease, it is necessary to highlight the hurdle Plaintiff must overcome. We cannot consider whether Plaintiff's silicone breast implants caused her specific autoimmune disease until Plaintiff presents reliable evidence that silicone breast implants are capable of causing disease in people in general.

[1] The district court correctly noted that, in silicone breast implant litigation, plaintiffs must show both general and specific causation. See *Raynor v. Merrell Pharm., Inc.*, 104 F.3d 1371, 1376 (D.C.Cir.1997) (causation in toxic tort cases is discussed in terms of general causation and specific causation); *Kelley v. American Heyer-Schulte Corp.*, 957 F.Supp. 873, 875 (W.D.Tex.1997); see also *Jones v. United States*, 933 F.Supp. 894, 900-01 (N.D.Cal.1996), *aff'd*, 127 F.3d 1154 (9th Cir.1997); *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1412-13 (D.Or.1996). General causation is whether a substance is capable of causing a particular injury or condition in the general population and specific causation is whether a substance caused a particular individual's injury. Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation. In other words, if silicone breast implants are incapable of causing systemic injuries in anyone, it follows *a fortiori* that silicone breast implants could not have caused systemic injuries in Plaintiff.

Addressing the question of general causation, the district court first discussed the necessity of epidemiological evidence. It did not hold that epidemiology is the only admissible evidence on causation. However, the district court did conclude that it needed epidemiological evidence in order for Plaintiff to overcome Defendant's motion for summary judgment in this case. This decision was grounded largely on the fact that many epidemiological studies and other data were available regarding the alleged association

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between silicone breast implants and immune system diseases. Defendant had already proffered a significant body of epidemiology in support of its contention that silicone breast implants do not cause disease in anyone. The volume of epidemiological evidence is reflected in the record and in other court cases dealing with the same subject matter.^{FN2}

FN2. There are at least seventeen, if not more, significant published, peer-reviewed epidemiological studies that were considered by the district court. *In re Breast Implant Litig.*, 11 F.Supp.2d 1217, 1227 (D.Colo.1998); Aplt.App., Vol. III, at 821 (district court's oral order incorporating the studies and articles discussed in *In re Breast Implant Litig.*, 11 F.Supp.2d at 1231-32).

One such examination of the alleged link was conducted in 1996 when Judge Pointer, United States District Court, Northern District of Alabama, appointed a Rule 706 *882 National Science Panel to look at available scientific literature to determine whether breast implants might cause connective tissue disease. In November 1998, the Panel issued its report, finding that "[t]he most likely conclusion from these several analyses is that there is no meaningful or consistent association between breast implants or silicone gel-filled implants and any of the conditions studied." Aplt.App., Vol. II, at 417. The Panel's immunologist, Dr. Diamond, testified that there is "no reproducible[,] reliable data" supporting the theory that silicone gel breast implants cause any immune system dysfunction. *Id.* at 438. The Panel's epidemiologist, Dr. Hulka, stated that she "did not find a reliable or consistent association between breast implants and any of the conditions that we studied." *Id.* at 457. Dr. Tugwell, the Panel's rheumatologist, stated that "there is no proven association between those diseases and silicone breast implants." *Id.* at 447.

In 1997, Congress instructed the United States Department of Health and Human Services to contract with the Institute of Medicine of the National Academy of Sciences to conduct a "comprehensive evaluation of the evidence for the association of silicone breast implants ... with human health conditions..." *Id.* at 427. In July 1999, the report concluded that there was "no elevated relative risk or odds ratio for an association of implants with dis-

ease." *Id.* at 430. The report further stated that there was not "even suggestive evidence" that silicone breast implants caused systemic disease. *Id.* at 432.

[2] We agree with the district court that epidemiology is the best evidence of general causation in a toxic tort case. See *In re Breast Implant Litig.*, 11 F.Supp.2d 1217, 1224 (D.Colo.1998); Linda A. Bailey, et al., "Reference Guide on Epidemiology," Reference Manual on Scientific Evidence at 126 (1994); see also *Wilson v. Merrell Dow Pharm., Inc.*, 893 F.2d 1149, 1154 (10th Cir.1990); *Renaud v. Martin Marietta Corp.*, 749 F.Supp. 1545, 1554 (D.Colo.1990), *aff'd*, 972 F.2d 304, 307 (10th Cir.1992). While the presence of epidemiology does not necessarily end the inquiry, where epidemiology is available, it cannot be ignored. As the best evidence of general causation, it must be addressed.

Plaintiff disputes the necessity of epidemiological evidence citing *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986 (8th Cir.2001); *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9th Cir.1998); and *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir.1995). See Aplt. Br. at 15-16. Plaintiff asserts that in all of these cases, epidemiological studies were unnecessary to prove general causation. These cases are inapposite. First, none involve breast implants. Second, and more importantly, in all three cases, unlike the case at hand, there was no body of epidemiological evidence demonstrating the absence of a causal relationship. In cases where there is no epidemiology challenging causation available, epidemiological evidence would not necessarily be required.

This is not a case where there is no epidemiology. It is a case where the body of epidemiology largely finds no association between silicone breast implants and immune system diseases. We are not holding that epidemiological studies are always necessary in a toxic tort case. We are simply holding that where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology.

In light of the significant body of epidemiological evidence proffered by Defendant, and in attempting to reach the epidemiological evidence proffered by Plaintiff, *883 the district court necessarily focused on two expert witnesses, Dr. Vasey and Dr. Espinoza,

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to establish a link. Both doctors asserted a belief that silicone breast implants can cause immune system diseases. Additionally, the doctors evaluated Appellant and concluded that her specific systemic injuries were a result of her silicone breast implants. After conducting a *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), inquiry ^{FN2}, the district court excluded both experts because they were unreliable.

FN2. The district court did not specifically state in its oral order that it was conducting a *Daubert* hearing. The district court did say, as part of its order, that “under *Daubert*, in Tenth Circuit law, the court must make the determination initially if there is a significant showing of causation based on some evidence.” Aplt.App., Vol. III, at 827. Additionally, in determining whether there was a genuine issue of material fact to overcome Baxter’s summary judgment motion, it was necessary for the district court to assess the admissibility of Plaintiff’s experts under *Daubert*. The court stated that “Dr. Vasey’s opinions, based on his report, appear to be based on matters which do not satisfy the scientific requirements.” The court further stated that “Dr. Espinoza suffers from the same problem.” *Id.* at 835-36.

[3] We review *de novo* whether the district court applied the proper standard in determining whether to admit or exclude expert testimony. *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1223 (10th Cir.2003) (citation omitted). That is, whether the district court properly performed its role as “gatekeeper” pursuant to Federal Rule of Evidence 702 and *Daubert*. *Id.*; *Bitler v. A.O. Smith Corp.*, 391 F.3d 1114, 1119 (10th Cir.2004). We then review the manner in which the district court “exercises its *Daubert* ‘gatekeeping’ role in making decisions whether to admit or exclude testimony” for an abuse of discretion. *Bitler*, 391 F.3d at 1119; *see also Dodge*, 328 F.3d at 1223. “[W]e will not disturb the district court’s ruling unless it is arbitrary, capricious, whimsical or manifestly unreasonable or when we are convinced that the district court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances.” *Dodge*, 328 F.3d at 1223 (citation and internal quotations omitted).

In evaluating the district court’s gatekeeping role, we are not necessarily concerned with its “exact conclusions reached to exclude or admit expert testimony.” *Bitler*, 391 F.3d at 1119. The district court must make some reliability determination on the record; however, “we recognize the wide latitude a district court has in exercising its discretion to admit or exclude expert testimony.” *Id.* (citation omitted). The district court “has wide discretion both in deciding how to assess an expert’s reliability and in making a determination of that reliability.” *Id.* at 1120 (citation omitted).

[4] Mindful of this deferential standard of review, we begin our discussion of the district court’s exclusion of Plaintiff’s expert testimony with Rule 702. *See id.* Rule 702 states that

[i]f 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....

Rule 702 requires the district court to “ensure that any and all scientific testimony or evidence is not only relevant, but reliable.” *Id.* (quoting *Daubert*, 509 U.S. at 589, 113 S.Ct. 2786). This obligation involves a two-part inquiry. *Id.* “[A] district court must [first] determine if the *884 expert’s proffered testimony ... has ‘a reliable basis in the knowledge and experience of his [or her] discipline.’ ” *Id.* (quoting *Daubert*, 509 U.S. at 592, 113 S.Ct. 2786). In making this determination, the district court must decide “whether the reasoning or methodology underlying the testimony is scientifically valid....” *Id.* (quoting *Daubert*, 509 U.S. at 592-93, 113 S.Ct. 2786). Second, the district court must further inquire into whether proposed testimony is sufficiently “relevant to the task at hand.” ^{FN2} *Daubert*, 509 U.S. at 597, 113 S.Ct. 2786. Because Plaintiff’s proffered expert testimony fails the first requirement, we need not specifically address the second. ^{FN3}

FN2. The second inquiry is related to the first. Under the relevance prong of the *Daubert* analysis, the court must ensure that the proposed expert testimony logically advances a material aspect of the case. *Daubert v. Merrell Dow Pharm., Inc.*, 43

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F.3d 1311, 1315 (9th Cir.1995) (on remand). The evidence must have a valid scientific connection to the disputed facts in the case. *Daubert*, 509 U.S. at 591, 113 S.Ct. 2786.

FN3. Additionally, even if an expert's opinion or evidence is relevant and admissible, if "insufficient to allow a reasonable juror to conclude that the position more likely than not is true," it may be the basis for a grant of summary judgment. *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786.

[5] In determining whether the expert's reasoning or methodology is valid,

the Supreme Court has suggested that a court consider: (1) whether a theory has been or can be tested or falsified, (2) whether the theory or technique has been subject to peer review and publication, (3) whether there are known or potential rates of error with regard to specific techniques, and (4) whether the theory or approach has "general acceptance." *Daubert*, 509 U.S. at 593-94, 113 S.Ct. 2786. The Court has made clear, however, that this list is neither definitive nor exhaustive.

....

Accordingly, a trial court's focus generally should not be upon the precise conclusions reached by the expert, but on the methodology employed in reaching those conclusions. *Daubert*, 509 U.S. at 595, 113 S.Ct. 2786.

Bitler, 391 F.3d at 1120-21.

[6] The district court noted that Dr. Vasey and Dr. Espinoza have impressive credentials in the field of rheumatology. However, as a basis for their conclusions regarding the connection between silicone breast implants and autoimmune diseases, Plaintiff's experts completely ignored or discounted without explanation the many epidemiological studies which found no medically reliable link between silicone breast implants and systemic disease. Therefore, the district court concluded that the methodology used by Plaintiff's experts was not medically or scientifically valid. *See Daubert*, 509 U.S. at 592-93, 113 S.Ct. 2786. Because of this, the district court determined

that Plaintiff's experts' opinions were not reliably grounded in the knowledge and experience of their discipline.

In Dr. Vasey's "opinion[,] silicone gel breast implants cause both local and systemic inflammatory conditions." *Aplt.App.*, Vol. II, at 305. As a basis for this opinion, Dr. Vasey primarily relied on his own "case series with sequential observations in many patients." *Id.* at 306. He further stated that his "opinion is based on the unique and atypical findings in women with silicone gel breast implants ... [and on] sequential observations including the beneficial effect of breast implant removal." *Id.*

*885 Dr. Vasey did not rely on any epidemiological studies or other controlled studies for his opinion that silicone gel breast implants can cause systemic disease. Additionally, Dr. Vasey completely ignored the many epidemiological studies that do not find a link between silicone gel breast implants and any systemic disease. He conclusively, and without support, stated that epidemiological studies relied on by the industry "are not definitive." *Id.* at 307.

In order to escape the volume of contrary opinions, Dr. Vasey indicated that the comprehensive syndrome he described, "atypical fibromyalgia chronic fatigue syndrome[,] has escaped study." *Id.* at 306. However, he asserted that Plaintiff has "silicone associated connective tissue disease." *Id.* It is unclear from Dr. Vasey's opinion how Plaintiff's disease fits into the category of disease that has allegedly escaped study. Additionally, he never discusses why the voluminous other studies on silicone gel breast implants are completely irrelevant to Plaintiff's stated condition.

Like Dr. Vasey, Dr. Espinoza relied not on epidemiology but on clinical case studies and differential diagnosis. Basing his conclusion on his "prior clinical experience in dealing with this unusual association," Dr. Espinoza stated that "[i]t is my personal opinion that some individuals exposed to silicone breast implants developed systemic illness that mimic idiopathic autoimmune disorders...." *Aplt.App.*, Vol. III, at 667-68. He further said that "[i]t is my feeling that [Plaintiff's] arthritis is related to her underlying silicone breast implants." *Id.* at 667. While stating that his "opinion is based on a reasonable degree of medical probability," Dr. Espinoza agreed that the body of

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the evidence says that there is no association between silicone breast implants and connective tissue diseases. Aplt. *Id.* at 667-69. He was unable to articulate why his view did not comport with the "body of the evidence," other than to say that "no study has been designed to specifically address atypical connective tissue disease...." *Id.*

Plaintiff's experts relied solely on differential diagnosis and case studies to support their belief that silicone gel breast implants can cause systemic disease. Their reliance on differential diagnosis without supporting epidemiological evidence is misplaced and demonstrates the unreliable nature of the testimony. Observations cannot define a disease. The foundational evidence that the doctors rely upon do not reach conclusions based on accepted scientific methodology. "[D]ifferential diagnosis assumes that general causation has been proven...." See *Hall*, 947 F.Supp. at 1413 (emphasis in original).

It is [] important to recognize that a fundamental assumption underlying [differential diagnosis] is that the final, suspected "cause" remaining after this process of elimination must actually be capable of causing the injury. That is, the expert must "rule in" the suspected cause as well as "rule out" other possible causes. And, of course, expert opinion on this issue of "general causation" must be derived from a scientifically valid methodology.

Id. (emphasis in original) (quoting *Cavallo v. Star Enterprise*, 892 F.Supp. 756, 771 (E.D.Va.1995)), *aff'd on this ground, rev'd on other grounds*, 100 F.3d 1150 (4th Cir.1996). Case reports suffer from a similar failing. Case reports that state that some women with breast implants developed disease do not provide an adequate scientific basis from which to conclude that breast implants in fact cause disease. A correlation does not equal causation.

We are unable to find a single case in which differential diagnosis that is flatly contrary to *all* of the available epidemiological*886 evidence is both admissible and sufficient to defeat a defendant's motion for summary judgment. Plaintiff's experts' differential diagnoses and case studies are scientifically unreliable because they assume what science has largely shown does not exist—a causal connection between silicone breast implants and disease.

The district court did not abuse its discretion in exercising its *Daubert* gatekeeping role. "Although it is not always a straightforward exercise to disaggregate method and conclusion, when the conclusion simply does not follow from the data, a district court is free to determine that an impermissible analytical gap exists between premises and conclusion." *Bitler*, 391 F.3d at 1121 (citing *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)); *Dodge*, 328 F.3d at 1222; see also *Bragdon v. Abbott*, 524 U.S. 624, 653, 118 S.Ct. 2196, 141 L.Ed.2d 540 (1998) ("Scientific evidence and expert testimony must have a traceable, analytical basis and objective fact before it may be considered on summary judgment.") (citing *Joiner*, 522 U.S. 136, 144-46, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)). Although "[t]rained experts commonly extrapolate from existing data," neither *Daubert* nor the Federal Rules of Evidence "require[] a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146, 118 S.Ct. 512. "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.*

The district court determined that Plaintiff's experts did not offer valid testimony to support either general or specific causation.^{FN4} As to the question of general causation, both experts ignored or discounted without explanation the contrary epidemiological studies. According to Plaintiff and her experts, the vast majority of epidemiological evidence which shows no strong consistent association between silicone breast implants and disease is not "useful" with regard to whether silicone breast implants cause systemic disease. Aplt. Br. at 19. Overcoming this large body of epidemiology requires more than simply stating that the studies are wrong. Mere criticism of epidemiology cannot establish causation. *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir.1994) (explaining that published critiques of studies "underscore the need for further studies" but do not establish causation).

FN4. We note that the district court was not the first court to hold that Dr. Vasey's and Dr. Espinoza's opinions did not meet the *Daubert* test for expert testimony. See *Bushore v. Dow Corning-Wright Corp.*, No. 92-344-CIV-T-26C, 1999 WL 1116920, at *7 (M.D.Fla. Nov.15, 1999) (citing *Kelley*,

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957 F.Supp. at 882).

Plaintiff's and her experts' efforts to discredit the epidemiology are not peer-reviewed, are not developed independent of litigation, and are not generally accepted by the relevant scientific community. These are all important *Daubert* considerations. 509 U.S. at 593, 113 S.Ct. 2786. Plaintiff and her experts have to base their positions on reliable studies and methodology. In failing to properly address the previous and contrary views, Plaintiff's experts made their opinions and testimony unreliable as to the issue of general causation.^{FN5}

FN5. We need not address the question of whether epidemiological studies showing a relative risk between 1.0 and 2.0 for developing symptoms of connective tissue disease from silicone breast implants are admissible evidence. The district court did not need to reach this issue because it excluded the expert opinions of Doctors Vasey and Espinoza. The district court excluded the experts' opinions not based on the epidemiological studies but based on their failure to address or discuss the prevailing contrary views out there.

*887 In addition, Plaintiff's experts were unreliable as to the issue of specific causation. Plaintiff's experts both based their opinions on examinations of Plaintiff, clinical experience, and case studies. In concluding that Plaintiff's systemic injuries were a result of her silicone breast implants, Plaintiff's experts attempted to demonstrate specific causation without first demonstrating general causation. Both of Plaintiff's experts agree that, at best, silicone-associated connective tissue disease is an untested hypothesis. At worst, the link has been tested and found to be untenable. Therefore, there is no scientific basis for any expert testimony as to its specific presence in Plaintiff.

Plaintiff attempted to use Dr. Vasey and Dr. Espinoza to get to epidemiological evidence which would allegedly support her position. However, the district court properly excluded these two experts that were trying to get the court to the epidemiological evidence. We cannot allow the jury to speculate based on an expert's opinion which relies only on clinical experience in the absence of showing a consistent,

statistically significant association between breast implants and systemic disease.^{FN6} This is not a case where the experts' opinions were based on "objective, verifiable evidence and scientific methodology of the kind traditionally used by rheumatologists." *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir.1998). Plaintiff's experts' conclusions about systemic disease have not gained acceptance in the relevant scientific community. Additionally, neither of the proffered experts demonstrated that their scientific methods were reliable to overcome the volume of contrary medical opinion regarding the alleged link between silicone breast implants and autoimmune disease. Plaintiff provided no explanation why Dr. Vasey's and Dr. Espinoza's opinions are reliable notwithstanding the epidemiological studies finding no significant risk of autoimmune disease resulting from silicone breast implants.

FN6. Non-epidemiological studies, "singly or in combination[.]" are "not capable of proving causation in human beings in the face of [an] overwhelming body of contradictory epidemiological evidence." *Raynor*, 104 F.3d at 1374; see also *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1073 (6th Cir.1993); *Daubert*, 509 U.S. at 592, 113 S.Ct. 2786.

[7][8] Plaintiff next argues that the district court erred by granting summary judgment to Defendant on Plaintiff's local injury claims because they were time barred. Colorado has adopted the discovery rule to determine when a product liability action accrues. See *Persichini v. Brad Ragan, Inc.*, 735 P.2d 168, 173 n. 6 (Colo.1987). Pursuant to the discovery rule, a plaintiff must bring her product liability and misrepresentation claims within three years^{FN7} of when she is aware or should be aware, in the exercise of reasonable diligence, of all of the elements of the cause of action. C.R.S. § 13-80-108(1); *Miller v. Armstrong World Industries, Inc.*, 817 P.2d 111, 113-14 (Colo.1991). Once a plaintiff has suspicion of wrongdoing, she is under a duty to attempt to find the facts. *Trinity Broad. of Denver, Inc. v. City of Westminster*, 848 P.2d 916, 926-27 (Colo.1993). Uncertainty as to the full extent of the damage does not stop the accrual of a cause of action. *Taylor v. Goldsmith*, 870 P.2d 1264, 1266 (Colo.App.1994); see also *Jones v. Cox*, 828 P.2d 218, *888 224 (Colo.1992); *Dove v. Delgado*, 808 P.2d 1270, 1273

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(Colo.1991).

FN7. Prior to 1986, the statute of limitations for products liability claims based upon strict liability and/or negligence in Colorado was three years after the claim for relief arose. In 1986, the statute was amended to a two-year statute of limitations. *See* C.R.S. § 13-80-106(1).

[9] Therefore, pursuant to Colorado law, the statute of limitations began to run when the fact of injury was known or should have been known. Plaintiff testified that, as early as 1978, she felt that something was not "normal" in her right breast (not the left which is the subject of this litigation). *Aplt.App.*, Vol. I, at 180. Plaintiff also admits that her doctor told her that he believed that her implants were causing the problem and informed her that both of her implants needed to be removed. *Id.* at 182-83. Plaintiff had both implants (including the one at issue) removed on May 26, 1978, and replaced with implants manufactured by Dow Corning. *Id.* at 134-35, 137. She admitted that there was scarring of the breasts at the time of this surgery. *Id.* at 137. Based on these facts, Plaintiff had an obligation, beginning in 1978, to investigate the problems with her breast implants.^{FN8} Plaintiff did not file suit until 1991, thirteen years later—ten years past the expiration of the statute of limitations for product liability and misrepresentation.^{FN9} The district court did not err in granting summary judgment to Baxter on Plaintiff's product liability and misrepresentation claims.

FN8. Plaintiff unsuccessfully attempts to use her alleged systemic injuries to argue that her claims based on her local injuries were not barred by the statute of limitations. *See Aplt. Br.* at 41-42.

FN9. We do not even begin to discuss how Plaintiff has been unable to dissect the alleged local injuries from Defendant's implant from all of the alleged local injuries caused by the Dow Corning implants. Even if Plaintiff were not barred by the statute of limitations, the record reflects that Plaintiff had continuous local injuries from her repeated explanation and implantation surgeries which were unrelated to Defendant's implant. *Aplt.App.*, Vol. I, at 137-38.

The district court also did not err in granting summary judgment to Baxter on Plaintiff's breach of warranty claims. A plaintiff is obligated to bring her breach of warranty claims within four years^{FN10} of the date of delivery or sale of the product unless the warranty explicitly extends to future performance of the product. C.R.S. § 4-2-725; *Wieser v. Firestone Tire & Rubber Co.*, 596 F.Supp. 1473, 1475 (D.Colo.1984); *Persichini*, 735 P.2d at 176. Plaintiff received Defendant's implant in 1974. Plaintiff has submitted no argument or evidence that Defendant provided her with a warranty explicitly based on the future performance of her implant. The statute of limitations for her breach of warranty claim expired in 1978.

FN10. The statute of limitations for breach of warranty claims in Colorado in 1974 was four years. *See* 1965 Colo. Sess. Laws, ch. 330, § 155-2-725(1), at 1344.

AFFIRMED.

C.A.10 (Colo.),2005.

Norris v. Baxter Healthcare Corp.

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THE PEOPLE, Plaintiff and Respondent,
 v.
 EDDIE BOBBY McDONALD, Defendant and Appellant
 Crim. No. 21770.

Supreme Court of California
 Nov 21, 1984.

SUMMARY

In a prosecution in which defendant was convicted of murder (Pen. Code, § 187), with the special circumstance finding that he committed the murder while robbing or attempting to rob the victim (Pen. Code, § 190.2, subd. (a)(17)(i)), and was found not guilty of the substantive charge of robbery (Pen. Code, § 211), the trial court excluded the testimony of a psychologist, who was a qualified expert witness, regarding psychological factors which generally affect the accuracy of eyewitness identifications. (Superior Court of Los Angeles County, No. A020403, Ernest L. Kelly, Judge.)

The Supreme Court reversed, holding that the trial court committed a prejudicial abuse of discretion in excluding the expert testimony. The eyewitness identifications of defendant as the perpetrator of the crimes constituted the only evidence connecting him with them, and there were factors in the eyewitness testimony which could have raised reasonable doubts in the jurors' minds as to the accuracy of the identifications. Thus, the court held that the exclusion of the expert testimony undercut the evidentiary basis of defendant's main line of defense, i.e., his attack on the accuracy of the eyewitness identifications, and deprived the jurors of information that could have assisted them in resolving that crucial issue. It also held that the jury's failure to specify the degree of murder in its verdict rendered defendant's conviction second degree murder by operation of Pen. Code, § 1157, even though the jury's intent to convict him of first degree murder may have been inferred from the jury's separate finding on the special circumstance allegation. It held that the key is not whether the true intent of the jury can be gleaned from circumstances

outside the verdict form itself; instead, application of Pen. Code, § 1157, turns only on whether the jury specified the degree in the verdict form. (Opinion by Mosk, J., with Bird, C. J., Kaus, Broussard, Reynoso and Grodin, JJ., concurring.)

HEADNOTES

Classified to California Digest of Official Reports

(1a, 1b, 1c, 1d, 1e, 1f) Criminal Law § 408--Evidence-- Admissibility--Opinion Evidence--Expert Witnesses--Subjects of Expert Testimony--Psychological Factors Affecting Accuracy of Eyewitness Identification.

In a prosecution for murder (Pen. Code, § 187) and robbery (Pen. Code, § 211), the trial court committed a prejudicial abuse of discretion in excluding the testimony of a psychologist, who was a qualified expert witness, regarding psychological factors which generally affect the accuracy of eyewitness identifications. The eyewitness identifications of defendant as the perpetrator of the crimes constituted the only evidence connecting him with the crimes, and there were factors in the eyewitness testimony which could have raised reasonable doubts in the jurors' minds as to the accuracy of the identifications. Thus, exclusion of the expert testimony undercut the evidentiary basis of defendant's main line of defense, i.e., his attack on the accuracy of the eyewitness identifications, and deprived the jurors of information that could have assisted them in resolving that crucial issue.

[See Cal.Jur.3d, Evidence, § 490; Am.Jur.2d, Expert and Opinion Evidence, § 165.]

(2) Evidence § 87--Opinion Evidence--Subjects of Expert Testimony-- Psychological Factors Affecting Accuracy of Eyewitness Identification.

Expert witness testimony regarding psychological factors that may impair the accuracy of a typical eyewitness identification, including the emotions of excitement or fear, with supporting references to experimental studies of such phenomena, falls well within the broad statutory description of "any matter that has any tendency in reason" to bear on the credibility of a witness (Evid. Code, § 780, permitting a witness to be impeached by discrediting his capacity to perceive, recollect, or communicate).

(3) Evidence § 87--Opinion Evidence--Subjects of Expert Testimony.

Evid. Code, § 801, governing the admissibility of expert testimony, applies only to expert testimony in the form of an opinion. If an expert testifies not as to his opinion but as to facts within his special knowledge, Evid. Code, § 801, is inapplicable. Factual testimony by an expert is admissible if it complies with the general statutory requirements that the witness be qualified by his special knowledge (Evid. Code, § 720) and that his evidence be relevant to the issues (Evid. Code, § 351).

(4) Evidence § 87--Opinion Evidence--Subjects of Expert Testimony-- Psychological Factors Affecting Accuracy of Eyewitness Identification.

Although jurors may not be totally unaware of the various psychological factors bearing on the accuracy of an eyewitness identification, the body of information now available on these matters is sufficiently beyond common experience that in appropriate cases expert opinion thereon could at least assist the trier of fact (Evid. Code, § 801, subd. (a)).

(5) Criminal Law § 292--Evidence--Admissibility--Claims and Defenses of Accused.

Evidence that is relevant to the prime theory of the defense cannot be excluded in wholesale fashion merely because the trial would be simpler without it. Rather, it should be accompanied by instructions clearly explaining to the jury the purpose for which it is introduced. Any excess in the quantity or complexity of such testimony can be controlled by the court's power to limit the presentation of evidence.

(6) Evidence § 81--Opinion Evidence--Expert Witnesses--Discretion of Trial Court.

Where expert opinion evidence is offered, much must be left to the discretion of the trial court in deciding whether to admit or exclude it.

(7) Criminal Law § 657--Appellate Review--Harmless Error--Evidence--Expert Testimony.

An error in excluding expert testimony may be found harmless.

(8) Criminal Law § 408--Evidence--Admissibility--Opinion Evidence--Expert Witnesses--Subjects of Expert Testimony--Psychological Factors Affecting Accuracy of Eyewitness Identification.

The decision to admit or exclude expert testimony on

psychological factors affecting eyewitness identification remains primarily a matter within the trial court's discretion. However, when an eyewitness identification of a defendant is a key element of the prosecution's case but is not substantially corroborated by evidence giving it independent reliability, and the defendant offers qualified expert testimony on specific psychological factors shown by the record that could have affected the accuracy of the identification but are not likely to be fully known to or understood by the jury, it will ordinarily be error to exclude that testimony.

(9) Criminal Law § 29--Former Jeopardy--Effect of Reversal on Appeal.

Where prejudicial error necessitated retrial of defendant, who had been convicted of murder (Pen. Code, § 187), with the special circumstance finding that he committed the murder while robbing or attempting to rob the victim (Pen. Code, § 190.2, subd. (a)(17)(i)), and who had been found not guilty of the substantive charge of robbery (Pen. Code, § 211), double jeopardy considerations and Pen. Code, § 1023, barred any further prosecution of defendant for robbery or attempted robbery. Further, since Pen. Code, § 190.4, subd. (a), requires the charging and proving of a substantive crime whenever a special circumstance requires proof of the commission or attempted commission of the crime, the prosecution was therefore also precluded from retrying defendant on the robbery special circumstance allegation.

(10) Homicide § 98--Trial and Punishment--Verdict--Consequence of Jury's Failure to Specify Degree of Crime.

In a prosecution in which prejudicial error necessitated retrial of defendant, who was convicted of murder (Pen. Code, § 187), the jury's failure to specify the degree of murder in its verdict rendered defendant's conviction second degree murder by operation of Pen. Code, § 1157, even though the jury's intent to convict defendant of first degree murder may have been inferred from its separate finding on a special circumstance allegation. The key is not whether the true intent of the jury can be gleaned from circumstances outside the verdict form itself; instead, application of Pen. Code, § 1157, turns only on whether the jury specified the degree in the verdict form.

(11) Criminal Law § 17--Defenses--Double Jeopardy.

Generally, the burden is on the defendant in a crimi-

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nal prosecution to enter a plea of double jeopardy at the appropriate time and to present a basis for the plea.

COUNSEL

Dean R. Gits, under appointment by the Supreme Court, for Defendant and Appellant.

John K. Van de Kamp, Attorney General, Daniel J. Kremer, Chief Assistant Attorney General, S. Clark Moore, Assistant Attorney General, Edward T. Fogel, Thomas L. Willhite, Jr., and Robert R. Anderson, Deputy Attorneys General, for Plaintiff and Respondent. *355

MOSK, J.

We address here a contention that is increasingly heard in the courts of California and our sister jurisdictions, i.e., that it may be an abuse of discretion to exclude the testimony of a psychologist who is a qualified expert witness on psychological factors shown by the evidence that may affect the accuracy of an eyewitness identification of the defendant. As will appear, we hold that on a proper showing such testimony is admissible, and that it should have been admitted in the case at bar.

Defendant was charged in count I with the murder of Jose Esparza. (Pen. Code, § 187.) As a special circumstance it was alleged that defendant committed the murder while robbing or attempting to rob Esparza. (*Id.*, § 190.2, subd. (a)(17)(i).) In count II defendant was charged with the same robbery of Esparza as a substantive offense. (*Id.*, § 211.) He pleaded not guilty on both counts. The jury convicted him of the murder and found the robbery special circumstance allegation to be true; nevertheless, the jury found defendant not guilty of the substantive charge of robbery in count II. The jury thereafter fixed the penalty at death. This appeal is automatic. (*Id.*, § 1239, subd. (b).)

At trial it was established without dispute that August 20, 1979, was payday for Esparza, a restaurant worker. At 4 p.m. he took a break from his job to cash his paycheck. Shortly after 5 p.m. he was shot and killed by a black man at the intersection of Pine and Seventh Streets in downtown Long Beach. The

principal issue was the identity of the perpetrator. The prosecution presented seven eyewitnesses who identified defendant as that person with varying degrees of certainty, and one eyewitness who categorically testified that defendant was *not* the gunman; the defense presented six witnesses who testified that defendant was in another state on the day of the crime. Because of these discrepancies and their bearing on the principal issue, we will set forth the relevant testimony in some detail.

Four prosecution witnesses positively identified defendant in the courtroom as the perpetrator; in the testimony of each, however, there were factors that could have raised reasonable doubts in the minds of jurors as to the accuracy of the identification. Thus Patricia Molinar testified that she was driving home after work on August 20 when she stopped for a red light at the intersection of Pine and Seventh Streets. While waiting at the light she noticed two men standing on the sidewalk diagonally across the intersection; one was Hispanic (Esparza) and the other was black. She testified that they "seemed to be arguing." The black man then grabbed the other "around his hands," and they began to struggle. After a few moments the *356 witness heard a shot and saw the black man pointing a gun at the victim. The latter fell back against a wall, a second shot was heard, and he slumped to the sidewalk. The gunman leaned over him for a few seconds, walked quickly across the street, and ran from the scene. The entire episode took no more than a few minutes. In open court Ms. Molinar identified defendant as the black man in question.

The witness conceded, however, that her view had been partly blocked by cars parked in front of the spot where the confrontation took place. A number of cars also drove through the intersection while she was waiting for the light to change, passing between her and the two men. She testified that during part of the struggle the gunman had his back towards her, and that when he looked in her direction as he left the scene she was "frightened." She acknowledged that after the event she failed to select defendant's picture out of a group of some 10 photographs shown to her by the police. Yet she claimed that a few days later she picked defendant's photograph out of a set of six, saying, "I'm not sure, but from the photograph I can't be completely positive, but I'm more than sure it's him." On cross-examination, however, she admitted

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that at the preliminary hearing she testified that she had been unable to identify defendant in either photographic display.

David Iglesias testified he was a passenger in the front seat of the car driven by Ms. Molinar, who was his fiancée. His version of the events was essentially the same as hers. He also identified defendant in the courtroom, but conceded that when he picked defendant out of a pretrial photographic display he told the police that although he was "pretty sure" defendant was the gunman, he was "not positive." On cross-examination Mr. Iglesias admitted that in fact he selected photographs of not one but two people (out of six) in the display - the defendant and another - "because they kind of looked alike."

Chad Wise testified he was sitting in his parked car at the intersection in question when he heard a gunshot. He got out of his car and went to the corner, where he saw a black man and a Hispanic who seemed to be fighting; the black man pointed a gun at the Hispanic and fired a second time, reached into the victim's back pocket, then ran down the street. The witness identified defendant in the courtroom. There was no evidence, however, that he had identified defendant before the trial; and defense counsel brought out certain discrepancies between the version that the witness gave on the stand and the statement he furnished to the police on the day of the events. Finally, his estimate of the time that it took the gunman to fire the second shot, bend over the victim, and run from the scene differed drastically from that of the other witnesses: they all testified that no more than two or three *357 minutes elapsed, but he insisted on both direct and cross-examination that it was "almost 25 minutes."

La Wahna Eldred testified she was walking towards the intersection in question when she heard two gunshots in close succession. Looking in the direction of the sounds, she saw a Hispanic struggling with a black man. The latter then stood up and walked across the street towards her, holding his hand at his waistband. She looked away because she was frightened; as he passed by she took a "sideward glance" at him. On this basis she identified defendant in the courtroom as the gunman.

Ms. Eldred conceded that her view of the encounter had been partly blocked by both parked and passing

cars. Several days later she was shown a set of six photographs by the police; after studying them for ten minutes, she selected the photograph of defendant as having the most "similarities" to the face she remembered seeing. She told the police, however, that his hairline looked different and she "wasn't totally positive" that defendant was the gunman.

None of the other prosecution witnesses were positive in their courtroom identifications of defendant. Thus the testimony of Erik Soderholm was very similar to that of Ms. Eldred. ^{FN1} When asked if he could identify the black man in the courtroom, however, Mr. Soderholm replied only that "I think this is the man," pointing to defendant. He explained that "The feeling I get, looking at his face, are [*sic*] similar to the feelings I had when I saw the man go." He conceded there was fairly heavy rush-hour traffic in the intersection at the time of the shooting, and that a number of cars passed between him and the scene as he watched. He also conceded that he had selected not one but two faces out of the set of six photographs subsequently shown to him by the police, and that he told the officer at the time, "I'm not sure. I only saw the side view of him and his back." When defense counsel squarely asked him on cross-examination whether "There is some doubt in your mind" about his courtroom identification of defendant, Mr. Soderholm said, "Yes."

FN1 He added that during the encounter the gunman was holding a "long black object," and that after reaching underneath the victim he put something in his pocket. Mr. Soderholm also followed the gunman to the next corner and saw him drive away, apparently alone, in a car that was parked there.

Two other witnesses did not see the actual shooting and were even less certain that the black man at the scene was defendant. Harold Malone testified he was in a hamburger stand on the corner of Pine and Seventh Streets when he heard shots and went outside to investigate. He saw a black man standing over a fallen figure, holding a gun; the man put the gun in his *358 waistband and crossed the street at a fast pace. The witness followed until the man got into a parked car and drove away.

There was no evidence that the witness identified defendant before the trial. When asked on direct ex-

amination, "Would you recognize that man if you saw him again?" Mr. Malone replied, "That I'm not sure of, sir." He explained that his attention had been focused on the man's weapon and on the need to follow him, and that at all times he was across the street and behind the man. The prosecutor persisted, asking the witness to "look around the courtroom and tell us if you see that man in court today." Mr. Malone did so, and answered, "I couldn't be positive." The prosecutor then asked if he could see anyone "similar" to the black man in question, and the witness finally pointed to defendant.^{FN2} When defense counsel asked him on cross-examination, "you're not certain it's [defendant], are you?" the witness admitted, "No, sir. I couldn't be positive, no."

FN2 Asked what it was about the defendant that appeared "similar" to the gunman, Mr. Malone emphasized, "I know his race. He was Negro." Pressed further, he also mentioned generally the defendant's complexion, build, and age.

Similarly, Richard Kaley testified he was standing near the intersection in question when he heard a shot and saw a man running "lickety-split" towards him. As the man passed him, Mr. Kaley saw that he was holding a gun in his waistband. The entire episode took about 90 seconds. The witness conceded that the police never showed him a photographic display and that he did not testify at the preliminary hearing. At trial he testified the man was black, but added that he (Kaley) was colorblind and was wearing sunglasses at the time. When the prosecutor asked, "Would you recognize this person if you saw him again?" Mr. Kaley answered, "That would be debatable." In response to the prosecutor's directive to look around the courtroom and say if the man was present, the witness said that defendant greatly "resembled" him. On cross-examination defense counsel asked him whether his identification of defendant was "positive," and Mr. Kaley replied, "I said that it was not."

The prosecution witnesses were in general agreement in their description of the clothing worn by the gunman, but two (Molinar and Iglesias) claimed the man had a large, round, gold earring in his left ear, about the size of a quarter, while none of the other witnesses testified that he wore any such distinctive jewelry. In addition, two witnesses (Eldred and Kaley) described the man as having "pockmarks" or "acne-

like" scars on the lower part of his face, while none of the other witnesses so testified.

Finally, one of the prosecution's own witnesses unequivocally testified that the black man at the scene was *not* defendant. Helen Waller was driving *359 slowly through the intersection of Pine and Seventh Streets when her attention was caught by two men "arguing and making loud noises" on the sidewalk just outside her right-hand window. She took her foot off her accelerator pedal and watched while one of the men, a black, shot the other with a large handgun and sought to wrest a bag or purse from his victim's grasp. Mrs. Waller testified that the gunman "looked directly in my eyes, and I looked at him." Her car continued to coast, and the struggle of the two men remained, she said, "all very much in my view." At that point there were no parked cars between her and the scene, and the traffic was light. After about a minute the struggle ended and the witness watched the gunman as he passed directly behind her car and across the street.

Mrs. Waller reported to the police that evening; several days later an officer showed her a set of six photographs, the same set that was shown to witnesses Molinar, Iglesias, Eldred, and Soderholm. She told the officer that "none of the photographs actually looked like the man," although she noted that in one of them the hair, eyes, and general shape of the face looked similar to those of the assailant.^{FN3} Mrs. Waller was troubled by the complexion of the person in the photograph, but the officer told her that a photograph may not accurately reproduce the subject's skin color.

FN3 The photograph referred to was the same one (No. 3) that the other witnesses had selected.

It was then brought out that Mrs. Waller testified in defendant's presence at the preliminary hearing; the prosecutor there asked her whether the black man who shot Esparza was in the courtroom, and she said he was not.^{FN4} At trial she acknowledged there were certain similarities between that man and defendant, pointing to their eyes, the shape of their faces, and their height. But she explained that defendant also exhibited a feature that was "very different. He has a different complexion. This man here [i.e., defendant] has a complexion that has a yellowish hue to it. And

the man that I saw had more brown, much deeper brown and much deeper color in his skin coloring than this man. And it's something that doesn't change with being inside or *360 outside. It's not like a tan. It's a coloring." FN5 For this reason Mrs. Waller was certain they were "Two different men altogether." On cross-examination defense counsel squarely asked her whether defendant was the black man in question, and she replied, "No, he's not."

FN4 The relevant preliminary hearing testimony was as follows:

"Q. [by the prosecutor]. When you first looked over and saw these two men, do you think that you would recognize either of them if you saw them again? A. Yes, I would.

"Q. Would you look around the courtroom and tell us if you see either of those two men in court today? A. No, I don't.

"Q. Could you describe either of those two men for us? A. Okay. The man that was shot, I really didn't get too good a look at him because he was on the ground at the time that I looked.

"Q. All right. A. But the man that was doing the shooting looked directly into my face, and I got a very good view of him. And the man is not here today."

The witness reiterated that testimony a few minutes later.

FN5 At the preliminary hearing Mrs. Waller further explained that "His complexion was darker than mine" As will appear, in a pretrial hearing on the admissibility of expert testimony on eyewitness identification, it was brought out that Mrs. Waller is also black.

The prosecution offered no other evidence to connect defendant with the crime in this case. The defense, however, called six witnesses to establish that on the date of the shooting (Aug. 20, 1979) defendant was visiting his grandfather in Saraland, Alabama, near

Mobile. Lovie Banks, defendant's fiancée, testified that on August 10, 1979, she drove defendant to San Diego, where he took a bus to Saraland, via Phoenix. She subsequently received two cards from defendant, both postmarked Phoenix, Arizona, August 11, 1979; the cards were introduced in evidence. She testified that she thereafter received a letter from defendant from Saraland, and that he called her twice from his grandfather's house.

Jessie Mae Pruitt, defendant's aunt, testified that on August 13, 1979, she received a collect call from defendant from the bus station in Mobile asking to be met; a copy of a long-distance telephone bill showing that a collect call was made on August 13 from Mobile to her number was introduced into evidence. The witness testified she then telephoned to Robert Pruitt, defendant's grandfather, and asked that defendant be met at the bus station. Her telephone bill showed that several calls were made that same day from her number to Alabama.

Robert Pruitt testified that his wife took the telephone call concerning defendant's arrival, and that he met defendant at the Mobile bus station between 4:30 and 5 p.m. on August 13 and took him home to Saraland. He further testified that defendant lived with him and his wife until the police took him back to California in September.

Three other witnesses placed defendant in Saraland from mid-August to September 1979, and specifically testified that they saw and/or spoke with him there on August 20, the date of the shooting in Long Beach. Two of these witnesses were unrelated to defendant. In addition, Ms. Banks testified that on August 7, before going to Saraland, defendant shaved his head; three witnesses testified that he was bald during his stay in Alabama. FN6 Lastly, five witnesses testified that defendant had never worn earrings of any kind. *361

FN6 According to the prosecution witnesses, the black man who shot Esparza had a moderate Afro hairdo.

I. Expert Testimony on Eyewitness Identification

(1a) Defendant contends the court abused its discretion in excluding the testimony of an expert witness on the psychological factors that may affect the accu-

racy of eyewitness identification. Prior to trial the defense moved for an order admitting the testimony of Dr. Robert Shomer. (Evid. Code, § 402.) Dr. Shomer is a practicing psychologist and professor of psychology of almost 20 years' experience. He has taught numerous courses on the psychology of perception, memory, and recall, and has spoken and written frequently on such topics in both medical and legal settings. He is conversant with the scientific literature on the psychology of eyewitness identification, has done experimental research on the subject himself, and has published articles on that research. He has qualified as an expert psychological witness in more than two dozen state and federal trials. The People do not question the witness' qualifications.

At the hearing on the motion Dr. Shomer explained that he proposed to inform the jury of various psychological factors that may affect the reliability of eyewitness identification, and to "help to counter some common misconceptions" about the process. He noted first that all eyewitness identification begins with the observer's initial perception of the event. The physical circumstances affecting that observation are generally known to laymen, such as lighting, distance, and duration. But psychological factors may also influence the accuracy of the perception: Dr. Shomer intended to review for the jury the results of certain experimental studies showing that perception may be affected by such factors as the observer's state of mind, his expectations, his focus of attention at the time, the suddenness of the incident, the stressfulness of the situation, and differences in the race and/or age of the observer and the observed. On the latter point he would have testified, for example, that there are substantial decreases in accuracy when the two persons are of different races or ages.

The next phase of the process is memory. Dr. Shomer intended to discuss with the jury the evidence showing that memory is not merely a passive recording event, producing an imperishable reproduction of the scene perceived; rather, it is both a selective and a constructive process, in which old elements fade and are lost while new elements - subsequent information or suggestions - are unconsciously interwoven into the overall recollection until the subject cannot distinguish one from the other.^{FN7}

FN7 We took note of studies demonstrating this phenomenon in *People v. Shirley* (1982)

31 Cal.3d 18, 57-62 [181 Cal.Rptr. 243, 641 P.2d 775].

The last step is retrieval. Dr. Shomer proposed to review the studies establishing that recall may be affected by such factors as the subject's *362 expectations, his suggestibility, the phrasing of the questions asked of him, and even the size and type of the photographs he is shown. For example, Dr. Shomer would have explained to the jury that witnesses who are asked to identify criminals in lineups or photo displays tend to find the experience psychologically unpleasant and wish to terminate it. Because of this self-induced pressure, such witnesses may subconsciously take a simple request to point out the offender if he is in the lineup and convert it into a demand that they find the face in the lineup that is the "most similar" to the offender; that alternative appears more legitimate to them than admitting they cannot identify anyone at all.

Turning to the case at bar, Dr. Shomer made it clear that he did not propose to offer an opinion that any particular witness at this trial was or was not mistaken in his or her identification of defendant. But he did intend to point out various psychological factors that could have affected that identification in the present case. Thus he emphasized that from the viewpoint of the witnesses the shooting of Esparza on a busy streetcorner was a sudden and unexpected event, occurring some distance away, and that because of parked and passing cars their observations were largely discontinuous. He also referred to the youth of certain of the witnesses, the words used in making the pretrial photographic identifications of defendant, and the ambiguity of those identifications. Dr. Shomer particularly noted the effect of the "cross-racial factor" in this case, emphasizing that the one witness who was certain that defendant, a black, was not the black man at the scene was herself a black (Waller); by contrast, two of the witnesses who positively identified defendant at trial as the assailant (Molinar and Iglesias) were of the same ethnic origin (Hispanic) as the victim.

Finally, Dr. Shomer intended to explain to the jury that empirical research has undermined a number of widespread lay beliefs about the psychology of eyewitness identification, e.g., that the accuracy of a witness's recollection increases with his certainty, that accuracy is also improved by stress, that cross-

racial factors are not significant, and that the reliability of an identification is unaffected by the presence of a weapon or violence at the scene.

On this showing, defendant offered the testimony of Dr. Shomer as an aid to the jurors in weighing the eyewitness identifications in this case. The People objected on the sole ground that to admit the testimony would "usurp the jury's function," citing *People v. Johnson* (1974) 38 Cal.App.3d 1, 6-7 [112 Cal.Rptr. 834], and similar decisions.^{FN8} The trial court, conceding *363 that it was the first time it had encountered this type of evidence, ruled the testimony inadmissible. The court declared that it "fully agreed" with the reasoning of *Johnson*: observing that none of the prosecution witnesses have "psychological defects," the court concluded that to allow Dr. Shomer to testify "would be invading the province of the jury." Defendant protested that Dr. Shomer would not give an opinion on the credibility of any particular witness, but would simply provide the jurors with information to help them determine the accuracy of the various identifications put before them. The court stood by its ruling, adding the further grounds that it intended to give a standard instruction on discrepancies in testimony (CALJIC No. 2.21 (4th ed. 1979)), that expert testimony on eyewitness identification "maybe would have a tendency" to "maybe cause confusion in the jurors' minds," and that such testimony "is really not what I consider scientific enough at this point in time" to be admissible.

FN8 *People v. Guzman* (1975) 47 Cal.App.3d 380, 385-386 [124 Cal.Rptr. 492]; *People v. Brooks* (1975) 51 Cal.App.3d 602, 608-609 [124 Cal.Rptr. 492]; see also *People v. Bradley* (1981) 115 Cal.App.3d 744, 751-752 [171 Cal.Rptr. 487].

A.

The United States Supreme Court has recognized that "The vagaries of eyewitness identification are well-known; the annals of criminal law are rife with instances of mistaken identification." (*United States v. Wade* (1967) 388 U.S. 218, 228 [18 L.Ed.2d 1149, 1158, 87 S.Ct. 1926].) The court noted "the high incidence of miscarriage of justice" caused by such mistaken identifications, and warned that "the dangers for the suspect are particularly grave when the

witness' opportunity for observation was insubstantial, and thus his susceptibility to suggestion the greatest." (*Id.* at pp. 228-229 [18 L.Ed.2d at pp. 1158-1159].)

Distinguished federal judges have echoed and amplified these warnings. Thus in *Jackson v. Fogg* (2d Cir. 1978) 589 F.2d 108, the court upheld an order vacating a robbery-murder conviction on habeas corpus because prelineup procedures were unduly suggestive and because the four eyewitnesses had only a brief opportunity to observe the gunman under stressful conditions and showed varying degrees of certainty in their identifications of the defendant. There was no other evidence connecting the defendant with the crime. Writing for a unanimous court, Judge Lumbard observed that "Centuries of experience in the administration of criminal justice have shown that convictions based solely on testimony that identifies a defendant previously unknown to the witness is highly suspect. Of all the various kinds of evidence it is the least reliable, especially where unsupported by corroborating evidence." (*Id.* at p. 112.)

Some of the reasons for that unreliability were discussed by Judge (later Solicitor General) McCree in *United States v. Russell* (6th Cir. 1976) 532 F.2d 1063, 1066: "There is a great potential for misidentification when a *364 witness identifies a stranger based solely upon a single brief observation, and this risk is increased when the observation was made at a time of stress or excitement. ... [T]his danger is inherent in every identification of this kind, ..." As Judge McCree noted, "This problem is important because of all the evidence that may be presented to a jury, a witness' in-court statement that 'he is the one' is probably the most dramatic and persuasive." (*Id.* at p. 1067.)

The rule that the testimony of a single witness is sufficient to prove identity (see Evid. Code, § 411) is premised in part on the assumption that an eyewitness identification is generally reliable. Yet Judge Hufstedler has declared that premise to be "at best, highly dubious, given the extensive empirical evidence that eyewitness identifications are not reliable." (*United States v. Smith* (9th Cir. 1977) 563 F.2d 1361, 1365 (conc. opn.)) And with his characteristic vigor, Chief Judge Bazelon has called on the courts to face up to the reliability problems of eyewitness identification, to inform themselves of the

results of scientific studies of those problems, and to allow juries access to that information in aid of their factfinding tasks. (*United States v. Brown* (D.C. Cir. 1972) 461 F.2d 134, 145-146, fn. 1 (conc. & dis. opn.))^{FN9}

FN9 Thus Judge Bazelon pointed out that "One critical problem [of eyewitness identifications] concerns their reliability, yet courts regularly protest their lack of interest in the reliability of identifications, as opposed to the suggestivity that may have prompted them, arguing that reliability is simply a question of fact for the jury. [Citation.] There already exists, however, great doubts - if not firm evidence - about the adequacy and accuracy of the process. Unquestionably, identifications are often unreliable - perhaps consistently less reliable than lie detector tests, which we have in the past excluded for unreliability." (*Id.* at p. 145, fn. 1.) Judge Bazelon continued, "we need more information about the reliability of the identification process and about the jury's ability to cope with its responsibility. For it should be obvious that we cannot strike a reasonable and intelligent balance if we take pains to remain in ignorance of the pitfalls of the identification process. The empirical data now available indicates that the problem is far from fanciful. [Citations.] But for a variety of reasons we have been unwilling to face up to the doubts to which this data gives rise. And despite repeated charges and counter-charges concerning the accuracy of inter-racial identifications, we have developed a reluctance that is almost a taboo [citation] against even acknowledging the question, much less providing the jury with all of the available information." (*Id.* at pp. 145-146, fn. 1.) And Judge Bazelon concluded that "More information is needed to assist the jury's resolution of identification issues," and "our doubts will not disappear merely because we run away from the problem." (*Id.* at p. 146, fn. 1.) (See also Bazelon, *Eyewitness News* (Mar. 1980) *Psychology Today*, p. 101.)

In the dozen years since Judge Bazelon's appeal, empirical studies of the psychological factors affecting

eyewitness identification have proliferated, and reports of their results have appeared at an ever-accelerating pace in the professional literature of the behavioral and social sciences. No less than five treatises on the topic have recently been published, citing and discussing literally scores of studies on the pitfalls of such identification. *365 (*Eyewitness Testimony: Psychological Perspectives* (Wells & Loftus edits. 1984) [hereinafter *Eyewitness Testimony: Psychological Perspectives*]; *Evaluating Witness Evidence: Recent Psychological Research and New Perspectives* (Lloyd-Bostock & Clifford edits. 1983); Sobel, *Eyewitness Identification: Legal and Practical Problems* (2d ed. 1983); Loftus, *Eyewitness Testimony* (1979); Yarmey, *The Psychology of Eyewitness Testimony* (1979); see also Johnson, *Cross-Racial Identification Errors in Criminal Cases* (1984) 69 *Cornell L.Rev.* 934 [hereinafter *Cross-Racial Identification Errors*]; Note, *Did Your Eyes Deceive You? Expert Psychological Testimony on the Unreliability of Eyewitness Identification* (1977) 29 *Stan. L.Rev.* 969 [hereinafter *Expert Psychological Testimony*].) Indeed, in 1984 two leading researchers estimated that on this topic "over 85% of the entire published literature has surfaced since 1978." (Wells & Loftus, *Eyewitness Research: Then and Now*, in *Eyewitness Testimony: Psychological Perspectives*, p. 3.) The consistency of the results of these studies is impressive, and the courts can no longer remain oblivious to their implications for the administration of justice.

B.

A traditional way of bringing scientific information to the attention of the judicial system, of course, is by the testimony of expert witnesses. But when that testimony relates to psychological factors affecting the accuracy of eyewitness identification, the courts have shown reluctance to admit it: appellate decisions almost unanimously hold that rulings excluding such evidence do not constitute an abuse of discretion. (See, e.g., *Com. v. Francis* (1983) 390 *Mass.* 89 [453 *N.E.2d* 1204, 1207-1208], and cases cited.) We inquire whether that reluctance remains justified.^{FN10}

FN10 Of course, the virtual unanimity of appellate decisions on the topic may well be misleading. Expert testimony on eyewitness identification is usually offered by the defendant. In cases in which the testimony is

admitted, the issue will not arise on appeal: if the defendant is convicted, he cannot complain of the admission of his own evidence; and if he is acquitted, no appeal is possible in any event. It follows that appellate courts ordinarily confront the issue only when the testimony has been *excluded*; and in all such cases appellate courts tend to affirm, because of the deference traditionally accorded to discretionary rulings of trial courts. Nevertheless, in a number of published opinions it emerges in various contexts that expert testimony on eyewitness identification was in fact admitted at the trial. (E.g., *United States v. Booth* (9th Cir. 1981) 669 F.2d 1231, 1240; *People v. Brown* (1982) 110 Ill.App.3d 1125 [443 N.E.2d 665, 668]; *State v. Chapman* (La. 1981) 410 So.2d 689, 702; *State v. Sellars* (1981) 52 N.C.App. 380 [278 S.E.2d 907, 921-922]; *Hampton v. State* (1979) 92 Wis.2d 450 [285 N.W.2d 868, 870-871].) In *State v. Warren* (1981) 230 Kan. 385 [635 P.2d 1236, 1243, 23 A.L.R.4th 1070], the court noted that Dr. Elizabeth Loftus presented an affidavit stating that she had been allowed to testify as an eyewitness identification expert in more than 34 cases in various jurisdictions, and that another nationally recognized expert, Dr. Robert Buckhout, had so testified in more than 20 cases.

This court has not previously addressed the admissibility of expert testimony on eyewitness identification. Several opinions of the Court of Appeal *366 discuss the issue, but on close analysis none appears satisfactory. The leading case in this state - followed by the trial court in the case at bar - is *People v. Johnson, supra*, 38 Cal.App.3d 1. There the sole evidence connecting the defendants with a robbery-murder at a liquor store was the eyewitness identification of the surviving robbery victims. The defense sought to discredit that identification on various grounds, including the offer of expert testimony by a psychologist as to the ability of eyewitnesses to accurately perceive, remember and relate, and the distorting effects of excitement and fear on those functions. The trial court excluded the testimony, and the Court of Appeal upheld the ruling on four grounds. None, however, is immune from criticism.

First, the opinion reasons that although Evidence Code section 780, subdivision (c), permits a witness to be impeached by discrediting his capacity to perceive, recollect or communicate, "it does not follow that a party has a right to impeach a witness by calling another witness to testify as to the former's capacity." (38 Cal.App.3d at p. 6.) The argument misses the point. The expert witness in *Johnson* - just as Dr. Shomer here - would not have testified that any particular prosecution witness lacked the *capacity* to perceive, remember and relate; rather, he would simply have informed the jury of certain psychological factors that may impair the accuracy of a typical eyewitness identification, including the emotions of excitement or fear, with supporting references to experimental studies of such phenomena. (2) Such evidence falls well within the broad statutory description of "any matter that has any tendency in reason" to bear on the credibility of a witness. (Evid. Code, § 780.)

(3) Second, the *Johnson* opinion states that Evidence Code section 801, subdivision (a), "limits expert testimony to subjects beyond the range of common experience" (38 Cal.App.3d at pp. 6-7). This paraphrase of the statutory scheme, however, is both incomplete and misleading. To begin with, by its terms section 801 applies only to expert testimony "in the form of an opinion." If an expert testifies not as to his opinion but as to *facts* within his special knowledge, section 801 is inapplicable. Factual testimony by an expert is admissible if it complies with the general statutory requirements that the witness be "qualified" by his special knowledge (Evid. Code, § 720) and that his evidence be relevant to the issues (*id.*, § 351).^{FN11} Much of the proposed testimony of the psychologist in *Johnson* and of Dr. Shomer here would have related primarily to matters of fact: the *contents* of eyewitness identification studies reported in the professional literature - their *367 methodology, their data, and their findings - are facts, verifiable by anyone who can read and understand the studies in question.^{FN12}

FN11 The testimony also remains subject to the court's general discretionary power to exclude evidence that is unduly time-consuming or confusing (Evid. Code, § 352), and to its special discretionary power to limit the number of expert witnesses called by any party (*id.*, § 723).

FN12 To illustrate, assume the witness testifies that journal A published an article B in which researcher C reported that he conducted an empirical study of the effect of factor D on the accuracy of eyewitness identification, that he designed the experiment in manner E, that the experiment produced raw data F, that he analyzed those data by statistical method G, and that such analysis yielded finding H; in that event, A, B, C, D, E, F, G, and H are facts, not opinions, and in relating them to the jury the expert witness is not testifying "in the form of an opinion." (Evid. Code, § 801, subd. (a).) By contrast, if the same expert goes on to assert, on the basis of these facts, that a particular eyewitness in the case before him was or was not mistaken in his identification of the defendant, that assertion would be opinion testimony. As noted above, however, no such testimony was offered in *Johnson* or the case at bar.

In any event, to the extent these cases may involve opinion testimony by the psychologist witness, the *Johnson* paraphrasing of section 801, subdivision (a), errs by omission. The statute does not flatly limit expert opinion testimony to subjects "beyond common experience"; rather, it limits such testimony to such subjects "*sufficiently beyond common experience that the opinion of an expert would assist the trier of fact*" (italics added). The emphasized words, omitted by the *Johnson* court, make it clear that the admissibility of expert opinion is a question of degree. The jury need not be wholly ignorant of the subject matter of the opinion in order to justify its admission; if that were the test, little expert opinion testimony would ever be heard. Instead, the statute declares that even if the jury has some knowledge of the matter, expert opinion may be admitted whenever it would "assist" the jury. It will be excluded only when it would add nothing at all to the jury's common fund of information, i.e., when "the subject of inquiry is one of such common knowledge that men of ordinary education could reach a conclusion as intelligently as the witness" (*People v. Cole* (1956) 47 Cal.2d 99, 103 [301 P.2d 854, 56 A.L.R.2d 1435]).

(1b) We apply this test to expert testimony on eye-

witness identification. It is doubtless true that from personal experience and intuition all jurors know that an eyewitness identification can be mistaken, and also know the more obvious factors that can affect its accuracy, such as lighting, distance, and duration. FN13 It appears from the professional literature, however, that *368 other factors bearing on eyewitness identification may be known only to some jurors, or may be imperfectly understood by many, or may be contrary to the intuitive beliefs of most. For example, in the case at bar Dr. Shomer would have testified to the results of studies of relevant factors that appear to be either not widely known to laypersons or not fully appreciated by them, such as the effects on perception of an eyewitness' personal or cultural expectations or beliefs (see Loftus, *Eyewitness Testimony* (1979) pp. 36-48), the effects on memory of the witness' exposure to subsequent information or suggestions (*id.* at pp. 54-87), and the effects on recall of bias or cues in identification procedures or methods of questioning (*id.* at pp. 89-99; see generally Hall et al., *Postevent Information and Changes in Recollection for a Natural Event*, in *Eyewitness Testimony: Psychological Perspectives*, pp. 124-141).

FN13 Even with respect to these factors, however, expert psychological testimony may be helpful in appropriate cases. For example, the length of time that an eyewitness observes the person he later identifies is often given significant weight by the jury. But in virtually every such case the only evidence of that duration is the witness's own estimate. Studies show that witnesses consistently overestimate the length of brief periods of time, especially in the presence of stressful stimuli: "during sudden, action-packed events such as crimes, people almost always overestimate the length of time involved because the flurry of activity leads them to conclude that a significant amount of time has passed." (*Expert Psychological Testimony*, p. 977; see also Schiffman & Bobko, *Effects of Stimulus Complexity on the Perception of Brief Temporal Durations* (1974) 103 J. Experimental Psychology 156.) In the case at bar, for example, the eyewitnesses' estimates of the duration of the crime ranged widely from 2 minutes to 25 minutes.

690 P.2d 709
 37 Cal.3d 351, 690 P.2d 709, 208 Cal.Rptr. 236, 46 A.L.R.4th 1011
 (Cite as: 37 Cal.3d 351)

Dr. Shomer would also have explained to the jury the pitfalls of cross-racial identification, evidently an important factor on the record in this case. To be sure, many jurors are likely to have some awareness of the fact that an eyewitness is more accurate in identifying a person of his own race than one of another race. (See, e.g., *People v. Dixon* (1980) 87 Ill.App.3d 814 [410 N.E.2d 252, 256].) But it appears that few jurors realize the pervasive and even paradoxical nature of this "own-race effect," information that has emerged from numerous empirical studies of the question. These studies establish that the effect is strongest when white witnesses attempt to recognize black subjects; in such circumstances "The impairment in ability to recognize black faces is substantial." (*Cross-Racial Identification Errors*, pp. 938-939.)^{FN14} In laboratory experiments, for example, it is common for own-race/other-race recognition rates to differ by as much as 30 percent. (*Id.* at pp. 942-943.) The studies also reveal two aspects of the matter that will probably be contrary to most jurors' intuitions: first, that white witnesses who are not racially prejudiced are just as likely to be mistaken in making a cross-racial identification as those who are prejudiced; and second, that white witnesses who have had considerable social contact with blacks may be no better at identifying them than those who have not. (*Id.* at pp. 943-944.) Finally, some jurors may deny the existence of the own-race effect in the misguided belief that it is merely a racist myth exemplified by the derogatory remark, "they all look alike to me," while others may believe in the reality of this effect but be reluctant to discuss it in deliberations for fear of being seen as bigots. (*Id.* at p. 969; see also Wells, *A Reanalysis of the Expert Testimony Issue*, in *Eyewitness Testimony: Psychological Perspectives*, p. 309.) *369

FN14 A recent overview of the literature cites no less than 10 studies documenting this impairment. (*Id.* at pp. 938-939, fn. 18.)

In addition to the foregoing counterintuitive aspects of the own-race effect, other psychological factors have been examined in the literature that appear to contradict the expectations of the average juror. Perhaps the foremost among these is the lack of correlation between the degree of confidence an eyewitness expresses in his identification and the accuracy of that identification. Numerous investigations of this phenomenon have been conducted: the majority of

recent studies have found no statistically significant correlation between confidence and accuracy, and in a number of instances the correlation is negative - i.e., the more certain the witness, the more likely he is mistaken. (Wells & Murray, *Eyewitness Confidence*, in *Eyewitness Testimony: Psychological Perspectives*, pp. 159-162.) Indeed, the closer a study comes to reproducing the circumstances of an actual criminal investigation, the lower is that correlation (*id.* at pp. 162-165), leading the cited authors to conclude that "the eyewitness accuracy-confidence relationship is weak under good laboratory conditions and functionally useless in forensically representative settings." (*Id.* at p. 165; see also Deffenbacher, *Eyewitness Accuracy and Confidence: Can We Infer Anything About Their Relationship?* (1980) 4 *Law & Human Behav.* 243.) The average juror, however, remains unaware of these findings: "A number of researchers using a variety of methods have found that people intuitively believe that eyewitness confidence is a valid predictor of eyewitness accuracy." (Wells & Murray, *supra*, at p. 159, citing five recent studies.)

(4) We conclude that although jurors may not be totally unaware of the foregoing psychological factors bearing on eyewitness identification, the body of information now available on these matters is "sufficiently beyond common experience" that in appropriate cases expert opinion thereon could at least "assist the trier of fact" (Evid. Code, § 801, subd. (a)).^{FN15}

FN15 We realize there is a minority view on this question: two psychologists are on record as opposing the use of expert testimony on the factors affecting eyewitness identification. They argue that for most of these factors, the claimed effect on witness accuracy either is not proved or is probably obvious to jurors. (Egeth & McCloskey, *Expert Testimony About Eyewitness Behavior: Is It Safe and Effective?* in *Expert Testimony: Psychological Perspectives*, p. 283; see also Egeth & McCloskey, *Eyewitness Identification: What Can a Psychologist Tell a Jury?* (1983) 38 *Am.Psychologist* 550.) Their reasoning, however, has been vigorously disputed by their peers. (E.g., Wells, *A Reanalysis of the Expert Testimony Issue*, in *Eyewitness Testimony: Psychological Perspectives*, p. 304; Loftus, *Silence is Not*

Golden (1983) 38 Am.Psychologist 564.) And on close examination it appears the principal complaint of Egeth and McCloskey is not so much that expert testimony on eyewitness identification should never be admissible, as that it is too soon to admit it: additional research is needed. (See, e.g., their cited article in 38 Am.Psychologist at p. 558 & fn. 6.) But this is a frequent conclusion of academic authors. As the present case makes plain, appellate judges do not have the luxury of waiting until their colleagues in the sciences unanimously agree that on a particular issue no more research is necessary. Given the nature of the scientific endeavor, that day may never come.

The third ground of the *Johnson* opinion is premised on its observation *370 (38 Cal.App.3d at p. 7) that "In cases not involving sex offenses California courts usually reject attempts to impeach a witness by means of psychiatric testimony," citing *Ballard v. Superior Court* (1966) 64 Cal.2d 159, 172 [49 Cal.Rptr. 302, 410 P.2d 838, 18 A.L.R.3d 1416]. *Ballard* held (at pp. 173-175) that in a sex offense case expert medical testimony of a psychiatrist may be admitted to impeach the credibility of the complaining witness by showing that she suffers from a particular physical or mental illness or disorder that impairs her ability to tell the truth. (See also *People v. Russel* (1968) 69 Cal.2d 187, 193, 195-196 [70 Cal.Rptr. 210, 443 P.2d 794].) The *Johnson* opinion then reasons (38 Cal.App.3d at p. 7) that "The present occurrence was frightening but hardly deranging. There is no evidence or claim of emotional disturbance or psychological 'abnormality' of any of the prosecution witnesses."

Again the argument misses the point. In neither *Johnson* nor the case at bar did the defense offer expert medical testimony by a psychiatrist to attack the truth-telling ability of any witness. The *Ballard* rule therefore has nothing to do with the case, and it is totally irrelevant that these are "cases not involving sex offenses" or that no witness was shown to be "abnormal."

Fourth, the *Johnson* opinion (*ibid.*) also upholds the trial court's ruling on the ground that to admit expert psychological evidence on eyewitness identification

would "take over the jury's task of determining the weight and credibility of the witness' testimony" - or, to put it in the more colorful language of legal cliché used by many courts, would "invade the province" or "usurp the function" of the jury, because such evidence "embraces the ultimate issue." As Dean Wigmore has said, however, such language "is so misleading, as well as so unsound, that it should be entirely repudiated. It is a mere bit of empty rhetoric," and "remains simply one of those impracticable and misconceived utterances which lack any justification in principle." (Fns. omitted.) (7 Wigmore on Evidence (Chadbourn rev. ed. 1978), § 1920, p. 18, § 1921, p. 22.) Specifically referring to expert psychological evidence on eyewitness identification, the author of a leading treatise on the topic asserts that "the objection based upon the 'province of the jury' is no more than a shibboleth which, if accepted, would deprive the jury of important information useful and perhaps necessary for a proper decision on a difficult issue." (Wall, Eye-Witness Identification in Criminal Cases (1965) p. 213.)

(1c) The reasons for these criticisms are several. The expert testimony in question does *not* seek to take over the jury's task of judging credibility: as explained above, it does not tell the jury that any particular witness is or is not truthful or accurate in his identification of the defendant. Rather, it informs the jury of certain factors that may affect such an identification in a typical case; and to the extent that it may refer to the particular circumstances *371 of the identification before the jury, such testimony is limited to explaining the potential effects of those circumstances on the powers of observation and recollection of a typical eyewitness. The jurors retain both the power and the duty to judge the credibility and weight of all testimony in the case, as they are told by a standard instruction.^{FN16}

FN16 CALJIC No. 2.20 (4th ed. 1979) provides in relevant part: "You are the sole judges of the believability of a witness and the weight to be given to his testimony."

Nor could such testimony in fact usurp the jury's function. As is true of all expert testimony, the jury remains free to reject it entirely after considering the expert's opinion, reasons, qualifications, and credibility. Indeed, the Penal Code commands (§ 1127b) that an instruction so informing the jury be given in any

criminal trial in which expert opinion evidence is received.^{FN17}

FN17 Implementing Penal Code section 1127b, CALJIC No. 2.80 (4th ed. 1979) provides in relevant part: "Duly qualified experts may give their opinions on questions in controversy at a trial. To assist you in deciding such questions, you may consider the opinion with the reasons given for it, if any, by the expert who gives the opinion. You may also consider the qualifications and credibility of the expert.

"You are not bound to accept an expert opinion as conclusive, but should give to it the weight to which you find it to be entitled. You may disregard any such opinion if you find it to be unreasonable."

Finally, California has abandoned the "ultimate issue" rule in any event: "in this state we have followed the modern tendency and have refused to hold that expert opinion is inadmissible merely because it coincides with an ultimate issue of fact." (*People v. Cole*, (1956) *supra*, 47 Cal.2d 99, 105, and cases cited.) Evidence Code section 805 codifies this case law, declaring that "Testimony in the form of an opinion that is otherwise admissible is not objectionable because it embraces the ultimate issue to be decided by the trier of fact."^{FN18}

FN18 The progeny of *Johnson* are no more persuasive than *Johnson* itself. Thus *People v. Guzman*, (1975) *supra*, 47 Cal.App.3d 380, 385-386, merely quotes portions of *Johnson* and *Ballard*; in turn, *People v. Brooks*, (1975) *supra*, 51 Cal.App.3d 602, 608-609, quotes *Johnson*, and *People v. Bradley*, (1981) *supra*, 115 Cal.App.3d 744, 751-752, quotes *Guzman*. Each opinion briefly disposes of the issue by deferring to the trial court's discretion to reject such expert testimony in order to prevent it from "invading the province" of the jury.

C.

For the reasons stated, the challenged ruling excluding the expert testimony of Dr. Shomer is not supported by the trial court's professed "agreement" with

the reasoning of *Johnson*, or by its observation that the prosecution witnesses have no "psychological defects" (i.e., the *Ballard* rule), or by its flat assertion that such expert testimony would "invade the province" of the jury. *372

Nor is the ruling supported by the court's announced intent to give the standard instruction on discrepancies in testimony. (CALJIC No. 2.21 (4th ed. 1979).) The instruction contains only a few general remarks on the topic;^{FN19} it does not even begin to convey to the jury the specific data on the eyewitness identification process that Dr. Shomer's testimony would have provided, a task that in any event is beyond the function of instructions. (Pen. Code, § 1127 ["Either party may present to the court any written charge on the law, but not with respect to matters of fact"].) Nor, again, is the ruling supported by the court's speculation that this testimony might tend to confuse the jurors. (5) Evidence that is relevant to the prime theory of the defense cannot be excluded in wholesale fashion merely because the trial would be simpler without it. Rather, it should be accompanied by instructions clearly explaining to the jury the purpose for which it is introduced. As noted above (fn. 11, *ante*), any excess in the quantity or complexity of such testimony can be controlled by the court's power to limit the presentation of evidence.

FN19 E.g., "Failure of recollection is a common experience; and innocent misrecollection is not uncommon. It is a fact, also, that two persons witnessing an incident or a transaction often will see or hear it differently."

(1d) Lastly, the ruling is not supported by the court's opinion that expert testimony on eyewitness identification is not yet "scientific enough" to be admissible. The court illustrated its point by referring to the general rule excluding lie-detector evidence. (See, e.g., *People v. Wochnick* (1950) 98 Cal.App.2d 124, 127-128 [219 P.2d 170].) The choice of words and example makes it clear the court was implicitly invoking the *Kelly-Frye* rule, i.e., the rule that evidence based on a new scientific method of proof is admissible only on a showing that the procedure has been generally accepted as reliable in the scientific community in which it developed. (*People v. Kelly* (1976) 17 Cal.3d 24 [130 Cal.Rptr. 144, 549 P.2d 1240]; *Frye v. United States* (D.C. Cir. 1923) 293 F. 1013 [34

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We are not persuaded, however, that the *Kelly-Frye* rule applies to expert testimony on eyewitness identification. (See *Cross-Racial Identification Errors*, p. 971; *Expert Psychological Testimony*, pp. 1021-1023.) It is important to distinguish in this regard between expert testimony and scientific evidence. When a witness gives his personal opinion on the stand - even if he qualifies as an expert - the jurors may temper their acceptance of his testimony with a healthy skepticism born of their knowledge that all human beings are fallible. But the opposite may be true when the evidence is produced by a machine: like many laypersons, jurors tend to ascribe an inordinately high degree of certainty to proof derived from an apparently "scientific" mechanism, instrument, or procedure. Yet the aura of infallibility *373 that often surrounds such evidence may well conceal the fact that it remains experimental and tentative. (*People v. Kelly*, *supra*, at p. 32, and cases cited.) For this reason, courts have invoked the *Kelly-Frye* rule primarily in cases involving novel devices or processes such as lie detectors, "truth serum," Nalline testing, experimental systems of blood typing, "voiceprints," identification by human bite marks, microscopic analysis of gunshot residue, and hypnosis (*People v. Shirley* (1982) 31 Cal.3d 18, 51-54 [181 Cal.Rptr. 243, 641 P.2d 775], and cases cited), and, most recently, proof of guilt by "rape trauma syndrome" (*People v. Bledsoe* (1984) 36 Cal.3d 236, 246-251 [203 Cal.Rptr. 450, 681 P.2d 291]). In some instances the evidence passed the *Kelly-Frye* test, in others it failed; but in all such cases "the rule serves its salutary purpose of preventing the jury from being misled by unproven and ultimately unsound scientific methods." (*Shirley*, *supra*, at p. 53.)

Here, by contrast, no such methods are in issue. We have never applied the *Kelly-Frye* rule to expert medical testimony, even when the witness is a psychiatrist and the subject matter is as esoteric as the reconstitution of a past state of mind or the prediction of future dangerousness, or even the diagnosis of an unusual form of mental illness not listed in the diagnostic manual of the American Psychiatric Association (*People v. Phillips* (1981) 122 Cal.App.3d 69, 86-87 [175 Cal.Rptr. 703] ("Munchausen's syndrome by proxy")). We see no reason to require a greater foundation when the witness is a qualified psychologist who will simply explain to the jury how certain

aspects of everyday experience shown by the record can affect human perception and memory, and through them, the accuracy of eyewitness identification testimony. Indeed, it would be ironic to exclude such testimony on *Kelly-Frye* grounds on the theory that jurors tend to be unduly impressed by it, when jurors are far more likely to be unduly impressed by the eyewitness testimony itself.

D.

(6) It remains true, of course, that "Where expert opinion evidence is offered, much must be left to the discretion of the trial court" (*People v. Cole*, *supra*, 47 Cal.2d 99, 105). Yet that discretion is not absolute: in various contexts it has been held that trial courts committed reversible error in excluding expert testimony. (E.g., *Brown v. Colm* (1974) 11 Cal.3d 639, 647 [114 Cal.Rptr. 128, 522 P.2d 688]; *People ex rel. Dept. Pub. Wks. v. Douglas* (1971) 15 Cal.App.3d 814, 820-822 [93 Cal.Rptr. 644]; *Varas v. Barco Mfg. Co.* (1962) 205 Cal.App.2d 246, 259-261 [22 Cal.Rptr. 737]; *Reynolds v. Natural Gas Equipment, Inc.* (1960) 184 Cal.App.2d 724, 739-740 [7 Cal.Rptr. 879]; *Burch v. Valley Motor Lines, Inc.* (1947) 78 Cal.App.2d 834, 840-844 [179 P.2d 47].) A recent decision of the Arizona *374 Supreme Court illustrates the kind of case in which the exclusion of expert testimony on psychological factors affecting eyewitness identification is a prejudicial abuse of discretion. (*State v. Chapple* (1983) 135 Ariz. 281 [660 P.2d 1208].) There the defendant was convicted of three counts of first degree murder. No direct or circumstantial evidence of any kind connected him with the crime other than the testimony of two eyewitnesses, and neither eyewitness had ever seen him before the events in question. The witnesses observed the crimes being committed, inter alia, by a man who had been introduced to them as "Dee." A few days later they were shown groups of photographs of acquaintances of a known participant. One of the witnesses tentatively identified a certain James Logan as "Dee"; although the defendant's photograph was in another of the displays, the witness did not identify it. More than a year later the witness was shown a further display that included a photograph of the defendant but none of Logan, and he identified the defendant as "Dee"; he was then shown the photograph of the defendant that he had previously failed to identify, but said he had no recollection of having seen it before. The other eyewitness then identified

the defendant as "Dee" from the later display, and both witnesses positively identified the defendant at trial.

The defendant presented seven witnesses who testified he was in another state on the date of the crimes. He also called psychologist Elizabeth Loftus, a nationally known expert on perception and memory, to testify to various psychological factors shown by the record that can affect the accuracy of eyewitness identification.^{FN20} The trial court excluded this testimony on the grounds that the information it sought to convey was within the common knowledge of the jurors and would be covered in cross-examination and closing arguments.

FN20 In addition to several of the matters that Dr. Shomer would have discussed in the case at bar, Dr. Loftus offered to testify on the phenomenon of the "forgetting curve," i.e., the tendency of memories to fade very rapidly at first, and then more slowly. She would also have explained "unconscious transfer," whereby a witness confuses a person seen in one situation with a different person seen in another, and the "feedback factor," whereby witnesses who discuss the case with each other after the event can unconsciously reinforce their confidence in their identifications. The eyewitnesses in *Chapple* were brother and sister, and had discussed the identity of "Dee."

The Arizona Supreme Court recognized that the admissibility of such testimony was in the first instance a matter of trial court discretion, but held that such discretion was abused on the record before it. The court began by rejecting claims that the testimony of Dr. Loftus would have "invaded the province of the jury," and pointed to an Arizona rule of evidence identical to our Evidence Code section 805. (*Id.* at p. 1219.) It further rejected claims that Dr. Loftus's testimony would have been prejudicial because the jury *375 might have given it undue weight, and that such testimony lacked probative value because it would not have included an opinion on whether the particular eyewitnesses in the case at hand were in fact mistaken in their identification. (*Ibid.*)

Turning to the key question of whether Dr. Loftus's testimony was a proper subject for expert opinion, the

court summarized that testimony (see fn. 20, *ante*) and declined to assume that the average juror would be aware of the information it contained. (*Id.* at p. 1221.) After reviewing the record, the court found that the testimony would have assisted the jury in deciding specific factual issues in the case. (*Id.* at pp. 1222-1223.) Finally, the court emphasized that the facts were close, the accuracy of the eyewitness identifications was a crucial issue, and the exclusion of Dr. Loftus's testimony "undercut the entire evidentiary basis" of the defendant's arguments on that issue. (*Id.* at p. 1222.)^{FN21} The court concluded (at p. 1224), "there were a number of substantive issues of ultimate fact on which the expert's testimony would have been of significant assistance. Accordingly, we hold that the order precluding the testimony was legally incorrect and was unsupported by the record. It was, therefore, an abuse of discretion." Holding the error to be prejudicial on the facts, the court reversed the judgment.

FN21 The court also rejected any claim that admission of this expert testimony would have consumed an undue amount of time, "since time spent on the crucial issue of the case can not be considered as 'undue' loss of time." (*Ibid.*)

(1e) In the case at bar a similar analysis leads to a like result. Here, too, the expert witness was undoubtedly qualified to testify on the particular matters he proposed to address.^{FN22} Like the Arizona Supreme Court, we decline to assume that the subject matter of Dr. Shomer's testimony would have been fully known to the jurors; rather, the professional literature persuades us to the contrary. Also as in *Chapple*, the record establishes that Dr. Shomer's testimony would have been of significant assistance to the jury. Because no other evidence connected defendant with the crime, the crucial factor in the case was the accuracy of the eyewitness identifications. Yet on that issue the evidence was far from clear. As we noted at the outset, in the testimony of each of the witnesses who identified defendant in the courtroom there were elements that could have raised reasonable doubts as to the accuracy of the identification. These elements included the suddenness and unexpectedness of the event, discontinuity and other difficulty of observation, fear and other stress at the time of perception, overestimation of the *376 duration of the event, "feedback" factors following the

event, failure or uncertainty of several witnesses in selecting defendant's photograph from police displays, and, particularly important, apparent cross-racial identification discrepancies. Further doubts could have arisen from the dramatic declaration in open court by a prosecution eyewitness that defendant was *not* the perpetrator, and from the testimony of six witnesses that defendant was not in the state on the day the crime was committed.

FN22 Not all psychologists, of course, have the special knowledge, experience, or training to qualify as experts on psychological factors affecting eyewitness identification - any more than all psychiatrists are qualified as experts, for example, on the "Munchausen syndrome by proxy." (See *People v. Phillips* (1981) *supra*, 122 Cal.App.3d 69, 85.) In the case at bar, Dr. Shomer's relevant expertise was both demonstrated by defendant and impliedly conceded by the prosecution.

In these circumstances the exclusion of Dr. Shomer's testimony undercut the evidentiary basis of defendant's main line of defense - his attack on the accuracy of the eyewitness identifications - and deprived the jurors of information that could have assisted them in resolving that crucial issue. The ruling excluding such testimony was therefore unsupported by the record. We have previously shown (Part I C, *ante*) that it was unsupported by the law. It follows that the ruling constituted an abuse of discretion.

(7) An error in excluding expert testimony may be found harmless. (E.g., *Majetich v. Westin* (1969) 276 Cal.App.2d 216, 218-219 [80 Cal.Rptr. 787].) (1f) In the case at bar, however, the record compels us to conclude that the error was prejudicial. As we have seen, the issue affected by the ruling was crucial, given the absence of any other evidence connecting defendant with the crime; and the evidence on that issue was close, given the potential weaknesses in the prosecution's testimony and the presence of both eyewitness and alibi testimony favorable to the defense. ^{FN23} An error that impairs the jury's determination of an issue that is both critical and closely balanced will rarely be harmless. Rather, after an examination of the whole record we find it reasonably probable that a result more favorable to defendant would have been reached in the absence of this error.

(*People v. Watson* (1956) 46 Cal.2d 818, 836 [299 P.2d 243].) There has therefore been a miscarriage of justice, and the judgment must be reversed. (Cal. Const., art. VI, § 13.) *377

FN23 Indeed, the closeness of the matter was dramatically illustrated by the course of the trial itself. The People's case was relatively uncomplicated: there was only one victim, one perpetrator, and essentially one crime, a robbery-murder. The defense was equally simple: defendant was in Alabama when the crime occurred. Apparently for these reasons, the trial was unusually brief for a capital case: the prosecution put on its entire case-in-chief in only four and a quarter hours, the defense took merely ninety-six minutes, and no rebuttal was offered. The main question to be answered by the jury was also relatively uncomplicated: were defendant and the black gunman the same person? Nevertheless, the jurors proceeded to deliberate for a total of 19 1/2 hours over a period of 6 days, before reaching their verdict of guilty. When jurors deliberate in these circumstances for more than three and a half times longer than it took to put on the entire prosecution and defense case, we may fairly infer they found the issue difficult to decide. (Cf. *People v. Rucker* (1980) 26 Cal.3d 368, 391 [162 Cal.Rptr. 13, 605 P.2d 843]; *People v. Woodard* (1979) 23 Cal.3d 329, 341 [152 Cal.Rptr. 536, 590 P.2d 391].)

(8) We reiterate that the decision to admit or exclude expert testimony on psychological factors affecting eyewitness identification remains primarily a matter within the trial court's discretion; like the court in *Chapple*, "we do not intend to 'open the gates' to a flood of expert evidence on the subject." (660 P.2d at p. 1224.) We expect that such evidence will not often be needed, and in the usual case the appellate court will continue to defer to the trial court's discretion in this matter. ^{FN24} Yet deference is not abdication. When an eyewitness identification of the defendant is a key element of the prosecution's case but is not substantially corroborated by evidence giving it independent reliability, and the defendant offers qualified expert testimony on specific psychological factors shown by the record that could have affected the accuracy of the identification but are not likely to be

fully known to or understood by the jury, it will ordinarily be error to exclude that testimony.

FN24 Even when the trial court correctly excludes such testimony, the defendant may be entitled to a special instruction specifically directing the jury's attention to other evidence in the record - e.g., facts developed on cross-examination of the eyewitnesses - that supports his defense of mistaken identification and could give rise to a reasonable doubt of his guilt. (See *People v. Hall* (1980) 28 Cal.3d 143, 158-160 [167 Cal.Rptr. 844, 616 P.2d 826]; *People v. Palmer* (1984) 154 Cal.App.3d 79, 85-89 [203 Cal.Rptr. 474]; *People v. Aho* (1984) 152 Cal.App.3d 658, 661-663 [199 Cal.Rptr. 671]; *People v. West* (1983) 139 Cal.App.3d 606, 608-610 [189 Cal.Rptr. 36].) The proper wording of such an instruction remains unsettled, however, and we express no view on the question here.

II. Other Issues

Defendant makes other contentions relating to the guilt and penalty phases that are not likely to arise on retrial. Because of the unusual posture of the case after the jury's verdict, however, we address certain contentions dealing with the crimes for which defendant may be prosecuted on such retrial.

A. Robbery

(9) The jury acquitted defendant of the robbery charged in count II of the information. Penal Code section 1023 unequivocally provides that when a defendant is acquitted of an offense, that acquittal "is a bar to another prosecution for the offense charged ..., or for an attempt to commit the same, or for an offense necessarily included therein, of which he might have been convicted under that accusatory pleading." (See also *Stone v. Superior Court* (1982) 31 Cal.3d 503, 510 [183 Cal.Rptr. 647, 646 P.2d 809].) Thus, *378 on retrial, double jeopardy considerations will bar any further prosecution of defendant for robbery or attempted robbery. ^{FN25}

FN25 Although the jury was instructed on attempts in general (CALJIC No. 6.00 (4th ed. 1979)), there was no specific instruction

concerning attempted robbery and informing the jury that if it was not satisfied beyond a reasonable doubt that defendant was guilty of the robbery, he could be found guilty of any lesser included offense shown by the evidence, and that attempted robbery is a lesser included offense of robbery. (See CALJIC No. 17.10.) The evidence here would have supported a *sua sponte* instruction on attempted robbery as a lesser included offense of robbery; the failure to so instruct was yet another complication among the many that plague this case.

As a result of this omission, the jury may not have realized that if it acquitted defendant of robbery it could consider his guilt of the lesser included offense of attempted robbery. Nevertheless, the acquittal of defendant for the robbery operates as an acquittal of all lesser included offenses including attempted robbery, and therefore bars retrial of defendant on these charges.

B. Special Circumstance

The determination that double jeopardy considerations prohibit retrial of defendant for robbery or attempted robbery also precludes the prosecution from retrying him on the robbery special circumstance allegation. Penal Code section 190.4, subdivision (a), provides in relevant part that "Whenever a special circumstance requires proof of the commission or attempted commission of a crime, such crime shall be charged and proved pursuant to the general law applying to the trial and conviction of the crime." Future prosecution of defendant on the underlying robbery is barred by the double jeopardy clause because defendant has been acquitted of that crime and impliedly of any lesser included offenses; accordingly, the statutory prerequisite to a finding of robbery special circumstance, i.e., charging and proving a robbery or attempted robbery, cannot be met and defendant cannot be retried on that special circumstance.

We recognize that in *People v. Robertson* (1982) 33 Cal.3d 21, 47 [188 Cal.Rptr. 77, 655 P.2d 279], and *People v. Velasquez* (1980) 26 Cal.3d 425, 434, footnote 6 [162 Cal.Rptr. 306, 606 P.2d 341], we held that failure to separately charge the underlying felony was not prejudicial error. In both decisions, however,

the focus was on prejudice, not on the error itself; both noted that the statutory requirement was not met and that the omission was in fact error. They held that the error was not prejudicial because the defendant was put on notice by the special circumstance allegation that he was required to defend against the underlying crime. The situation here is completely different. In *Velasquez* and *Robertson* there was no legal impediment to charging the underlying crime; by contrast, in the present case the prosecution may not recharge defendant with robbery or any lesser included offense without violating double jeopardy protections, and hence may not *379 retry defendant on the special circumstance allegation predicated on that crime.

C. Murder

(10) Defendant contends that the jury's failure to specify the degree of murder in its verdict renders his conviction second degree murder by operation of law. (Pen. Code, § 1157.) Although the issue is not likely to arise on retrial in this precise factual form, the effect of the jury's action may well be to bar the prosecution of defendant for a crime greater than second degree murder because of double jeopardy considerations. For this reason we inquire into the matter in some detail.

Defendant was charged with the crime of murder in the usual manner, i.e., without specification of degree. (Pen. Code, § 187; see also § 951.) The jury was instructed that "Before you may return a verdict in this case, you must agree unanimously not only as to whether the defendant is guilty or not guilty, but also, if you should find him guilty of an unlawful killing, you must agree unanimously as to whether he is guilty of *murder of the first degree*." (Italics added; CALJIC No. 8.74 (1976 rev.)) The jury was also instructed with respect to the special circumstance that "If you find the defendant guilty of *murder in the first degree*, you must then determine if the murder was committed under the following special circumstance, while engaged in the commission or the attempted commission of a robbery." (Italics added; CALJIC No. 8.80 (4th ed. 1979.)) The jury returned the following verdict: "We, the jury in the above-entitled action, find the Defendant Eddie Bobby McDonald, guilty of *MURDER*, in Violation of Section 187 Penal Code, a felony, *as charged in Count I of the information*." (Italics added.) The jury was

polled and the verdict was recorded and filed.

Three and a half weeks later, the jury was reconvened for the penalty phase. ^{FN26} At that time, the court submitted a new guilty verdict form to the jury and explained that because of inadvertence or mistake there had been an omission in the original verdict form. The new form added the phrase, "and we further find it to be murder of the first degree, to be true/not true." The jury deliberated briefly and returned a finding of first degree murder on this form.

FN26 The delay between the guilt and penalty phases was caused by defendant's effort to obtain a writ of prohibition from the Court of Appeal. He sought to prohibit the court from going forward with the penalty phase because of the inconsistency in the verdict between the acquittal on the robbery charge and the affirmative finding on the robbery special circumstance allegation.

Defendant contends that because the jury failed to specify the degree of murder in its original verdict, the degree of the crime was fixed at second *380 degree murder by operation of law. Penal Code section 1157 provides that "Whenever a defendant is convicted of a crime or attempt to commit a crime which is distinguished into degrees, the jury ... must find the degree of the crime or attempted crime of which he is guilty. *Upon the failure of the jury ... to so determine, the degree of the crime or attempted crime of which the defendant is guilty, shall be deemed to be of the lesser degree.*" (Italics added.)
FN27

FN27 A parallel provision appears in Penal Code section 1192: "Upon a plea of guilty, or upon conviction by the court without a jury, of a crime or attempted crime distinguished or divided into degrees, the court must, before passing sentence, determine the degree. Upon the failure of the court to so determine, the degree of the crime or attempted crime of which the defendant is guilty, shall be deemed to be of the lesser degree."

Respondent insists that because the statute requires only that the jury "find" the degree of the crime and does not mandate any specific procedure for so do-

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ing, a determination of degree can be inferred from the jury's separate finding on the special circumstance allegation. Respondent stresses that the jury was instructed to determine whether or not the special circumstance was true only if it found defendant guilty of first degree murder; because the jury found the special circumstance true, respondent reasons, it must have found first degree murder as well.

This precise contention has been rejected in a long line of decisions which require that the degree be explicitly specified by the verdict. (*People v. Dixon* (1979) 24 Cal.3d 43, 51-52 [154 Cal.Rptr. 236, 592 P.2d 752]; *People v. Flores* (1974) 12 Cal.3d 85, 94-95 [115 Cal.Rptr. 225, 524, P.2d 353]; *People v. Beamon* (1973) 8 Cal.3d 625, 629, fn. 2 [105 Cal.Rptr. 681, 504 P.2d 905]; *People v. Thomas* (1978) 84 Cal.App.3d 281, 285 [148 Cal.Rptr. 532]; *People v. Baeske* (1976) 58 Cal.App.3d 775, 778, fn. 1 [130 Cal.Rptr. 35]; *People v. Doran* (1974) 36 Cal.App.3d 592 [111 Cal.Rptr. 793]; *People v. Cox* (1973) 33 Cal.App.3d 378, 381-382 [109 Cal.Rptr. 43]; *People v. Fernandez* (1963) 222 Cal.App.2d 760, 769 [35 Cal.Rptr. 370]; *People v. Hughes* (1959) 171 Cal.App.2d 362, 369-370 [340 P.2d 679]; see also *In re Candelario* (1970) 3 Cal.3d 702, 706, fn. 2 [91 Cal.Rptr. 497, 477 P.2d 729].)

In *Beamon*, for example, the defendant was convicted of robbery; an allegation that the defendant was armed with a deadly weapon at the time of the commission of the crime was found to be true. The jury, however, failed to fix the degree of the crime. We held that despite the jury's finding on the arming allegation, its failure to specify the degree of the crime required that the conviction be deemed to be of the second degree. (8 Cal.3d at p. 629, fn. 2.) "We cannot assume, contrary to the clear legislative direction, that because a factual finding was made which would have warranted *381 a determination of first degree robbery, the jury unmistakably intended [citation] to make that determination when it refrained from *expressly fixing the degree*." (*Ibid.*; italics added.)

Further support for defendant's position on this point is found in our opinion in *Dixon*, in which we comprehensively reviewed the historical development of section 1157. As we noted in *Dixon*, throughout its history the statute has been applied in cases in which the "failure" of the jury to determine the degree of crime "consisted in an omission to perform that func-

tion because of mistake or inadvertence or in circumstances suggesting an intended act of leniency." (24 Cal.3d at pp. 51-52.) The rule is thus firmly established that the statute applies whenever the jury neglects to explicitly specify the degree of the crime.
 FN28

FN28 It does not, however, extend to situations in which the jury expressly disagrees on the matter of degree. (*Id.* at p. 52.)

People v. Hughes, supra, 171 Cal.App.2d 362, presents a factual situation almost identical to that before us. In *Hughes*, the defendant was charged with first degree murder in a capital case. The verdict form returned by the jury found him guilty of murder "as charged in the information"; this verdict was received and entered in the minutes. The jury was then released and told to return the next morning to consider the issue of penalty. At the outset of the penalty phase, the court inquired of the jury whether it understood that "guilty as charged in the information" referred to a charge of murder in the first degree; the foreman responded affirmatively. After evidence was taken at the penalty phase, the court informed the jurors that because of technical legal requirements the verdict fixing the degree had to be in writing. It therefore submitted a supplemental verdict form as to the degree of the crime, and the jury fixed the degree at first degree murder.

The appellate court held that the second verdict was invalid because it essentially constituted a resubmission of the issue of degree to the jury. (171 Cal.App.2d at p. 369.)^{FN29} The court concluded that after the original verdict "had been received and the jury had been released that verdict under the provisions of the code section was a verdict of second degree murder. Of that crime and of that crime only has appellant been convicted and by that verdict he had been acquitted of first degree murder. ... So far as the jury was concerned it ended the trial on the issue of guilt. That being so, it results that all proceedings thereafter were nullities. There was no issue of penalty for the jury to determine. ... Therefore the trial of the appellant *382 was complete and the court had no jurisdiction to recall the jury for further proceedings." (*Id.* at p. 370.)

FN29 Respondent appears to concede that the trial court's attempt to "correct" the error

in the verdict in the present case by resubmitting a modified form at the outset of the penalty phase similarly failed to cure the original defect.

These decisions illustrate the rule that the statute applies to reduce the degree even in situations in which the jury's intent to convict of the greater degree is demonstrated by its other actions, i.e., by signing a subsequent verdict form (*Hughes*) or making a finding on an enhancement (*Beamon*). Contrary to respondent's assertion, the key is not whether the "true intent" of the jury can be gleaned from circumstances outside the verdict form itself; instead, application of the statute turns only on whether the jury specified the degree in the verdict form. In the present case the verdict form failed to specify the degree; in the absence of such specification, the jury's finding on the special circumstance allegation is irrelevant and the conviction must be deemed second degree murder as a matter of law pursuant to the unambiguous language of section 1157.

Respondent contends further that because the jury was instructed solely on first degree murder, any verdict of guilt on the murder charge could only be in the first degree. The jury was instructed that before it could return a verdict of guilt on the murder charge, it must unanimously agree on whether defendant was guilty of murder of the first degree. Thus, respondent submits, the jury's verdict of guilty of murder "as charged" constituted an implied finding of first degree murder.

While respondent is correct that the jury was not instructed on the lesser included offense of second degree murder,^{FN30} we see no reason why this variation in the facts should lead to a different result. First, the terms of the statute are unambiguous. No special exception is created for the situation presented by this case; had the Legislature chosen to make section 1157 inapplicable to cases in which the jury was instructed on only one degree of a crime, it could easily have so provided. The statute requires that "if the jury shall find the defendant guilty, the verdict shall specify the degree of murder It establishes a rule to which there is to be no exception, and the Courts have no authority to create an exception when the statute makes none." (*People v. Campbell* (1870) 40 Cal. 129, 138.)

FN30 Defendant challenges as error the court's failure to instruct *sua sponte* on the lesser included offenses of second degree murder and voluntary manslaughter. Our disposition of the case renders it unnecessary to discuss the merits of this claim.

Furthermore, prior applications of the statute suggest no rationale for excepting this case from the plain language of section 1157. As we have noted, this is not the first case in which the statute compels the court to deem the crime to be of the lesser degree despite indications that the jury's *383 failure to specify degree was not intentional but resulted from mistake or inadvertence. (See, e.g., *People v. Hughes, supra*, 171 Cal.App.2d at pp. 369-370.)

In fact, this court in *Campbell* was faced with a dilemma similar to that which respondent asserts exists in the present case. In *Campbell*, the People claimed that because the facts alleged in the indictment would support only a conviction of first degree and not of second degree murder, the failure of the jury to specify the degree did not require reversal. The court rejected this contention, stating that "We have no right to disregard a positive requirement of the statute, as it is not our province to make laws, but to expound them." (40 Cal. at p. 138.) In interpreting the statutory provision which then required that the jury "designate" (rather than the equivalent current term "find") the degree of the crime, the court stated: "The word 'designate,' as here employed, does not imply that it will be sufficient for the jury to intimate or give some vague hint as to the degree of murder of which the defendant is found guilty; but it is equivalent to the words 'express' or 'declare,' and it was evidently intended that the jury should expressly state the degree of murder in the verdict so that nothing should be left to implication on that point. ... [T]he very letter of the statute ... requires the jury to 'designate,' or in other words, to express or declare by their verdict the degree of the crime. However absurd it may, at the first blush, appear to be to require the jury to designate the degree of the crime, when it appears on the face of the indictment that the offense charged has but one degree, there are plausible and, perhaps, very sound reasons for this requirement. ... But whatever may have been the reasons for this enactment, it is sufficient for the Courts to know that the law is so written and it is their duty to enforce it." (*Id.* at pp. 139-140.)

(11) (See fn. 31.) Respondent's attempt to distinguish the present case on this basis must therefore fail, and it must be deemed as a matter of law that defendant was convicted of second degree murder. (See also *People v. Johns* (1983) 145 Cal.App.3d 281, 294-295 [193 Cal.Rptr. 182].) ^{FN31} *384

FN31 We do not decide at this time the question whether double jeopardy principles will bar retrial of defendant on a charge greater than second degree murder. First, the question has not been raised by the parties, and its answer is not immediately obvious. In the usual case a defendant is convicted by the trier of fact of a lesser degree of the crime charged and the judgment is reversed on appeal; in that event it has long been held that the defendant cannot be retried on the greater degree because of the double jeopardy clause. (*Green v. United States* (1957) 355 U.S. 184 [2 L.Ed.2d 199, 78 S.Ct. 221, 61 A.L.R.2d 1119]; *Gomez v. Superior Court* (1958) 50 Cal.2d 640 [328 P.2d 976].) Here defendant's conviction of the lesser degree follows not from a finding of the trier of fact but by operation of law. Whether the same prohibition against retrial on the greater degree applies in such circumstances may require weighing a number of policy considerations that have not been briefed and argued on this appeal.

Second, the issue will not be presented on retrial unless the prosecution seeks a first degree murder conviction. But the prosecution's sole theory of first degree murder at trial was felony murder; given the jury's acquittal of defendant on the robbery charge and thus its implied acquittal on attempted robbery, the prosecution may be hard put to prove an underlying felony. If the prosecution limits itself to a maximum charge of second degree murder on retrial, the double jeopardy issue will manifestly not arise. Finally, as a general rule, the burden is on the defendant to enter a plea of double jeopardy at the appropriate time and to present a basis for the plea.

The judgment is reversed.

Bird, C. J., Kaus, J., Broussard, J., Reynoso, J., and Grodin, J., concurred.

On December 20, 1984, the opinion was modified to read as printed above. *385

Cal.

People v. McDonald

37 Cal.3d 351, 690 P.2d 709, 208 Cal.Rptr. 236, 46 A.L.R.4th 1011

END OF DOCUMENT

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(Cite as: 27 Misc.3d 322, 898 N.Y.S.2d 772)

Ratner v. McNeil-PPC, Inc.
27 Misc.3d 322, 898 N.Y.S.2d 772
NY,2010.

27 Misc.3d 322898 N.Y.S.2d 772, 2010 WL 366641,
2010 N.Y. Slip Op. 20023

Margalit Ratner, Plaintiff
v
McNeil-PPC, Inc., Defendant.
Supreme Court, Kings County

January 19, 2010

CITE TITLE AS: Ratner v McNeil-PPC, Inc.

HEADNOTE

Evidence
Scientific Evidence
Admissibility of Expert Testimony That Normal
Dosages of Acetaminophen Cause Cirrhosis of Liver

Plaintiff's supporting materials, consisting of the affidavits of various experts, failed to satisfy the evidentiary requirements of the *Frye* standard and were thus inadmissible to prove that plaintiff developed cirrhosis of the liver from ingesting acetaminophen at normal dosages. To be admissible under *Frye*, a scientific theory must incorporate methodology, technique, and conclusions that are basically accepted within the scientific community. There was no acceptance within the scientific community of the novel theory that ingestion of acetaminophen at normal dosages causes cirrhosis, and plaintiff failed to introduce any studies, peer articles, professional literature, judicial opinions or recognized textbooks that supported the theory.

RESEARCH REFERENCES

Am Jur 2d, Expert and Opinion Evidence §§ 29, 221, 223.

Carmody-Wait 2d, Presentation of the Case §§ 56:132-56:134, 56:139.

NY Jur 2d, Evidence and Witnesses §§ 639, 644, 658-662, 679, 680, 729, 730.

ANNOTATION REFERENCE

See ALR Index under Cirrhosis; Expert and Opinion Evidence; Frye Test.

FIND SIMILAR CASES ON WESTLAW

Database: NY-ORCS

Query: expert /2 testimony /6 preclud! & frye /2 standard /s support!

APPEARANCES OF COUNSEL

Dechert, LLP, New York City (*Debra D. O'Gorman* of counsel), for defendant. *Weitz & Luxenberg*, New York City (*Lawrence Goldhirsch* of counsel), for plaintiff.

OPINION OF THE COURT

Leon Ruchelsman, J.

*323 The defendant has filed a motion seeking to preclude the expert testimony offered by the plaintiff and for summary judgment pursuant to CPLR 3212 on the grounds that the plaintiff cannot succeed on the claims alleged. The plaintiff opposes the motion seeking preclusion and has cross-moved seeking summary judgment arguing that there is no dispute that the plaintiff is entitled to judgment. Papers were submitted by both parties and arguments held. After reviewing the papers of the parties, including the medical affidavits submitted this court now makes the following determination.

Background

This lawsuit was filed against the defendant, the maker of Tylenol, alleging that normal dosage ingestion of Tylenol, and specifically acetaminophen, a significant component of Tylenol, caused her to develop cirrhosis of the liver which required a liver transplant in 2004. Following the exchange of significant medical discovery both parties move seeking summary judgment. The defendant presents essentially two arguments why the case should be dismissed. The first is that the plaintiff did not suffer from cirrhosis of the liver and that any case reports

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connecting cirrhosis and ingestion of acetaminophen, even if true and scientifically sound, are completely irrelevant. Moreover, the defendant argues that there is no scientifically acceptable evidence linking cirrhosis and acetaminophen and the plaintiff will simply be unable to prove this necessary causative element at trial. The plaintiff disputes both of these contentions and argues that the medical evidence submitted sufficiently demonstrates the causal link between acetaminophen and cirrhosis and that at least a *Frye* hearing should be held to further explore the issue.

Conclusions of Law

Summary judgment may be granted where the movant establishes sufficient evidence which would compel the court to grant judgment in his or her favor as a matter of law (*Zuckerman v City of New York*, 49 NY2d 557 [1980]). Summary judgment would thus be appropriate where no right of action exists foreclosing the continuation of the lawsuit.

It is well settled that expert testimony which involves novel scientific theories or techniques will be admissible at trial only upon a showing that such theories and such techniques are generally accepted within the scientific community (*Frye v United States*, 293 F 1013 [DC Cir 1923]). As the court explained in *People v Wesley* (83 NY2d 417, 422 [1994]) "the test pursuant to *Frye v United States* (293 F 1013) poses the more elemental question of whether the accepted techniques, when properly performed, generate results accepted as reliable within the scientific community generally." Thus, the conclusion reached need not be a consensus opinion since "general acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions" (*Zito v Zabarsky*, 28 AD3d 42, 44 [2d Dept 2006]).

These principles are equally applicable in cases such as the one at bar which concern a plaintiff attempting to prove that a certain drug caused a certain medical condition. To permit the medical expert evidence necessary to prove causation the plaintiff must submit relevant scientific data or studies showing such causal link (*Hooks v Court St. Med., P.C.*, 15 AD3d 544 [2d Dept 2005]). Therefore, in *Blackwell v Wyeth*

(408 Md 575, 971 A2d 235 [Ct App 2009]) the court excluded expert testimony linking certain vaccines with autism finding that the tests conducted to prove that causal connection were methodologically flawed and unreliable. Similarly, in *Ruggiero v Warner-Lambert Co.* (424 F3d 249 [2d Cir 2005]), the court did not permit expert testimony seeking to establish a causal link between the ingestion of the drug Rezulin and cirrhosis of the liver since the court found there was no evidence to support such a link. The court held that the only link consisted of the plaintiff's doctor's opinion based upon a differential diagnosis, in other words a process of elimination identifying the most likely cause from a list of possible causes. The court concluded that basis was insufficient to permit introduction of that medical testimony.^{FN*}

Again, in *Shepard v Barnard* (949 So 2d 232, 32 Fla L Wkly D217 [Dist Ct App 2007]) the court refused to permit expert testimony linking the drug Verteporfin with photoallergy. In that case the only evidence linking the two was the testimony of *325 the doctor who based his opinion solely upon the "temporal relationship" between ingesting the drug and contracting the illness. The court held such scientific evidence failed to satisfy the *Frye* standard and excluded the evidence. New York cases likewise exclude scientific evidence where the methodology or techniques utilized are not accepted within the scientific community. In *Selig v Pfizer, Inc.* (290 AD2d 319 [1st Dept 2002]) the court excluded testimony demonstrating a link between the drug Viagra and heart attacks. The court found that studies were not conducted with Viagra itself but a similar drug with important medical differences. Moreover, a study submitted on the subject did not draw any conclusions about the connection between Viagra and cardiac failure, only that further study was required. The court held such medical information insufficient to demonstrate causality and consequently the medical evidence was excluded. Similarly, in *Kaczor v Vanchem, Inc.* (262 AD2d 1041 [4th Dept 1999]) the court excluded expert testimony that chemical exposure caused chronic fatigue syndrome. The only evidence supporting such a link between the two was evidence from a doctor that fumes from chemical exposure cause increased liver enzyme levels which can cause chronic fatigue syndrome and that plaintiff had such increases in liver enzyme levels after the incident with the fumes. However, the doctor did not offer any basis to substantiate the assertion that high enzyme levels are caused by chemical fumes. With-

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out any basis the evidence was excluded. Once again, in *Lewin v County of Suffolk* (18 AD3d 621 [2d Dept 2005]) the court excluded expert testimony attempting to link certain pesticides with birth defects. The court noted that the methodology used by the experts was speculative.

While the particular deficiencies which prompted the courts to exclude the expert evidence varied from case to case there was one overarching principle that underscored them all. In all the cases the methods utilized by the experts were not accepted within the scientific community and hence did not satisfy the *Frye* test.

These cases must be contrasted with those that held expert testimony admissible under *Frye* seeking to prove that a certain drug caused a specific injury. Thus, in *Rodriguez ex rel. Posso-Rodriguez v Feinstein* (793 So 2d 1057, 26 Fla L Wkly D1813 [Dist Ct App 2001]) the court permitted expert testimony linking exposure to certain drugs in utero as a cause of birth defects. Specifically, in that case the defendant prescribed the antifungal *326 drug Sporanox to treat a toenail fungus infection to a pregnant woman. When the child was born with an eye defect the doctor was sued for malpractice. Expert evidence was sought to be introduced linking ingestion of Sporanox as a cause for the birth defects. The conclusion of the three experts was based upon seven factors enumerated by the court. They included

“(1) the timing and duration of the exposure to the drug; (2) the lingering effect of the drug in the system even after the patient stops taking it due to the drug's lipophilic aspect (attraction to the fatty tissue); (3) the drug's molecular weight which is small enough to be transferred through the placenta; (4) the Federal Drug Administration's classification of the drug as a category C drug, teratogenic in animals; (5) the manufacturer's package insert which warns against taking this particular drug during pregnancy; (6) animal studies which have shown the drug to cause birth defects; and (7) the statistical increase in birth defects according to FDA adverse reaction reports.” (*Id.* at 1058-1059.)

The court concluded that the scientific views expressed by plaintiff's experts were accepted within the scientific community and the fact the conclusions differed from those of defendant's experts did not mean they were unreliable. Thus, the court admitted

the expert testimony.

However, an important clarification of the *Frye* standard was developed in *Nonnon v City of New York* (32 AD3d 91 [1st Dept 2006]) and cases which followed. In that case the court conceded that epidemiological studies were not novel and hence did not require *Frye* analysis. The court defined epidemiology as “a science which focuses on the question of general causation (i.e., is the [landfill] capable of causing disease?) rather than that of specific causation (i.e., did [the landfill] cause disease in a particular individual?)” (*id.* at 112 [internal quotation marks and citations omitted]). Thus, “this field of science is the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease” (*id.* at 104 [internal quotation marks and citations omitted]). The court found that the experts engaged in standard scientific procedure and methodology and reached acceptable conclusions. Therefore, the court permitted expert evidence linking carcinogens found at a landfill causing injuries to plaintiffs. In *Marso v Novak* (42 AD3d 377 [1st Dept 2007]) the court refined its earlier pronouncement in *Nonnon*. In *Marso*, *327 the plaintiff suffered a stroke and sued his doctor claiming the stroke was caused by a slow heart rate (bradycardia) which his doctor failed to address. Indeed, the plaintiff sought to introduce expert testimony that the stroke was caused by bradycardia, although the expert conceded that there was no acceptance within the scientific community that a stroke is a risk factor of bradycardia. The conclusion reached by the expert was therefore, based upon a differential diagnosis, a process of elimination which excludes all other causes. The court rejected the reading of *Nonnon* as permitting the introduction of any expert evidence provided the methodology is acceptable. The court stated that the

“[p]laintiff interprets *Nonnon* to mean that generally accepted methodology such as differential diagnosis when properly performed leads to admissible expert conclusions. This case prompts us to add ‘but not when there is a generally or widely held view in the scientific community rejecting such conclusions outright.’ In this case, plaintiff's expert's own unambiguous answer at trial was that the result generated, which purportedly confirmed the expert's initial theory, was not accepted in the medical community.” (*Id.* at 378.)

Thus, methodology, standing alone cannot confer acceptance. What *Frye* demands is a scientific “theory” which incorporates methodology, technique and conclusions which are basically accepted within the scientific community. As noted, there need not be an overwhelming consensus regarding the conclusions reached, but if the conclusions are not deemed acceptable within the scientific community, methodology alone will not satisfy the requirements of *Frye*.

Applying those principles to this case, therefore, requires an examination of the evidence presented by the parties. The defendant satisfied its burden demonstrating that there is no scientific evidence linking acetaminophen with cirrhosis. Such evidence consists of an affidavit of Dr. Howard Worman, an expert in the field of hepatology, wherein he states that there are no scientific peer studies that link acetaminophen with cirrhosis. He further states that indeed there is no evidence linking the two and that the experts supplied by the plaintiff purporting to do just that are flawed and without acceptance within the scientific community.

In opposition, the plaintiff has submitted various expert affidavits that will now be examined. Plaintiff submitted an affidavit*328 from Dr. Douglas Dieterich, a hepatologist. He stated that there is no dispute concerning the hepatotoxicity of acetaminophen. That means there is no dispute that acetaminophen has the ability to cause liver cell death. However, he cautioned that it is dose-dependant and that its toxic effects can only be manifested at doses greater than those recommended for standard use. Indeed, Dr. Dieterich cited to a recent notice promulgated by the Food and Drug Administration conceding that there is scientific agreement that ingestion of acetaminophen could lead to liver disease. The Food and Drug Administration noted that there is little agreement concerning the “specific threshold dose for toxicity” and in conformance with the findings recommended a reduction of the daily adult dosage from 4,000 milligrams per day to 3,250 milligrams per day. Thus, Dr. Dieterich concluded that there is no disagreement that acetaminophen can cause liver disease. Dr. Dieterich further opined that whether the liver disease is acute or chronic does not have any bearing upon the cause of the disease and is thus only a function of its duration and that long-term exposure to toxins or other drugs can cause cirrhosis. Further, Dr. Dieterich explained that this conclusion is not

new but has been recognized for many years. Further, Dr. Dieterich introduced numerous case studies all purporting to show that the ingestion of acetaminophen can cause cirrhosis. Lastly, Dr. Dieterich stated that a differential diagnosis of the plaintiff leads to the conclusion that the ingestion of acetaminophen caused the cirrhosis.

However, as noted, there must be acceptance of this theory within the scientific community. As the court stated in *Matter of Neurontin Prod. Liab. Litig.* (24 Misc 3d 1215[A], 2009 NY Slip Op 51459[U], *7 [Sup Ct, NY County 2009]) “[a]n expert opinion on causation will be excluded where it is unsupported by any scientific studies or medical literature or where the literature is plainly insufficient to support the opinion.” There are no studies or medical literature which conclude that the ingestion of normal doses of acetaminophen causes cirrhosis. There are numerous studies and a reasonable medical consensus that doses greater than the recommended daily dosage can cause cirrhosis. Thus, Dr. Dieterich attempts to draw a medical parallel between proper doses and greater doses of acetaminophen to conclude that acetaminophen causes cirrhosis. However, that theory is not accepted within the scientific community.

First, it is widely agreed that ingestion within the recommended dosages is safe. Dr. Dieterich himself agrees with this *329 assessment. He states “acetaminophen is known to be a dose-dependent (or overt) hepatotoxin, whose acutely toxic effects can be seen at doses that are only slightly greater than recommended therapeutic doses” (see affidavit of Dr. Dieterich ¶ 9). Dr. Dieterich attempted to prove that the recommended dosage was too high citing the Food and Drug Administration's notice reducing the daily recommended dosage. However, the Food and Drug Administration did not conclude the dosage was too high because that dosage caused liver disease and had to be lowered to preserve the health of people ingesting acetaminophen. In fact, the notice conceded the recommended dosage as safe. The notice states that “taking more than the recommended amount [of acetaminophen] can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death.” Thus, admitting that taking more than the recommended dosage could prove fatal, the notice recounts the reality that such overdoses nevertheless take place. The notice explains that overdosing can occur for a number of rea-

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sons and detailed six distinct reasons why an overdose can occur. The first reason cited was the fact such overdoses were inadvertent. The notice further explained that tests revealed that even slight overdoses could prove unsafe and cited a study that found liver injury could occur where the doses were increased to between 5 and 7 1/2 grams per day while the recommended amount was four grams per day. Thus, "recommended doses and table strengths of acetaminophen leave little room for error." Another reason cited is that acetaminophen is found in so many products and someone ingesting multiple products that contain acetaminophen could potentially ingest more than the daily recommended amount. A similar reason cited concerned the fact that sometimes products do not adequately identify acetaminophen and therefore people overdose without even knowing they are overdosing. Another reason concerned liquid doses often given to children and mistakes that could be made since liquid doses contain different concentrations and hence parents could possibly administer overdoses without intending it. The last two reasons are of particular importance in this case. One concerned the fact that the public is simply uninformed about the dangers of increased ingestion of acetaminophen and, since they are uninformed, they do not appreciate the risks involved, and considering the marketing of products that contain acetaminophen they could overdose. The last reason offered stated that "some individuals may be especially sensitive to liver injury *330 from acetaminophen. The maximum safe dose may not be the same for all persons. Individuals with sensitivity may experience toxic effects at lower acetaminophen doses." The reason offered concluded that individuals who consume alcohol "or have liver disease" may have a greater sensitivity to the effects of acetaminophen but that more research is needed to explain why some individuals are more sensitive.

Thus, the Food and Drug Administration never confirmed "Extra-Strength Tylenol use is dangerous to the liver" (plaintiff's mem of law in opposition at 2). Rather, they concluded that ingesting overdoses of acetaminophen could prove dangerous and lowered the dosage for a variety of reasons as noted. The fact the Food and Drug Administration conceded that some individuals are particularly sensitive to liver disease does not mean there is a general acceptance within the scientific community that acetaminophen causes cirrhosis. In fact, the remainder of the Food and Drug Administration notice proves the very op-

posite conclusion. The notice continues and states that while the daily recommended dosage is being lowered a doctor may prescribe the old recommended dosage of four grams per day. It strains credulity that the Food and Drug Administration would permit doctors to prescribe a dosage, under any circumstances, that plaintiff claims poses serious health risks. In any event, there is clearly no scientifically accepted consensus which can be gleaned from the Food and Drug Administration's notice that normal dosages of acetaminophen cause cirrhosis.

Concerning the case reports cited by Dr. Dieterich, almost of all them concern situations where the individual ingested doses that were far greater than the recommended daily dosage or suffered a disease other than cirrhosis, and even if case reports are an acceptable method of proof satisfying *Frye's* requirement of general acceptance within the scientific community the case reports are completely irrelevant. There are only two case reports, those of Itoh and Johnson, which involved normal doses of acetaminophen and the development of cirrhosis. However, those case reports do not unequivocally state with any certainty that acetaminophen caused cirrhosis. Rather, both studies guardedly entertain the possibility that the liver injuries sustained are related to ingestion of normal doses of acetaminophen. That is simply an insufficient basis upon which to demonstrate acceptance within the scientific community.

In truth, these infirmities permeate the remainder of the affidavit of Dr. Dieterich. Isolated references or even whole sentences*331 that are found in medical texts or journals which mention liver disease and acetaminophen and cirrhosis fail to ever state with any degree of medical certainty that normal dose ingestion of acetaminophen is a direct cause of cirrhosis. Lastly, differential diagnosis is likewise an insufficient basis upon which to establish that acetaminophen causes cirrhosis since, as noted, that is an insufficient basis upon which to prove causation (*Ruggiero*), especially where the totality of this theory has been shown not to be accepted within the scientific community.

The affidavit of Dr. Neil David These does not fare any better. Dr. These offers an insightful and readable affidavit concerning liver diseases and their causes with a focus upon the plaintiff and the medical background tailored to her condition. First, Dr.

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Theise concedes that there are hardly any case reports which study consistent, normal dose ingestion, since that very combination is rare. Thus, Dr. Theise argues the facts related to the plaintiff are "uncommon" (*see* affidavit of Dr. Theise at 9). After explaining the relevant medical background necessary, Dr. Theise notes that in 1997 the plaintiff had a biopsy of her liver with no indications of fully developed cirrhosis, although it did reveal portal hypertension. At this time she had been ingesting normal doses of acetaminophen for 12 years. Four years later, in 2001 an MRI revealed cirrhosis. Dr. Theise opines that an examination of the cause of the cirrhosis suggested that hepatoportal sclerosis (HPS), a lesion affecting the smaller portal veins, must have been present in 1997 even though not evidenced in the biopsy, since how else to explain the portal hypertension. Dr. Theise then offers three ways to explain the existence of HPS as well as incomplete septal cirrhosis (ISC), a certain type of lesion now thought to signal the regression of cirrhosis, found following plaintiff's liver transplant in 2004. The first is that the lesions are independent unrelated diseases, the second that ISC is a late stage of HPS and are both a "single disease process" and third, that "HPS predisposes to subsequent development of cirrhosis; regression of cirrhosis follows if the etiology underlying the process is stopped or removed." Dr. Theise eliminates the second cause as a possibility in this case and states as follows:

"according to explanation 1, the HPS was independent of the cirrhotic development and is a coincidental occurrence. According to explanation 3, the HPS actually potentiates the progression to cirrhosis. Either way, in the absence of any other known cause of cirrhosis and in the presence of a toxin with the *332 potential to cause chronic injury, the finding of both HPS and ISC in her liver does not undermine the likelihood that acetaminophen played a significant role in her endstage liver disease" (*see* affidavit of Dr. Theise at 30).

The problem with this conclusion is that it simply does not enjoy any acceptance within the scientific community. Indeed, novel scientific theories such as the one presented by Dr. Theise must be generally accepted for their admission in court. The court, of course, cannot and does not pass judgment upon the scientific methodology or conclusions of Dr. Theise. However, without evidence of wider acceptance of the theory proposed it cannot be admitted at trial. The affidavit of Dr. Theise, aside from the few sentences

taken from larger texts, cannot demonstrate consensus concerning a "theory" and does not cite to any other peer articles or conclusions of any kind that state that normal ingestion of acetaminophen causes cirrhosis.

The affidavit of Gerald Rosen, Ph.D., a chemist and a pharmacologist, does not raise any issues concerning whether acetaminophen causes cirrhosis. First, Dr. Rosen chiefly opines that acetaminophen is not safe, causes liver failure and the pharmaceutical companies that manufacture acetaminophen refused to consider his patented alternatives that remove those threats. More importantly, in his 17-page affidavit he never once mentions cirrhosis or any relationship between acetaminophen and cirrhosis and does not discuss dosage levels, particularly normal dosages such as the case at bar. Thus, Dr. Rosen does not provide any expert support for the assertion that normal ingestion of acetaminophen causes cirrhosis.

Likewise, the affidavit of Dr. Suzanne Parisian does not mention cirrhosis at all. Dr. Parisian a former medical officer of the Food and Drug Administration and an advocate of proper labeling of drugs and an investigator of adverse effects of drugs opined concerning the health risks associated with acetaminophen and acute liver failure. She criticized the failure of the makers of acetaminophen to conduct proper testing to consider alternatives and the addition of other ingredients that would make acetaminophen safer. Moreover, many of her arguments against Tylenol and its "misleading practices" do not prove in any meaningful way at all that acetaminophen causes cirrhosis. They are policy arguments essentially directed at the marketing and research practices of Tylenol, not upon the medical connection, if any, between acetaminophen and cirrhosis. The closest the affidavit comes to linking the two is on page 20. There, Dr. Parisian notes that

*333 "the defendants provided warnings that certain conditions may be evidence of an overdose (e.g., nausea, vomiting, diaphoresis or general malaise), but never warned that liver toxicity could occur from ingestion of the recommended therapeutic doses, despite medical literature indicating that some people sustained liver injury while using therapeutic doses of Tylenol. Had such information been present, the plaintiff would have been able to recognize that the symptoms she was experiencing (weakness, fatigue, anorexia, nausea, vomiting, and pain) were caused by

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her prolonged Tylenol use.”

END OF DOCUMENT

However, that analysis does not pinpoint the specific disease, namely cirrhosis, that plaintiff claims was caused by normal ingestion of acetaminophen. The reference to generic liver failure and general liver maladies do not necessarily involve cirrhosis and cannot serve as expert support and acceptance of the proposed theory of causation. As the court noted in *Cinquemani v Old Slip Assoc., LP* (43 AD3d 1096, 1098 [2d Dept 2007]), medical reports and affidavits that do not discuss the precise injury claimed are “irrelevant.” Furthermore, as previously noted, any medical literature that actually states that prolonged normal ingestion of acetaminophen causes cirrhosis are fleeting sentences in much larger passages which, although not taken out of context, are far less sweeping and definitive than urged by plaintiff. In any event they do not support a comprehensive theory that normal ingestion of acetaminophen causes cirrhosis. Any authoritative statements that seem to so indicate are small snippets of far larger and more complex discussions. Thus, the plaintiff has wholly failed to introduce any studies, peer articles, professional literature, judicial opinions or recognized textbooks that state plaintiff's simple yet novel premise, namely that normal ingestion of acetaminophen causes cirrhosis to develop in the liver. Without that supporting material the plaintiff fails to satisfy the evidentiary requirements of the *Frye* standard. Consequently, the defendant's motion seeking to dismiss the complaint and the case is granted. The plaintiff's motion is denied and the case is hereby dismissed.

FOOTNOTES

FN* It should be noted that while *Ruggiero* was decided pursuant to the federal standard enunciated in *Daubert v Merrell Dow Pharmaceuticals, Inc.* (509 US 579 [1993]), the result would have been identical under the stricter *Frye* standard. A conclusion that no rational basis exists for admission of the evidence under *Daubert* would surely demand exclusion under *Frye*.

Copr. (c) 2010, Secretary of State, State of New York
NY, 2010.
RATNER v MCNEIL-PPC, INC.

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424 F.3d 249, 68 Fed. R. Evid. Serv. 304
(Cite as: 424 F.3d 249)

United States Court of Appeals,
Second Circuit.
Anne RUGGIERO, Individually and as Representa-
tive of the Estate of Albert Ruggiero, Plaintiff-
Appellant,
v.
WARNER-LAMBERT COMPANY and Parke
Davis, Defendants-Appellees.
Docket No. 04-6674-CV.

Argued: July 11, 2005.
Decided: Sept. 16, 2005.

Background: Widow, individually and representa-
tive of her husband's estate, brought products liability
suit against drug manufacturer, alleging that hus-
band's cirrhosis and death were caused by Rezulin, a
diabetes medication. Case was consolidated for pre-
trial proceedings in multi-district litigation (MDL).
The United States District Court for the Southern
District of New York, Kaplan, J., entered summary
judgment for manufacturer, and widow appealed.

Holdings: The Court of Appeals, Jacobs, Circuit
Judge, held that:

- (1) spouse was not unfairly prejudiced by court's reli-
ance on argument that was subsumed in broader ar-
gument advanced in moving papers and explicitly
raised in reply papers, and
- (2) court could exclude expert's opinion as to general
causation as insufficiently reliable.

Affirmed.

West Headnotes

[1] Federal Civil Procedure 170A ⚡2554

170A Federal Civil Procedure
170AXVII Judgment
170AXVII(C) Summary Judgment
170AXVII(C)3 Proceedings
170Ak2547 Hearing and Determination
170Ak2554 k. Matters Considered.
Most Cited Cases
District court had discretion to consider arguments

that allegedly were raised for first time in summary-
judgment reply papers. Fed.Rules Civ.Proc.Rule 56,
28 U.S.C.A.

[2] Federal Courts 170B ⚡914

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)6 Harmless Error
170Bk914 k. Judgment and Relief;
Summary Judgment. Most Cited Cases
Products liability plaintiff was not unfairly prejudiced
by district court's consideration, on motion for sum-
mary judgment, of argument concerning general cau-
sation that, even if not explicitly raised in drug manu-
facturer's moving papers, was subsumed in broader
argument that plaintiff could not establish causation
between patient's liver failure and diabetes drug
Rezulin and which was more explicitly raised in re-
ply papers; plaintiff recognized general causation
issue in opposition papers and did not claim surprise
in district court or seek to file sur-reply. Fed.Rules
Civ.Proc.Rule 56, 28 U.S.C.A.

[3] Federal Courts 170B ⚡634

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(D) Presentation and Reservation in
Lower Court of Grounds of Review
170BVIII(D)2 Objections and Exceptions
170Bk634 k. Amount or Extent of Re-
lief; Costs; Judgment. Most Cited Cases
Court of Appeals would not consider argument raised
for first time on appeal from entry of summary judg-
ment, to effect that court should not have considered
causation issue because it was being litigated by ex-
ecutive committee in multi-district litigation with
which products liability case had been joined for pre-
trial proceedings, given expertise of district judge in
presiding over multi-district litigation and plaintiff's
failure to offer reason for failure to raise argument
below. Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.

[4] Federal Courts 170B ⚡823

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170B Federal Courts
170BVIII Courts of Appeals
170BVIII(K) Scope, Standards, and Extent
170BVIII(K)4 Discretion of Lower Court
170Bk823 k. Reception of Evidence.

Most Cited Cases

A district court's decision as to how the reliability of expert testimony should be determined, as well as the ultimate decision as to whether that testimony is reliable, are reviewed for abuse of discretion. Fed.Rules Evid.Rule 702, 28 U.S.C.A.

[5] Evidence 157  555.10

157 Evidence

157XII Opinion Evidence
157XII(D) Examination of Experts
157k555 Basis of Opinion
157k555.10 k. Medical Testimony.

Most Cited Cases

Federal Civil Procedure 170A  2545

170A Federal Civil Procedure

170AXVII Judgment
170AXVII(C) Summary Judgment
170AXVII(C)3 Proceedings
170Ak2542 Evidence
170Ak2545 k. Admissibility. Most

Cited Cases

Medical expert's differential diagnosis that use of diabetes drug Rezulin led to patient's cirrhosis was insufficiently reliable to support opinion as to general causation in opposition to summary judgment motion in products liability suit; opinion assumed that final, suspected cause remaining after differential diagnosis process of elimination was actually capable of causing cirrhosis without using scientifically valid methodology for "ruling in" drug as one of possible competing causes, and expert could not point to any studies suggesting that cirrhosis could be caused or exacerbated by Rezulin. Fed.Rules Civ.Proc.Rule 56, 28 U.S.C.A.; Fed.Rules Evid.Rule 702, 28 U.S.C.A.

*250 Ronald R. Benjamin, Law Office of Ronald R. Benjamin, Binghamton, NY, for Appellant.

David Klingsberg, Kaye Scholer LLP, New York, N.Y. (Bert L. Slonim and Steven Glickstein, on the brief), for Appellees.

Before: JACOBS and B.D. PARKER, Circuit Judges,
and HURD, District *251 Judge.^{FN*}

FN* The Honorable David N. Hurd of the United States District Court for the Northern District of New York, sitting by designation.

DENNIS JACOBS, Circuit Judge.

Plaintiff Anne Ruggiero appeals from a judgment entered by the United States District Court for the Southern District of New York (Kaplan, J.), dismissing on summary judgment a complaint alleging that her husband's cirrhosis and death were caused by Rezulin, a diabetes medication manufactured and sold by defendants Warner-Lambert Co. and Parke Davis ("Defendants"). The ground for dismissal was that Ruggiero failed to produce sufficient evidence that Rezulin was capable of causing or exacerbating cirrhosis (so-called "general" causation). On appeal, Ruggiero argues principally that [i] the ruling on general causation was error because that issue was first raised in Defendants' summary-judgment reply papers, and is a subject of on-going consolidated proceedings in the multi-district litigation ("MDL") of which Ruggiero's case is part; and [ii] medical expert evidence attributing Mr. Ruggiero's cirrhosis and death to Rezulin was erroneously ruled inadmissible. For the following reasons, we affirm.

BACKGROUND

Albert Ruggiero was diagnosed with Type-II diabetes in 1982, and in May 1997, he began taking Rezulin, a diabetes medication manufactured and sold by Defendants. His death on August 24, 1998 was attributed to liver failure caused by cirrhosis. On March 21, 2000, Defendants halted distribution of Rezulin at the request of the Food and Drug Administration, in light of concerns that the drug caused increased liver toxicity.

Anne Ruggiero commenced this product-liability action, claiming that Rezulin caused Albert's cirrhosis. The case was added to the "[m]ore than one thousand" Rezulin-related cases consolidated for pretrial proceedings in the Southern District of New York, before Judge Kaplan. *In re Rezulin Prods. Liab. Litig.* (MDL No. 1348), 223 F.R.D. 109, 111 (S.D.N.Y.2004). Defendants subsequently moved for summary judgment in Ruggiero's individual case.

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I

The district court granted summary judgment, holding that Ruggiero produced insufficient evidence of “general” causation, *i.e.*, evidence that Rezulin is capable of causing or exacerbating cirrhosis of the liver.^{FN1} Specifically, the court ruled that the sole evidence of general causation submitted by Ruggiero—the expert opinion of Dr. Douglas T. Dietrich—was inadmissible (as to that issue) under Fed. R. Evid. 702 (“Testimony by Experts”) and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The court reasoned that “Dr. Dietrich was unable to point to any studies or, for that matter, anything else that suggested that cirrhosis could be caused or exacerbated by Rezulin.” Dr. Dietrich’s opinion rested on a review of Albert’s medical records and a “differential diagnosis,” *i.e.*, a patient-specific process of ruling out potential causes of an illness as unlikely, until one cause remains.^{FN2} The court concluded*252 that this approach did not provide a reliable basis for Dr. Dietrich’s opinion that Rezulin is capable of causing or exacerbating cirrhosis.

FN1. General causation bears on whether *the type of injury at issue can be caused or exacerbated* by the defendant’s product. “Specific” causation bears on whether, in the particular instance, *the injury actually was caused or exacerbated* by the defendant’s product. See *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir.2002).

FN2. The district court assumed for the purpose of analysis that Dietrich relied on a differential diagnosis but noted that “it was not really clear” that he did so.

DISCUSSION

We review the grant of summary judgment *de novo*. See *Anthony v. City of New York*, 339 F.3d 129, 134 (2d Cir.2003). A ruling as to the admissibility of expert evidence is reviewed for abuse of discretion. See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) (“On a motion for summary judgment ... the question of admissibility of expert testimony ... is reviewable under the abuse-of-discretion standard.”).

As a threshold matter, Ruggiero claims that the district court should not have reached the issue of general causation.

[1] First, she argues that the issue was first raised in Defendants’ summary-judgment reply papers. See, *e.g.*, *Playboy Enters., Inc. v. Dumas*, 960 F.Supp. 710, 720 n. 7 (S.D.N.Y.1997) (“Arguments made for the first time in a reply brief need not be considered by a court.”). Assuming that is so, the district court had discretion to consider it. See *Bayway Ref. v. Oxygenated Mktg. & Trading*, 215 F.3d 219, 226 (2d Cir.2000) (reviewing for abuse of discretion district court’s decision to rely on evidence submitted with moving party’s reply papers).

[2] Defendants’ moving papers did not argue expressly in terms of general causation. However [i] the motion was cast in terms of the broader and subsuming argument that Ruggiero could not “establish the essential element of causation”; [ii] a declaration appended to the moving papers noted that “[t]here are no scientific studies in the medical literature that conclude Rezulin can cause cirrhosis”; and [iii] Ruggiero’s opposition papers cited as a genuine issue of material fact “[w]hether or not there are scientific studies in the medical literature that conclude Rezulin can cause liver failure such as caused decedent Albert Ruggiero’s death.” Under the circumstances, Ruggiero cannot claim that she was blindsided by Defendants’ reliance on general causation or that she was prejudiced by the district court’s consideration of that issue.^{FN3} In any event, it is hard for Ruggiero to claim unfair prejudice now, because she could have claimed surprise in the district court and sought to file a responsive sur-reply.^{FN4}

FN3. See, *e.g.*, *Bayway*, 215 F.3d at 227 (district court properly relied on evidence submitted with moving party’s reply, where, *inter alia*, record showed that opposing party knew such evidence could refute its claim but “chose not to introduce any evidence” of its own); *Cifarelli v. Village of Babylon*, 93 F.3d 47, 53 (2d Cir.1996) (district court properly relied on evidence submitted with defendants’ summary-judgment reply, where record showed that plaintiff “was fully aware prior to the defendants’ re-

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ply of' the issue to which evidence pertained); *Bridgeway Corp. v. Citibank*, 201 F.3d 134, 140 (2d Cir.2000) (district court's *sua sponte* grant of summary judgment neither surprised nor prejudiced losing party where, *inter alia*, party had previously claimed that it had introduced sufficient evidence concerning the very issue on which the court based its decision).

FN4. *See, e.g., Bayway*, 215 F.3d at 227 (district court properly considered evidence submitted with plaintiff's reply brief where, *inter alia*, defendant "did not move the district court for leave to file a sur-reply to respond"); *Bridgeway Corp. v. Citibank*, 201 F.3d 134, 140 (2d Cir.2000) (plaintiff was not prejudiced by district court's *sua sponte* grant of summary judgment where, *inter alia*, plaintiff "did not, before the district court, raise any objections based on lack of notice. Nor did it subsequently seek to introduce additional evidence that might have convinced the district court to change its position."); *cf. Gwozdzinsky v. Magten Asset Mgmt. Corp.*, 106 F.3d 469, 472 (2d Cir.1997) ("[A]bsent manifest injustice or a showing of extraordinary need, we will not decide an issue on appeal not first presented to the district court.").

*253 Second, Ruggiero argues that the district court should not have considered the issue of general causation because that issue [i] is being litigated by the "Plaintiffs Executive Committee" in the consolidated MDL proceedings and [ii] implicates the law-of-the-case doctrine by reason of a previous contrary decision in those consolidated proceedings (or somewhere else). Even assuming that the law-of-the-case doctrine would apply, Ruggiero's brief directs us to no such contrary ruling.

[3] In any event, we decline to consider the merits of this argument because Ruggiero failed to present it to the district court. *Id.* We have discretion to consider issues that a party failed to raise in the district court, *see Booking v. Gen. Star Mgmt. Co.*, 254 F.3d 414, 418-19 (2d Cir.2001), but we decline to do so here. For the reasons stated above, there is no good excuse for Ruggiero's failure to bring this complaint to the district court's attention; and we are most hesitant to

consider it in the first instance, given the unmatched expertise Judge Kaplan has acquired while presiding over the Rezulin MDL over the past five years.

II

The district court granted summary judgment to Defendants on the ground that Ruggiero submitted no admissible evidence to show, as a matter of general causation, that Rezulin can cause or exacerbate cirrhosis of the liver. Her only submission arguably on point was the expert opinion of Dr. Dietrich, who concluded with reasonable medical certainty that "Albert Ruggiero's liver disease was caused by his taking Rezulin." The district court ruled it inadmissible under the standards set out in Fed.R.Evid. 702 and *Daubert*.

Rule 702 states:

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, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

As the Supreme Court explained in *Daubert*, Rule 702 requires the district court to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589, 113 S.Ct. 2786. As to reliability, "*Daubert* enumerated a list of factors that, while not constituting a 'definitive checklist or test,' a district court might consider ...: whether a theory or technique has been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique's application or operation." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir.2005) (quoting *Daubert*, 509 U.S. at 593-94, 113 S.Ct. 2786). "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d

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256, 266 (2d Cir.2002).

[4] A district court's decision as to how the reliability of expert testimony should *254 be determined, as well as the ultimate decision as to whether that testimony is reliable, are reviewed for abuse of discretion. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999); see also *Joiner*, 522 U.S. at 142-43, 118 S.Ct. 512 (abuse-of-discretion standard persists at summary judgment stage).

[5] Judge Kaplan applied the *Daubert* factors and concluded that there was no reliable basis for Dr. Dietrich's opinion that Rezulin could cause or exacerbate cirrhosis of the liver: "Dr. Dietrich was unable to point to any studies or, for that matter, anything else that suggested that cirrhosis could be caused or exacerbated by Rezulin." The judge further concluded that insofar as Dr. Dietrich's opinion relied on a differential diagnosis, that technique was insufficiently reliable to support the opinion as to general causation (though it might suffice to support an opinion that a drug shown to be capable of causing the condition likely did so in a particular case).

We see no error. A differential diagnosis is "a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes." *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387, 1413 (D.Or.1996); *Hines v. Consol. Rail Corp.*, 926 F.2d 262, 270 n. 6 (3d Cir.1991) (defining "differential diagnosis" as a "process whereby medical doctors experienced in diagnostic techniques provide testimony countering other possible causes ... of the injuries at issue"). As the district court observed, this method does not (necessarily) support an opinion on general causation, because, like any process of elimination, it assumes that "the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury." *Cavallo v. Star Enter.*, 892 F.Supp. 756, 771 (E.D.Va.1995), *aff'd on this ground, rev'd on other grounds*, 100 F.3d 1150 (4th Cir.1996); *Hall*, 947 F.Supp. at 1413 (noting that a differential diagnosis "assumes that general causation has been proven for the list of possible causes it eliminates"). Where an expert employs differential diagnosis to "rule out" other potential causes" for the injury at issue, he must also "rule in" the suspected cause," and do so using

"scientifically valid methodology." *Id.* Here, Dr. Dietrich may have used a differential diagnosis to rule out competing causes of cirrhosis without establishing that Rezulin is among them.

We cannot say that a differential diagnosis *may never* provide a sufficient basis for an opinion as to general causation. There may be instances where, because of the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance, a differential diagnosis is sufficient to support an expert's opinion in support of both general and specific causation. Cf. *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043-44 (2d Cir.1995) (district court did not abuse discretion in ruling that opinion on causation was admissible, where opinion was based on care and treatment of plaintiff, medical history, pathological studies, product's safety data sheet, reference to scientific and medical treatises, expert's training and experience, as well as differential diagnosis). The district judge has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support such an opinion.^{FN5}

FN5. On this score, the district court indicated that even if a differential diagnosis *could* be probative of general causation in an appropriate case, it was not so here:

It is not at all clear ... that a district court lacks discretion to conclude in an individual case that an expert's opinion as to general causation based on an unreliable differential diagnosis must be received in evidence.

This case illustrates the fundamental problem with differential diagnosis The doctor has not offered any reliable basis for concluding that Rezulin is capable of causing the cirrhosis that caused the liver failure that resulted in Mr. Ruggiero's death. In other words, he has offered no reliable ground upon which Rezulin may be "ruled in" as a plausible cause of the cirrhosis.

*255 As a final matter, Ruggiero-relying on language in *McCullock*-argues that any fault in Dr. Dietrich's

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use of a differential diagnosis goes to weight, not admissibility. After the *McCullock* Court reviewed a number of factors underlying the opinion of the plaintiff's expert, the Court stated that "[d]isputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony." *Id.* at 1044. Ruggiero is over-reading that passage. The opinion had held, *supra*, that the district court did not abuse its discretion in ruling that the expert's opinion *in that case* was admissible; in the quoted passage, the Court was merely signaling that any remaining objection as to the expert's credentials or methodology was for the consideration of the jury. In any event, Ruggiero's reading of *McCullock* is precluded by the Supreme Court's subsequent decision in *Joiner*. In *Joiner*, the Court held that "conclusions and methodology are not entirely distinct from one another," and that "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." 522 U.S. at 146, 118 S.Ct. 512. Following *Joiner*, we held that "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir.2002). In light of *Joiner* and *Amorgianos*, Ruggiero's reliance on *McCullock* is unpersuasive.

We have considered Ruggiero's remaining arguments and find each to be without merit. The judgment of the district court is affirmed.

C.A.2 (N.Y.),2005.
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END OF DOCUMENT

Supreme Court of Arizona, In Banc.
 STATE of Arizona, Appellee,
 v.
 Robert Wayne JOHNSON, Appellant.
 No. CR-95-0393-PR.

July 16, 1996.

Defendant was convicted in the Superior Court, Cochise County, Cause No. CR-91-00286, James L. Riley, J., of sexual assault, and he appealed. The Court of Appeals, Espinosa, P.J., affirmed, 183 Ariz. 623, 905 P.2d 1002. Defendant petition for review, claiming testimony on odds of DNA match was error. The Supreme Court, Feldman, C.J., held that: (1) *Frye* test continued to remain standard for admissibility of new scientific evidence, and (2) DNA probability evidence using restricted fragment length polymorphism (RFLP) protocol and modified ceiling method was generally accepted in scientific community.

Affirmed.

West Headnotes

[1] Criminal Law 110  388.2

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.2 k. Particular Tests or Experiments. Most Cited Cases
 DNA analysis involves three basic steps; creating the DNA profiles of evidence samples, determining whether profiles of different samples match, and if samples match, articulating the significance of the match, preferably by computing the probability of a random match.

[2] Criminal Law 110  388.2

110 Criminal Law

110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.2 k. Particular Tests or Experiments. Most Cited Cases
 In evaluation of a DNA analysis under *Frye*, assumption of linkage equilibrium for purposes of restricted fragment length polymorphism (RFLP) analysis and use in applying the product rule has been demonstrated to be generally accepted in the relevant scientific community.

[3] Criminal Law 110  1139

110 Criminal Law
 110XXIV Review
 110XXIV(L) Scope of Review in General
 110XXIV(L)13 Review De Novo
 110k1139 k. In General. Most Cited Cases
 Under *Frye*, Supreme Court conducts a de novo review to determine whether a scientific principle used as a basis for expert testimony is generally accepted in the relevant scientific community.

[4] Criminal Law 110  388.1

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.1 k. In General. Most Cited Cases
 Endorsement by the National Research Council (NRC) of scientific probability statistics is strong evidence of general acceptance within the relevant scientific community for *Frye* analysis.

[5] Criminal Law 110  388.2

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence

922 P.2d 294
 186 Ariz. 329, 922 P.2d 294
 (Cite as: 186 Ariz. 329, 922 P.2d 294)

110k388.2 k. Particular Tests or Experiments. Most Cited Cases
 Modified ceiling method is generally accepted in the relevant scientific community and DNA probability calculations computed with that method are admissible under *Frye*.

[6] Criminal Law 110 ⚡388.1

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.1 k. In General. Most Cited Cases
Frye test remains the standard for admissibility of new scientific evidence.

[7] Criminal Law 110 ⚡388.2

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.2 k. Particular Tests or Experiments. Most Cited Cases
 DNA probability evidence calculated by use of the restricted fragment length polymorphism (RFLP) protocol and with the modified ceiling method is generally accepted in the relevant scientific community and is therefore admissible under the *Frye* test, subject to proper foundational showing, and upon such a showing, the significance of a DNA profile match may be explained with probability estimates based on the method's calculations.
 **294 *329 Grant Woods, Arizona Attorney General by Paul J. McMurdie, Galen H. Wilkes, Phoenix, for State of Arizona.

Robert F. Arentz, Phoenix, for Robert Wayne Johnson.

OPINION

FELDMAN, Chief Justice.

We granted review in this case to re-examine questions involving the admissibility of DNA profile

probability statistics. The questions addressed are those left open by *State v. Bible*, 175 Ariz. 549, 858 P.2d 1152 (1993), our previous opinion on this subject.

****295 *330 FACTS AND PROCEDURAL BACKGROUND**

On the morning of July 9, 1991, in Sierra Vista, Arizona, a storekeeper was surprised by an intruder as she opened her business. The intruder overpowered the woman and raped her. The woman was taken to the emergency room where Sierra Vista police interviewed her and gathered her clothing. They then returned to the crime scene and retrieved paper towels the victim had used to clean herself.

Terry Hogan, a criminalist at the Arizona Department of Public Safety (DPS) crime laboratory, found that DNA extracted from blood and semen stains on the clothes and paper towels matched the DNA of a suspect, Robert Wayne Johnson. At Johnson's jury trial on sexual assault charges, the state presented evidence of the DNA match, and Hogan testified, over objection, that the probability of such a match occurring randomly was one in 312 million. The jury evidently believed that odds of one to 312 million established guilt beyond a reasonable doubt and found Johnson guilty of one count of sexual assault, a class two felony. The trial judge imposed an aggravated term of fourteen years' imprisonment and Johnson appealed, raising several issues. The court of appeals affirmed Johnson's conviction and sentence. *State v. Johnson*, 183 Ariz. 623, 636, 905 P.2d 1002, 1015 (App.1995).

Johnson then petitioned this court for review, claiming that the trial judge erred in admitting Hogan's testimony about the odds of a random match between Johnson's DNA and DNA extracted from the semen stains. In light of the importance of the issue and the uncertainty of the law on the point, we granted review of Johnson's claim regarding admission of the DNA evidence. See Ariz.R.Crim.P. 31.19.

DISCUSSION

A. DNA analysis

[1] DNA analysis involves three basic steps: 1) creat-

ing the DNA profiles of evidence samples; 2) determining whether profiles of different samples match; and 3) if samples match, articulating the significance of the match, preferably by computing the probability of a random match. *State v. Bible*, 175 Ariz. 549, 577, 858 P.2d 1152, 1180 (1993), *cert. denied*, 511 U.S. 1046, 114 S.Ct. 1578, 128 L.Ed.2d 221 (1994).

Hogan used restricted fragment length polymorphism (RFLP) to create the DNA profiles and determine that they matched. The scientific principles underlying RFLP, its validity, and the process for declaring a match are well-documented and unchallenged here. Accordingly, we will not add to the literature by describing the complex technology and science underlying RFLP.^{FN1}

FN1. For a more detailed explanation of RFLP analysis, with cites to the scientific literature, see *Bible*, 175 Ariz. 549, 858 P.2d 1152; *State v. Anderson*, 118 N.M. 284, 881 P.2d 29 (1994); or *State v. Cauthron*, 120 Wash.2d 879, 846 P.2d 502 (1993).

RFLP produces a picture or DNA profile of the suspect's blood, semen, or other specimen, which is compared to the DNA profile produced from the evidence sample. These profiles are referred to as autorads. An autorad resembles an x-ray and depicts with dark stripes or bands the presence of certain gene pairs. The particular genes represented on the autorad are called alleles.

If the two DNA profiles do not match then the suspect is positively excluded. If they do match, the evidence sample came either from the suspect or an identical twin, or the match was a complete coincidence. If there is no identical twin, as in the present case, the significance of a match can be expressed in terms of the probability that the suspect's DNA profile would occur randomly. See generally M. KRAWCZAK & J. SCHMIDTKE, DNA FINGERPRINTING 61-77 (Bios Scientific Publishers 1994). The probability can be expressed either qualitatively—"probable," "highly probable"—or mathematically, as Hogan did in this case: one in 312 million. The issue under review concerns only this third step of DNA analysis: are DNA probability statistics produced by the modified ceiling method and expressed mathematically admissible under the standard for new scientific evidence? We held in *Bible*

that admission of such evidence calculated by the product**296 *331 rule was error. *Bible*, 175 Ariz. at 577, 858 P.2d at 1180.

B. The standard for admitting new scientific evidence

The state urges us to jettison the *Frye*^{FN2} test for determining when new scientific evidence is ready for the courtroom and to adopt in its place the standard articulated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

FN2. *Frye v. United States*, 293 F. 1013 (D.C.Cir.1923) (use of lie detectors).

Under *Frye*, scientific evidence based on a newly postulated theory is admissible when that theory has been generally accepted in the relevant scientific community. See *Bible*, 175 Ariz. at 578, 858 P.2d at 1181. In contrast, *Daubert* says the trial judge in each case must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93, 113 S.Ct. at 2796.

The *Frye* rule has long been followed in Arizona, both before and after adoption of the Arizona Rules of Evidence. See, e.g., *State v. Velasco*, 165 Ariz. 480, 486, 799 P.2d 821, 827 (1990); *State ex rel. Collins v. Superior Court*, 132 Ariz. 180, 195-202, 644 P.2d 1266, 1281-99 (1982); *State v. Valdez*, 91 Ariz. 274, 277-80, 371 P.2d 894, 896-98 (1962).

In *Bible* we noted that *Daubert* "leaves many questions unanswered" and concluded that we would continue to follow *Frye*, at least for the present. In doing so we stated that

notwithstanding legitimate criticism of *Frye*, and our desire to preserve uniformity when possible [that] ... even were we to use *Daubert*'s reliability/scientific validity analysis, we would still be left with the problem posed by *Frye*: precisely when "in [the] twilight zone the evidential force of the [scientific] principle must be recognized."

175 Ariz. at 580, 858 P.2d at 1183. We have seen nothing since and, as in *Bible*, find nothing in the arguments or briefs to persuade us that this case presents us with a reason to abandon *Frye* and follow *Daubert*. The federal courts have not yet had a fair opportunity to apply *Daubert*; thus, it is too early to properly evaluate it. We therefore conclude that for the present, and for the reasons stated in *Bible*, the *Frye* rule, which has been followed without causing significant problems since it was first adopted in 1962, remains the rule in Arizona. We turn then to apply that rule to the problem presented in this case.

C. Admissibility of probability evidence

1. *State v. Bible*

In *Bible*, we reviewed the admissibility of DNA probability evidence calculated with the product rule^{FN3} and held that the DNA probability calculations based on Cellmark Laboratory's application of the product rule were inadmissible because,

FN3. The product rule is described as follows:

Suppose, for example, that a pair of DNA [profiles] match on two bands, and that one band reflects an allele found in ten percent of the population and the other an allele found in fifty percent of the population. Applying the product rule, an analyst would conclude that the probability of a coincidental match on both alleles is $0.10 \times 0.50 = .05$, or a five percent probability.

William C. Thompson & Simon Ford, *DNA Typing*, 75 VA.L.REV. 45, 81-82 (1989).

[f]or purposes of *Frye*, these probability calculations are flawed in three ways: (1) they are impermissibly based on the disputed assumption of linkage equilibrium; (2) the database relied on is of disputed statistical validity; and (3) the database relied on is [concededly] not in Hardy-Weinberg equilibrium.

Id. at 585-86, 858 P.2d at 1188-89. The modified ceiling method, which was used to calculate the probabilities introduced at Johnson's trial, is inex-

tricably linked to the product rule. Therefore, as a threshold requirement, the modified ceiling method must produce results untainted by the shortcomings articulated for the product rule in *Bible*.

**297 *332 2. Assumption of linkage equilibrium

Cellmark's application of the product rule was rejected in *Bible*, in part because of "the disputed assumption of linkage equilibrium." *Id.* Linkage equilibrium refers to the principle of independent assortment, which states that the frequency of occurrence of alleles expressing different genetic traits will be determined independently of the frequency of the occurrence of other alleles in the sample. See MONROE W. STRICKBERGER, *GENETICS* 104-05 (3d ed., Macmillan Publishing Co., 1985). The National Research Council (NRC), in its 1992 report, *DNA Technology in Forensic Science* (NRC report),^{FN4} illustrates the principle thusly:

FN4. The National Research Council's members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members who prepared this report were chosen for their special competencies. The report was reviewed by a group other than the authors who prepared it, according to procedures approved by a Report Review Committee, consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. NRC report at *ii*.

From a statistical standpoint, the situation is analogous to estimating the proportion of blond, blue-eyed, fair-skinned people in Europe by separately counting the frequencies of people with blond hair, people with blue eyes, and people with fair skin and calculating their proportions [by application of the product rule].

NRC report at 76.

Thus, by way of illustration only, linkage equilibrium assumes that whether a person inherits the allele for blue eyes is unrelated to whether that person inherits the allele for blond hair or fair skin. Of course, as the NRC report points out, these three traits tend to co-occur in Nordics. Therefore the actual frequency of

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these three traits occurring together (assuming each trait occurs one time in ten) is not simply a straight calculation under the product rule of $.10 \times .10 \times .10$ equals 1 in 1000. Instead, because of the co-occurrence of such observable, physical traits in certain sub-populations, the actual frequency in the total population of all three traits appearing in any one individual is probably considerably higher than 1 in 1000. *Id.*

[2] This does not, however, necessarily invalidate the assumption of linkage equilibrium because the alleles chosen to create the DNA profile with the RFLP protocol are non-coding, that is, they are not responsible for producing any observable characteristic. See NRC report at 77; KRAWCZAK & SCHMIDTKE, *supra*, at 74; MAJ. DOUGLAS A. DRIBBENN, *DNA Statistical Evidence and the "Ceiling Principle": Science or Science Fiction?*, 146 MILITARY L.REV. 94, 105 (1994). Furthermore, these alleles are known to be extremely variable from person to person, and scientific studies have not shown any statistical correlation between them. NRC report at 77; KRAWCZAK & SCHMIDTKE, *supra*, at 74. Thus, as the NRC report makes clear, the assumption of linkage equilibrium inherent in protocols such as RFLP is well-grounded and has been proved accurate for purposes of DNA profiles. NRC report at 77. Accordingly, the assumption of linkage equilibrium for purposes of RFLP analysis and use in applying the product rule has been demonstrated to be generally accepted in the relevant scientific community. NRC report at 77; KRAWCZAK & SCHMIDTKE, *supra*, at 74.

3. Hardy-Weinberg equilibrium

The statistical validity of the product rule also assumes that mates are chosen randomly within any population, resulting in an equally random occurrence of any particular allele. Populations that are in random-mating proportions are said to be in Hardy-Weinberg equilibrium. See THE EVALUATION OF FORENSIC DNA EVIDENCE 4-2 (National Academy Press 1996) (prepublication copy) (1996 NRC report).

Of course people who live in close geographic proximity to each other are more likely to choose each other as mates, and people often select mates on the basis of certain physical, racial, cultural, and behav-

ioral characteristics. However, the alleles used in DNA profiling do not represent physical, racial, cultural, and behavioral characteristics and are therefore not the basis for the choice of mates. Accordingly, the alleles **298 *333 used for profiling remain in Hardy-Weinberg equilibrium. *Id.*

Our concern with Hardy-Weinberg equilibrium in *Bible* was not with the general acceptance of the scientific principle but instead was limited to Cellmark's admittedly defective database. *Bible*, 175 Ariz. at 585-86, 858 P.2d at 1160-61. Unlike the situation with Cellmark's database, Hogan testified to testing for and finding the DPS database in Hardy-Weinberg equilibrium. Nothing in the record refutes this testimony.

4. Statistical validity of the database-size, randomness and representativeness

To estimate the probability that a defendant's DNA is the same as that taken from a crime scene, the expert relies on a previously constructed database. LORNE T. KIRBY, *DNA FINGERPRINTING: AN INTRODUCTION* 171 (1990). This database allows the expert to calculate the frequency of the alleles with which such a match could be expected in the general population. See *State v. Cauthron*, 120 Wash.2d 879, 846 P.2d 502, 513 (1993).

Cellmark's concededly flawed database in *Bible* and the then-disputed assumption of linkage equilibrium made it unnecessary to consider other statistical qualities of Cellmark's database. *Bible*'s other concerns have been addressed here, but Johnson also challenges the statistical validity of the DPS database used in this case. Thus, we must determine whether the DPS database, which is comprised of samples from blood banks, is generally accepted in the relevant scientific community. See *Bible*, 175 Ariz. at 583 n. 22, 858 P.2d at 1186 n. 22.

With respect to size, "the scientific community now generally agrees that a database consisting of as few as 150 individuals will suffice, so long as the individuals are unrelated." DRIBBENN, *supra*, at 104-05 (citing Ranajit Chakraborty, *Sample Size Requirements for Addressing the Population Genetic Issues of Forensic Use of DNA Typing*, 64 HUM. BIOLOGY 141, 157 (1992)). Additionally, the recommended sample size for the NRC's "non-

modified" ceiling method, proposed in the same report, is 100 for a given racial group. The DPS database consisted of approximately 200 samples for each of four racial groups.

As for randomness, the NRC report concludes that to be sufficiently random, the database need only consist of samples drawn at random from designated populations. NRC report at 77, 83. Randomness is satisfied when there is linkage equilibrium and Hardy-Weinberg equilibrium. *See Cauthron*, 846 P.2d at 514; NRC report at 83. Finally, to ensure the database is sufficiently representative, the modified ceiling method calls for samples drawn from at least three racial populations. NRC report at 91. The DPS database was drawn from four different racial populations. Three of these populations were used by Hogan in his calculations, and the samples were identified only by race.

Hogan tested for and found the database to be in Hardy-Weinberg equilibrium. We have already determined that the assumption of linkage equilibrium has been sufficiently proven. Thus, we believe the size, randomness, and representativeness of the DPS database were such that the database was generally accepted in the relevant scientific community.

5. The modified ceiling method

The modified ceiling method is an application of the product rule. This method, however, has the added dimension of addressing any effect subpopulations might have on product rule calculations. Subpopulations refer to stratifications within distinct racial groups. *See* NRC report at 11-15, 91-93. The modified ceiling method addresses the possible effects of subpopulations by making product rule calculations more conservative. *See id.* at 13, 91-93. It does this by utilizing databases containing frequency information on at least three principal racial populations. The occurrence frequency of alleles represented in the autorads are calculated for each racial population. If any allele's frequency in any of the populations is less than ten percent, that allele is assigned the frequency of ten percent. In other words, no allele will be assumed to occur less frequently than ten percent of the time in any of the several populations, regardless of how infrequently it **299 *334 might actually have occurred. If an allele's frequency is greater than ten percent in any population, then the highest observed

frequency is used to compute the ninety-five percent confidence interval ^{FN5} for that frequency. This results in moving the highest observed frequency, if it was over ten percent, higher still. NRC report at 14-15, 91-93. Employing these occurrence frequencies for the individual alleles, the product rule is then applied to determine the probability of a suspect's DNA profile occurring randomly. This probability is both race-neutral and conservative, thereby accounting for any effect of subpopulations. NRC report at 13, 91-92. Any error in the probability would be in the direction of increased probability of a random match, so that the final calculation favors defendants. *Id.*

FN5. According to the NRC, the upper 95% confidence limit is given by the formula:

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Here, p is the observed frequency and N is the number of chromosomes studied, which should correspond to the number of loci multiplied by the size of the population studied. NRC report at 92.

6. Admissibility of the modified ceiling method under *Frye*

Hogan testified at the *Frye* hearing and at trial about the modified ceiling method procedures he used to compute the DNA probability evidence. Johnson asserted at oral argument that admissibility of the modified ceiling method was not ruled on by the trial judge and is not properly an issue before this court. We have reviewed the transcript of the *Frye* hearing, the trial testimony, and the NRC report describing the modified ceiling method. We conclude that the issue of admissibility of the modified ceiling method was squarely ruled on by the trial judge and is properly before us. *See* Reporter's Transcript (R.T.), Sept. 23, 1992, at 126-36; R.T., Oct. 15, 1992, at 317-22; NRC report at 91-92.

[3][4] Under *Frye*, this court conducts a *de novo* review to determine whether a scientific principle used as a basis for expert testimony is generally accepted in the relevant scientific community. *Bible*, 175 Ariz. at 578, 858 P.2d at 1181. At the *Frye* hearing, Hogan testified that the modified ceiling method is recommended by the NRC. *See* NRC report at 91-92. Other

courts have recognized that

the [NRC] is a distinguished cross section of the scientific community.... Thus, that committee's conclusion regarding the reliability of forensic DNA typing, specifically RFLP analysis, and the proffer of a conservative method for calculating probability estimates can easily be equated with general acceptance of those methodologies in the relevant scientific community.

United States v. Porter, 618 A.2d 629, 643 n. 26 (D.C.App.1992), quoting *United States v. Bridgett*, 120 Daily Wash.L.Rep. 1697 (D.C.Super.Ct.1992); see also *Cauthron*, 846 P.2d at 517 (NRC's adoption of ceiling method "indicates sufficient acceptance within the scientific community" for *Frye* purposes). We, too, believe that endorsement by the NRC of the modified ceiling method is strong evidence of general acceptance within the relevant scientific community. But we need not rely solely on the NRC's endorsement. Several other courts have addressed this issue and found the modified ceiling method to be generally accepted. See *Commonwealth v. Lanigan*, 419 Mass. 15, 641 N.E.2d 1342 (1994); *State v. Bloom*, 516 N.W.2d 159, 167 (Minn.1994); *State v. Anderson*, 118 N.M. 284, 881 P.2d 29, 47 (1994).

These judicial views are supported by the weight of scientific opinion. Eric S. Lander and Bruce Budowle were two of the principal antagonists involved in the initial debate over forensic DNA typing. See *DNA Fingerprinting Dispute Laid to Rest*, 371 NATURE 735 (Oct.1994). Both Lander and Budowle have concluded that following the NRC's report "there is no scientific reason to doubt the accuracy of forensic DNA typing results," such as the modified ceiling method. *Id.*

****300 *335** Most telling, perhaps, is that those forensic experts who take issue with the modified ceiling method do so because they believe it produces excessively conservative results that unduly favor the defendant. See, e.g., Eric E. Wright, *DNA Evidence: Where We've Been, Where We Are, And Where We're Going*, 10 MAINE BAR J. 206 (1995); David H. Kaye, *DNA Evidence: Probability, Population Genetics, and the Courts*, 7 HARV. J.L. & TECHH. 101 (1993); DRIBBEN, *supra*, at 124-42; Peter Aldhous, *Geneticists Attack NRC Report as Scientifically Flawed*, 259 SCIENCE 755 (1993); B. Devlin, Neil

Risch, Kathryn Roeder, *Statistical Evaluation of DNA Fingerprinting: A Critique of the NRC's Report*, 259 SCIENCE 748 (1993); Richard Lempert, *DNA, Science and the Law; Two Cheers For The Ceiling Principle*, 34 JURIMETRICS J. 41 (1993); Kenneth R. Kreiling, *DNA Technology in Forensic Science*, 33 JURIMETRICS J. 449 (1993).

The National Research Council's Committee on DNA Forensic Science and Commission on DNA Forensic Science have released a pre-publication version of THE EVALUATION OF FORENSIC DNA EVIDENCE updating the 1992 NRC report. This report concludes that sufficient data has been gathered to make the conservative approach of the ceiling principles no longer needed. *Id.* at 5-32. It further concludes that alternative methods, primarily the product rule, are now appropriate. *Id.* We fail to see any prejudice to a defendant in results produced by a method that, if biased, is biased in the defendant's favor.

[5] Based on our review of the NRC reports, legal commentary, scientific literature, and consideration and acceptance of the modified ceiling method by other jurisdictions, we conclude that the method is generally accepted in the relevant scientific community and that DNA probability calculations computed with that method are admissible under *Frye*. Our holding extends only to the issue presented in this case—the modified ceiling method. Notwithstanding the 1996 NRC report's conclusions, we do not at this time address the admissibility of probability statistics calculated with the "pure" product rule.

D. DPS methodology

Johnson also argues that even if the modified ceiling method is generally accepted, the procedures Hogan used did not properly implement that method. Specifically, Johnson claims that the entire procedure used to calculate the probability of a match was invalid because Hogan did not search the DPS database for a match with his DNA profile. We disagree.

In its first report, the NRC recommends that the defendant's profile be checked against all the profiles in the database to see if it matches any of them. NRC report at 91. "Assuming that it does not, [the jury should be told] that the [profile] was compared to a database of N individuals from the population and no

match was observed, indicating its rarity in the population." *Id.* The purpose of testing for such a match is to generate a separate and unrelated statistic to indicate the rarity of a suspect's profile in the database and "make[] clear the size of the database being examined." *Id.* Although such a statistic is arguably helpful, it is not part of the modified ceiling method and does not affect the probability calculation that is admissible under that method.

CONCLUSION

[6][7] The *Frye* test remains the standard for admissibility of new scientific evidence. DNA probability evidence calculated by use of the RFLP protocol and with the modified ceiling method is generally accepted in the relevant scientific community and is therefore admissible under the *Frye* test, subject to proper foundational showing. *See Bible*, 175 Ariz. at 580, 858 P.2d at 1183. Upon such a showing, the significance of a DNA profile match may be explained with probability estimates based on the method's calculations. Accordingly, we approve the court of appeals' opinion finding that the trial judge did not err in permitting testimony on the mathematical probability of Johnson's **301 *336 DNA profile occurring randomly and affirm Johnson's conviction and sentence.

ZLAKET, V.C.J., MOELLER and MARTONE, JJ., and JACOBSON, Judge (retired), concurring.
ROBERT J. CORCORAN, J., did not participate in the determination of this matter; pursuant to Ariz. Const. art. VI, § 3, the Honorable EINO M. JACOBSON, Judge (retired) of the Arizona Court of Appeals, Division One, was designated to sit in his stead.

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Supreme Court of New Hampshire.
 The STATE of New Hampshire
 v.
 Daniel VANDEBOGART (DNA).
 No. 92-016.

Nov. 20, 1992.

Defendant was convicted in the Superior Court, Rockingham County, Mohl, J., of murder, and he appealed admission of DNA identification evidence. The Supreme Court, Thayer, J., held that: (1) underlying DNA profiling analysis is generally accepted in relevant scientific community; (2) technology used by FBI to conduct such analysis is generally accepted in relevant scientific community; but (3) statistical technique used by FBI to estimate population frequencies was not generally accepted among relevant community.

Reversed and remanded.

West Headnotes

[1] Criminal Law 110 ↪ 388.1

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.1 k. In general. Most Cited Cases

(Formerly 110k388(1))
 Admissibility of scientific evidence requires general acceptance in relevant scientific community of scientific theory or principle, and general acceptance in relevant scientific community of techniques, experiments, or procedures applying that theory or principle; issue of whether testing laboratory in any particular case adhered to generally accepted techniques addresses matter that properly goes to either admissibility or weight to be given evidence in particular case, and not to admissibility of scientific evidence in general.

[2] Criminal Law 110 ↪ 1134.49(1)

110 Criminal Law
 110XXIV Review
 110XXIV(L) Scope of Review in General
 110XXIV(L)4 Scope of Inquiry
 110k1134.49 Evidence
 110k1134.49(1) k. In general. Most Cited Cases

(Formerly 110k1134(3))
 In reviewing trial court's admission of scientific evidence, appellate court independently reviews record and makes its own determination as to whether the theory or principle is generally accepted in the relevant scientific community without regard to findings of trial court.

[3] Criminal Law 110 ↪ 304(1)

110 Criminal Law
 110XVII Evidence
 110XVII(A) Judicial Notice
 110k304 Judicial Notice
 110k304(1) k. In general. Most Cited Cases

Criminal Law 110 ↪ 388.2

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General
 110k388 Experiments and Tests; Scientific and Survey Evidence
 110k388.2 k. Particular tests or experiments. Most Cited Cases
 (Formerly 110k388(2))
 Theory underlying DNA profiling is generally accepted in relevant scientific community, for purpose of admitting such scientific evidence on issue of identification, and trial court may properly take judicial notice of its acceptance.

[4] Criminal Law 110 ↪ 388.2

110 Criminal Law
 110XVII Evidence
 110XVII(I) Competency in General

616 A.2d 483
 136 N.H. 365, 616 A.2d 483
 (Cite as: 136 N.H. 365, 616 A.2d 483)

110k388 Experiments and Tests; Scientific and Survey Evidence

110k388.2 k. Particular tests or experiments. Most Cited Cases

(Formerly 110k388(2))

Restriction fragment length polymorphism (RFLP) analysis, as DNA profiling forensic technique, is generally accepted technique in scientific community.

[5] Criminal Law 110  388.2

110 Criminal Law

110XVII Evidence

110XVII(I) Competency in General

110k388 Experiments and Tests; Scientific and Survey Evidence

110k388.2 k. Particular tests or experiments. Most Cited Cases

(Formerly 110k388(2))

Challenges to FBI's DNA profiling forensic technique, which involved consideration of reliability of particular test results and whether techniques were generally accepted as capable of producing reliable results, went to admissibility or weight to be given evidence in particular case, and not to admissibility of such evidence per se.

[6] Criminal Law 110  388.2

110 Criminal Law

110XVII Evidence

110XVII(I) Competency in General

110k388 Experiments and Tests; Scientific and Survey Evidence

110k388.2 k. Particular tests or experiments. Most Cited Cases

(Formerly 110k388(2))

FBI's population frequency calculation, used to determine likelihood that DNA profile match identifies provider of known sample as depositor of crime scene sample, has not found general acceptance in field of population genetics, and thus was not admissible; FBI's method relied on "product rule," a statistical method which relied for its accuracy on absence of intraracial substructures, which issue was subject of considerable current debate among population geneticists.

**484 *366 John P. Arnold, Atty. Gen., and Nelson, Kinder, Mosseau & Gordon, P.C., Manchester (Peter G. Beeson on the brief and orally), for the State.

James E. Duggan, Chief Appellate Defender, Concord, and Albert E. Scherr, Public Defender, Concord (James E. Duggan and Albert E. Scherr on the brief, and Albert E. Scherr orally), for the defendant.

THAYER, Justice.

The defendant, Daniel Vandebogart, appeals from his conviction for first degree murder, RSA 630:1-a, based on a jury verdict in the Superior Court (*Mohl, J.*). Upon motion by the State, we bifurcated the defendant's appeal in order to expedite our consideration of issues he raises relating solely to the admissibility of forensic DNA profiling. The defendant complains that the trial judge misapplied the legal standard for admitting novel scientific evidence under *Frye v. United States*, 293 F. 1013 (D.C.Cir.1923), and *State v. Coolidge*, 109 N.H. 403, 260 A.2d 547 (1969), *rev'd on other grounds*, 403 U.S. 443, 91 S.Ct. 2022, 29 L.Ed.2d 564 (1971). We reverse and remand.

On September 12, 1989, Kimberly Goss was raped and murdered. In October, the New Hampshire State Police asked the FBI to perform forensic DNA analysis. Subsequently, the FBI's DNA laboratory received a package of forensic samples which included known blood samples from Kimberly Goss and the defendant together with two vaginal swabs taken from Kimberly Goss at her autopsy. On February 27, 1990, the FBI's DNA laboratory reported to the New Hampshire State Police that the genetic profile of the defendant's blood sample matched the genetic profile of semen found on the vaginal swabs at three genetic locations. The FBI further reported that the probability that an unrelated individual selected at random from the Caucasian population would have a genetic profile matching the defendant's at those three locations was 1 in 50,000.

Prior to trial, the defendant filed a motion *in limine* seeking to exclude the DNA evidence of a match and the probability calculation. *367 In response to the defendant's motion, the trial court held a pretrial *Frye* hearing which lasted ten days. At the hearing, the court heard expert testimony from five witnesses for the prosecution and three for the defendant. The State's witnesses and their backgrounds were as follows: (1) Dr. Dwight Adams, a biologist, a member of the American Academy of Forensic Sciences, and

the FBI special agent responsible for the DNA analysis in this case; (2) Dr. Steven Daiger, Professor of Medical Genetics at the University of Texas Health Science Center; (3) Dr. David Goldman, Chief of the Genetics Studies Section of the National Institutes of Alcohol Abuse and Alcoholism, National Institute of Health; (4) Dr. Michael Conneally, Distinguished**485 Professor of Medical Genetics and Neurology at Indiana University Medical Center; and, as a rebuttal witness, (5) Dr. Bruce Budowle, a molecular biologist and human population geneticist in charge of the FBI's DNA research program. The following witnesses testified for the defendant: (1) Dr. William Shields, Professor at State University of Environmental Science Technology, Syracuse, New York; (2) Dr. Joseph Nadeau, a scientist working at Jackson Laboratory and recipient of a Ph.D. in population genetics from Boston University; and (3) Dr. Everett Mendelsohn, a Professor of History of Science at Harvard University with a Ph.D. in the History of Science.

Following the hearing, the court issued an order denying the defendant's motion. After a trial in which the evidence derived from the DNA testing was admitted, the jury convicted the defendant of first degree murder, and the court sentenced him to life in prison without parole.

In this portion of the defendant's bifurcated appeal, the sole issue for our consideration is whether the trial court properly applied the standard for admissibility of novel scientific evidence. The defendant argues here, as he did below, that the proper test for admissibility of novel scientific evidence requires a three-prong analysis under *Frye* and *Coolidge*, and that the trial court erred by not applying the second and third prongs. Specifically, he contends that the trial court only examined the general acceptance of the theory underlying DNA profiling, and that if it had properly applied the second prong, it would have found that the particular technology used by the FBI to perform the DNA profiling analysis was not generally accepted as reliable by the relevant scientific community. The State responds that the trial court properly applied the *Frye* standard and that in its order the court correctly found that both the theory and technology of DNA profiling were generally accepted.

*368 I. DNA Background

A basic understanding of the theories and procedures involved in DNA profiling is necessary to understand the legal issues surrounding its use as evidence in court. Therefore, before we discuss the issues surrounding the admissibility of novel scientific evidence, we shall first consider the general nature of the particular evidence the State sought to have admitted. We derive our scientific exposition of DNA and DNA profiling from testimony given at the *Frye* hearing and from a report entitled "DNA Technology in Forensic Science," which the National Research Council published in April 1992. For more comprehensive descriptions of these topics, see *United States v. Jakobetz*, 747 F.Supp. 250, 250-54 (D.Vt.1990), *aff'd*, 955 F.2d 786 (2d Cir.1992), *cert. denied*, 506 U.S. 834, 113 S.Ct. 104, 121 L.Ed.2d 63 (1992); *People v. Wesley*, 140 Misc.2d 306, 533 N.Y.S.2d 643, 645-50 (County Ct.1988); E. Imwinkelried, *The Debate in the DNA Cases over the Foundation for the Admission of Scientific Evidence: The Importance of Human Error as a Cause of Forensic Misanalysis*, 69 Wash.U.L.Q. 19 (1991); W. Thompson & S. Ford, *DNA Typing: Acceptance and Weight of the New Genetic Identification Tests*, 75 Va.L.Rev. 45 (1989).

A. DNA Theory

Deoxyribonucleic acid (DNA) is an organic substance found in the chromosomes contained in the nucleus of a cell. It provides the genetic blueprint that determines the physical structures and individual characteristics of every living organism—humans, animals, plants, and even bacteria. In humans, DNA exists in all cells that have a nucleus, including white blood cells, sperm, cells surrounding hair roots, and the cells in saliva. These are the cells most often discovered at crime scenes and are the most useful in forensic DNA analysis.

With exceptions not relevant here, DNA does not vary within an individual, *i.e.*, the DNA contained in one cell in an individual will be identical to the DNA contained in every other cell of that individual. For forensic purposes, the important characteristic of DNA is that, excepting identical **486 twins, no two persons have the same DNA structure.

The DNA molecule is shaped like a double helix which resembles a twisted ladder. Each component strand of the helix, similar to the rungs on a ladder,

consists of a sequence of nucleotides. The nucleotides are sometimes referred to as bases. There are four types of nucleotides in the DNA molecule, and they are designated as adenine *369 (A), guanine (G), cytosine (C), and thymine (T). The nucleotides bond in predictable patterns, A to T and C to G. A pair of complementary bases-A-T, T-A, C-G, or G-C is designated as a base pair. The order in which these base pairs appear on the DNA ladder constitutes the genetic code for the cell. This code carries the necessary information to produce the many proteins which comprise the human body. A sequence of base pairs responsible for producing a particular protein is called a "gene." A gene, the basic unit of heredity, consists of a sequence of between 1,000 and 2 million nucleotides. Scientists estimate that the human genome, the complete genetic makeup of a person, contains 50,000 to 100,000 genes and that in a human set of 23 chromosomes there are about 3 billion nucleotides.

Inheritable characteristics are controlled by pairs of genes, or alleles, which occupy the same sites, or loci, on paired chromosomes. One of each pair of alleles is inherited from the father, and one is from the mother. When the alleles that comprise a pair differ, the individual is said to be "heterozygous" for that allele. When the maternal and paternal alleles in a pair are the same, the individual is "homozygous." A particular combination of alleles is referred to as a genotype.

DNA technology allows scientists to detect genetic variations. A characteristic that differs among individuals is termed a polymorphism. In DNA profiling, the terms polymorphism and variation are used interchangeably. Some regions of DNA contain repetitive strings of nucleotides that are highly polymorphic. These are called "variable number tandem repeats" (VNTRs). At VNTRs, the number of repetitions of a nucleotide sequence can vary among individuals. For this reason, VNTRs are commonly used as genetic markers to detect variations.

A variation of even one nucleotide in the sequence of DNA is detectable. Such a variation can be detected by applying a biological catalyst, called a "restriction enzyme," to the DNA. The restriction enzyme will cut the DNA into fragments of different lengths depending on the cutting sites recognized by the enzyme. These fragments of varying lengths are called

"restriction fragment length polymorphisms" (RFLPs). Differences among individuals can be detected by the differences in the lengths of restriction fragments. Because of its extensive variability, the VNTR class of RFLPs is the most useful in distinguishing among individuals.

B. DNA Profiling Techniques

DNA profiling can inculpate a criminal suspect by comparing the suspect's genetic material with genetic material obtained from human*370 tissue left at the crime scene. DNA profiling involves two distinct procedures. First, RFLP analysis determines if there is a "match." A "match" does not mean that the suspect was definitely the source of the genetic material found at the crime scene, however, but simply that the suspect cannot be eliminated as the potential source. Even if there is a perfect match, there is a possibility that the two samples came from different people whose DNA patterns at the targeted loci are indistinguishable. Thus the second procedure, population frequency calculation, generates a ratio which accompanies a match in order to express the statistical likelihood that an unrelated individual chosen at random from a particular population could have the same DNA profile as the suspect.

DNA analysis is generally performed by first disassembling the DNA molecular ladder in one of several different ways. The FBI uses "RFLP analysis," and follows a written protocol that requires certain procedures for quality control and verification. The operative steps of RFLP analysis are outlined below:

**487 1. *Extraction of DNA.* The DNA is first extracted from the evidentiary sample by using chemical enzymes and then purified.

2. *Restriction of digestion.* The DNA is then cut with chemical scissors called "restriction endonucleases." These endonucleases recognize certain base pairs and sever the DNA molecule at specifically targeted base pair sites to produce RFLPs.

3. *Gel electrophoresis.* The cut fragments of DNA molecules are next placed in an agarose gel which is later electrically polarized to sort the fragments by length. Because DNA is negatively charged, the fragments will migrate toward the positive end of the gel. The distance traveled will depend upon the

length of the fragment, with the shorter fragments traveling further in the gel. Molecular weight standards, also called "size markers," are placed in separate lanes to measure the distance that the fragments travel. For comparison, several different samples of DNA from known and unknown sources are run on the same gel, but in different tracks or lanes.

4. *Southern blotting or transfer.* Because the agarose gel is very difficult to work with, the fragments are transferred to a more functional surface by a method called "Southern transfer." A nylon membrane is placed over the gel, which is set upon a sponge saturated with sodium hydroxide solution. The solution carries the fragments from the gel onto the nylon membrane, and they become permanently fixed on the membrane, referred to as a "blot," in the same pattern as in the gel. Also during this step, a denaturation process severs each double-stranded DNA fragment into two single strands—one inherited from the father and one from the mother.

*371 5. *Hybridization.* Next, a single-locus genetic probe is used to locate a specific polymorphic region of the DNA on the blot. A genetic probe is a single-stranded segment of DNA designed to complement a single-stranded DNA base sequence that is associated with a particular locus on a chromosomal pair. The probe will bond with any single-stranded fragments containing that particular base sequence. The typical result is that the probe will bind to DNA fragments at one or two locations in each lane, depending on whether the individual is homozygous or heterozygous for that particular allele. The genetic probe is tagged with a radioactive marker, which attaches to the probe and emits radiation without altering the function of the probe. The marker is used to determine the probe's position on the blot after it hybridizes with polymorphic segments.

6. *Autoradiography.* Autoradiography is the photographic process that reveals the position of the polymorphic DNA segments. After hybridization, the nylon membrane is placed between two pieces of X-ray film. The radioactive probes expose the film at their respective locations. Black bands appear on the processed film where the radioactive probes have bonded to the RFLPs, producing a DNA "print." Typically, each probe will expose one or two bands for each DNA sample, which reflects the maternal or paternal contributions to the individual's DNA pro-

file. The position of each band indicates the location of a polymorphic segment on the blot. Location, in turn, indicates the length of the DNA fragment that contains the segment. Because the length of the DNA fragments varies among individuals, the position of their bands on a DNA print can differentiate individuals.

After the first probe has been applied and the autoradiography process is complete, the first probe is stripped from the membrane. The hybridization process is then repeated on the same membrane using a second probe. This process is designed to locate a different VNTR base sequence on another chromosomal pair. The FBI usually repeats the hybridization and autoradiography processes using four or five different probes sequentially on a single blot. Repeating the processes with different probes decreases the likelihood that a match between the defendant's profile and the forensic profile is a random event. It is rare for two unrelated persons to have **488 eight or ten matching alleles across four or five different VNTR loci.

7. *Interpretation of autoradiographs.* The final step is to determine if a match exists in the two lanes of the autoradiograph between the DNA sample taken from the suspect and the forensic sample taken from the crime scene or victim. The FBI uses a two-stage procedure*372 for deciding whether a match exists. First, the FBI looks for a visual match. A visual match means that the forensic sample of DNA and the suspect's DNA have the same number of bands in approximately the same locations on each autoradiograph. If no visual match exists, the FBI decides whether the non-match should be interpreted as inconclusive or as excluding the suspect. If a visual match is declared, the FBI uses a computer-assisted process to verify the existence of a match. Through a series of calculations, the computer will determine whether the difference in size of the fragments detected in the defendant's sample and the forensic samples is within accepted limits. If the size of the suspect's DNA fragments and the forensic samples are within plus or minus two and one-half percent of each other, then the visual match is confirmed. If the difference between the two exceeds the "matching criteria" of plus or minus two and one-half percent, then the autoradiograph is considered either inconclusive or as excluding the suspect. In this case, the FBI confirmed a visual match between the defen-

dant's DNA and that from the victim's body because the degree of variation did not exceed plus or minus one percent.

Once the suspect's DNA profile is declared to match the forensic sample, the FBI relies on statistical methods used in population genetics to calculate the likelihood of a random match. "Fixed bin analysis" is the FBI's method for assigning to each band in a DNA profile a value or frequency that represents how often a particular allele may occur at a specific VNTR locus in a given population. To estimate population frequencies for particular alleles at targeted VNTR loci, the FBI has compiled data bases for Caucasian, Black, Asian, and Hispanic populations. The FBI's Caucasian data base was derived from RFLP analyses of blood samples of approximately 225 FBI agent-trainees. The end result of the FBI's fixed bin analysis of RFLPs from a forensic sample is a statistic which estimates the probability that the DNA profile of an individual chosen at random from a given population might match the DNA profile of the forensic sample for the targeted VNTR loci.

To calculate this statistic, the FBI applies the "product rule." Use of the product rule in this context requires two assumptions about the statistical independence of allele matches: (1) that there is no greater or lesser likelihood that a person carrying one allele at a VNTR locus will also carry another particular allele at the same locus; and, (2) that carrying one pair of alleles at a locus neither increases nor decreases the chance of carrying another particular pair at a different locus on a separate chromosome. If these assumptions *373 are proper, then the product rule indicates that multiplying the population frequencies of all alleles detected in a DNA sample will yield an estimate of how common that DNA profile is in a given population. In this particular case, the FBI calculated that the chance that an unrelated individual chosen at random from the Caucasian population would have a DNA profile matching the forensic sample pattern is 1 in 50,000.

II. The Legal Standard of Admissibility

The sole issue we address in this appeal is the defendant's contention that the trial court misapplied the legal standard for the admissibility of novel scientific evidence. Although both parties agree that the proper standard for determining the admissibility of scien-

tific evidence is derived from *Frye* and *Coolidge*, they differ with regard to its proper formulation. We note that although we have recently adopted the New Hampshire Rules of Evidence, neither party has asked us to reconsider our use of the *Frye* standard.

Most courts that have considered the admissibility of novel scientific evidence have adopted the *Frye* test. See *Jakobetz*, 955 F.2d at 794 (describing *Frye* test as majority**489 rule). The *Frye* court stated in its seminal decision:

"Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while the courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs."

Frye, 293 F. at 1014. "The *Frye* court assumed that general acceptance indicated reliability and that only reliable evidence should be admissible." *Jakobetz*, 955 F.2d at 794. As one commentator noted:

"In effect, *Frye* envisions an evolutionary process leading to the admissibility of scientific evidence. A novel technique must pass through an 'experimental' stage in which it is scrutinized by the scientific community. Only after the technique has been tested successfully in this stage and has passed into the 'demonstrable' stage will it receive judicial recognition."

*374 P. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 Colum.L.Rev. 1197, 1205 (1980).

Although the *Frye* standard has received substantial criticism, adherence to it: (1) permits disputes concerning scientific validity to be resolved by the relevant scientific community, *United States v. Addison*, 498 F.2d 741, 743-44 (D.C.Cir.1974); *People v. Barbara*, 400 Mich. 352, 405, 255 N.W.2d 171, 194 (1977); (2) ensures that "a minimal reserve of experts exist who can critically examine the validity of a scientific determination in a particular case," *Addison*, 498 F.2d at 744; (3) spares courts from the time-

consuming and difficult task of repeatedly assessing the validity of innovative scientific techniques, *Reed v. State*, 283 Md. 374, 388, 391 A.2d 364, 371-72 (1978); and (4) "promote[s] a degree of uniformity of decision," *People v. Kelly*, 17 Cal.3d 24, 31, 549 P.2d 1240, 1244-45, 130 Cal.Rptr. 144, 148-49 (1976).

The defendant contends that the trial court applied a single-prong *Frye* test that was deficient for two reasons. First, he argues that the trial court failed to determine whether the particular technology employed by the FBI in performing its DNA analysis was generally accepted in the relevant scientific community. Second, he argues that the trial court erred by not assessing the reliability of the particular test results. The State contends that the trial court did consider the general acceptance of the techniques used in DNA profiling and that the reliability of the particular test results is a matter which affects the weight of the evidence, not its admissibility.

We adopted the *Frye* standard in *Coolidge*, 109 N.H. at 421-22, 260 A.2d at 560-61. We stated the *Frye* test as follows: "[I]n order for the results of scientific tests to be admissible in evidence, the scientific principle involved 'must be sufficiently established to have gained general acceptance in the particular field in which it belongs.'" *Id.* at 421, 260 A.2d at 560 (quoting *Frye*, 293 F. at 1014). In *Coolidge*, we examined the admissibility of evidence derived from neutron activation analysis and held that the *Frye* standard of general acceptance had been satisfied for some applications but not others. In applying *Frye*, we upheld the trial court's exclusion of hair identification evidence developed by means of neutron activation analysis based on expert testimony that the tester's *methods* would not be acceptable to scientists in the field. *Id.* at 420-22, 260 A.2d at 561. However, with regard to the comparison of particles vacuumed from the victim's and defendant's clothing, also derived from neutron*375 activation analysis, we stated that the trial court "could properly find that the test of particles produced an accurate analysis of the chemical elements which they contained, by means of *procedures* sufficiently accepted by scientists familiar with this limited field." *Id.* at 422, 260 A.2d at 561 (emphasis added). Thus, although in *Coolidge* we did not plainly **490 state the scope of our inquiry under *Frye*, it is clear that our analysis went beyond mere inquiry into the general acceptance of the theory underlying neutron activation analysis.

Generally, courts applying the *Frye* standard to determine the admissibility of DNA evidence have employed a two-prong test that requires both the theory and the techniques implementing the theory to be generally accepted in the relevant scientific community. *See, e.g., United States v. Yee*, 134 F.R.D. 161, 194 (N.D. Ohio 1991) (admissibility of DNA evidence is conditioned on general acceptance of principles and procedures); *State v. Ford*, 301 S.C. 485, 488, 392 S.E.2d 781, 783 (1990) (under *Frye*, admissibility of scientific evidence depends upon general acceptance of theory and technique); *see also* G. Lilly, *An Introduction to the Law of Evidence* 494 (2d ed. 1987) (in applying *Frye*, courts tend to apply standard of general acceptance to validity of scientific principle and process).

The defendant argues that the *Frye* test is a three-prong analysis similar to that used in *People v. Castro*, 144 Misc.2d 956, 545 N.Y.S.2d 985 (Sup.Ct.1989). The *Castro* court acknowledged that New York follows the *Frye* test, *id.* 545 N.Y.S.2d at 986, but because of the complexity of DNA profiling evidence and the potential, powerful impact it might have on the jury, the court added a third prong as an additional hurdle to the admissibility of scientific evidence.

Prong I. Is there a theory, which is generally accepted in the scientific community, which supports the conclusion that DNA forensic testing can produce reliable results?

Prong II. Are there techniques or experiments that currently exist that are capable of producing reliable results in DNA identification and which are generally accepted in the scientific community?

Prong III. Did the testing laboratory perform the accepted scientific techniques in analyzing the forensic samples in this particular case?"

Id. 545 N.Y.S.2d at 987. In applying its test, the *Castro* court found that the theory underlying DNA testing and the tests themselves met the *Frye* standard of admissibility. *Id.* 545 N.Y.S.2d at 999. The court, however, ultimately held that the inculpatory evidence derived from the tests was inadmissible*376 because the laboratory had failed to follow generally accepted techniques. *Id.*

The first two prongs of the *Castro* court's test are firmly embedded in the *Frye* test. See *Jakobetz*, 955 F.2d at 794. The third prong, however, reaches beyond the requirements normally associated with *Frye*. We are aware of no court that has included the third prong as part of its *Frye* analysis. Even the *Castro* court acknowledged that its third prong involved a consideration of factors beyond the scope of the *Frye* test. See *Castro*, 545 N.Y.S.2d at 988 (first two prongs deal exclusively with *Frye* test and third prong involves issue of reliability of particular evidence); see also *People v. Mohit*, 153 Misc.2d 22, 579 N.Y.S.2d 990, 992 (County Ct.1992) (third prong developed in *Castro* not properly part of *Frye* test).

[1] Based on our consideration of how the *Frye* test is applied in other jurisdictions and our decision in *Coolidge*, we conclude that the admissibility of scientific evidence requires: (1) general acceptance in the relevant scientific community of the scientific theory or principle; and (2) general acceptance in the relevant scientific community of the techniques, experiments, or procedures applying that theory or principle. In our opinion, the third prong applied by the *Castro* court, as to whether the testing laboratory adhered to generally accepted techniques, addresses matters that properly go to either the admissibility or the weight to be given the evidence in a particular case, not admissibility under *Frye*. See *Mohit*, 579 N.Y.S.2d at 992 (concluding that third prong in *Castro* should go to weight of evidence, not its admissibility).

[2] We now turn to an examination of the general acceptance of the theory and technology of DNA profiling techniques, **491 including both RFLP analysis and population frequency calculation. The State urges us to uphold the trial court's finding of general acceptance unless we decide that it was an abuse of discretion. However, whether a scientific theory and the technique used to implement it are generally accepted does not vary according to the circumstances of each case, and thus the determination of general acceptance is not a matter to be left to each trial judge's individual discretion. See *Reed*, 283 Md. at 381, 391 A.2d at 367. Therefore, on appeal, we independently review the record and make our own determination of general acceptance without regard to the findings of the trial court. See *Com-*

monwealth v. Curnin, 409 Mass. 218, 223, 565 N.E.2d 440, 443 (1991); see also *Giannelli, supra* at 1222-23.

The majority of the jurisdictions that have ruled on this issue have found the DNA profiling theory and procedures for declaring a *377 match to be generally accepted as reliable. See *State v. Montalbo*, 73 Haw. 130, 144-46, 828 P.2d 1274, 1283 (1992) (evidence derived from DNA testing admissible under *Frye* standard and Rules 702 and 703); *State v. Brown*, 470 N.W.2d 30, 32 (Iowa 1991) (finding that procedure was sufficiently reliable and met general test for admissibility); *Smith v. Deppish*, 248 Kan. 217, 239, 807 P.2d 144, 159 (1991) (trial court did not err in admitting DNA evidence because testing and RFLP analysis is recognized as reliable); *State v. Davis*, 814 S.W.2d 593, 602-03 (Mo.1991) (finding reliability of procedures sufficiently established, and no abuse of discretion in admitting DNA evidence); *State v. Pennington*, 327 N.C. 89, 100, 393 S.E.2d 847, 854 (1990) (DNA testing method is reliable and trial court did not err in admitting DNA evidence); *Ford*, 301 S.C. at 488-90, 392 S.E.2d at 783-84 (DNA print testing and RFLP analysis recognized as reliable and gained general acceptance); *State v. Wimberly*, 467 N.W.2d 499, 505-06 (S.D.1991) (holding DNA analysis meets *Frye* test of general acceptance); *Spencer v. Commonwealth*, 238 Va. 275, 290, 384 S.E.2d 775, 783 (1989) (undisputed evidence established DNA testing as generally accepted in scientific community), *cert. denied*, 493 U.S. 1036, 110 S.Ct. 759, 107 L.Ed.2d 775 (1990); *State v. Woodall*, 182 W.Va. 15, 385 S.E.2d 253, 260 (1989) (finding DNA typing analysis generally accepted). While recognizing DNA testing as generally accepted, some courts have imposed limitations on the admissibility of population frequency statistics. See *Caldwell v. State*, 260 Ga. 278, 393 S.E.2d 436 (1990) (DNA evidence admissible, but only with conservative frequency estimate); *Curnin*, 409 Mass. at 224-27, 565 N.E.2d at 444-45 (finding method used by tester to calculate population frequency not generally accepted); *State v. Schwartz*, 447 N.W.2d 422, 428-29 (Minn.1989) (evidence of match derived from RFLP analysis admissible under *Frye* standard, but accompanying statistics inadmissible); *Mohit*, 579 N.Y.S.2d at 995, 999 (finding FBI's method for conducting RFLP analysis and declaring match generally accepted, but population frequency estimate admissible only if most conservative method used). Generally, courts that have excluded DNA profiling

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evidence have done so because the particular testing laboratory failed to adhere to generally accepted techniques for obtaining relevant, reliable results, not because the theory or procedures were not generally accepted. *See, e.g., Castro*, 545 N.Y.S.2d at 999 (test results deemed inadmissible because laboratory failed to follow generally accepted techniques); *Woodall*, 385 S.E.2d at 260 (particular test results inadmissible under Rule 401 as inconclusive).

*378 A. General Acceptance of DNA Theory

[3] The defendant does not contest the general acceptance of the theory underlying DNA profiling. As commentators have stated:

“There is nothing controversial about the theory underlying DNA typing. Indeed, this theory is so well-accepted that its accuracy is unlikely even to be raised as an issue in hearings on the admissibility of the new tests.... The theory has been repeatedly put to the test and has **492 successfully predicted subsequent observations.”

W. Thompson & S. Ford, *supra* at 60-61. Based on our review of the record and the available literature, we also conclude that the theory underlying DNA profiling is generally accepted in the relevant scientific community. In future cases, a trial court may properly take judicial notice of its general acceptance and thus avoid relitigation on this issue.

B. General Acceptance of DNA Profiling Forensic Techniques

DNA profiling primarily involves the scientific disciplines of molecular biology and population genetics. The RFLP laboratory procedures that are used to determine whether there is a match between the sample taken from the suspect and the sample taken from the crime scene are largely drawn from the fields of molecular biology, biochemistry, and related fields. The significance of a declared match, as expressed by the probability that there is a coincidental match, is a matter of population and human population genetics. Accordingly, it is helpful to analyze the general acceptance of each procedure separately.

1. RFLP Analysis

At the pretrial *Frye* hearing, Dr. Adams testified to the general acceptance within the scientific community of forensic scientists of each step used in RFLP analysis individually and together. Drs. Daiger and Goldman each testified to the general acceptance in the field of molecular biology of the methods used in the FBI's RFLP analysis. Dr. Shields, a defense expert, agreed with the State's experts that the RFLP process employed by the FBI, except their use of a matching window, was generally accepted in the scientific community of molecular biologists. Dr. Nadeau, another defense expert, also agreed that the methods used in RFLP analysis are well accepted. In its order, the trial court noted that the RFLP process is used in thousands of laboratories worldwide for hundreds of different purposes and concluded that “[t]here does not appear to be any serious question*379 in the field of molecular biology that the RFLP process used in DNA profiling to measure or size the number of repeating fragments of the DNA is generally accepted.” (Emphasis added.)

[4] The defendant's primary challenge centers on the transfer of this science to the field of forensics, not the general acceptance of the RFLP techniques themselves. At the hearing, the State produced evidence that although the application of these methods in the field of forensics may be a “societal breakthrough,” it is not a “scientific breakthrough.” After reviewing the record, we agree with the analysis of the South Carolina Supreme Court:

“We recognize that the use of DNA analysis in forensic settings is a recent development. This type of analysis has been utilized for a number of years in diagnostic settings. Because the focus is different than in diagnostic settings, problems may exist that are unique to forensic DNA tests. For example, in forensic DNA testing, there is a higher probability that the sample may be contaminated by bacteria. Such problems, however, concern the reliability of the particular tests performed in a particular case....”

Ford, 301 S.C. at 489, 392 S.E.2d at 783. As such, we agree with the trial court's finding that the RFLP analysis, as outlined above, used to determine a match is a generally accepted technique in the scientific community.

[5] The defendant raises three additional challenges

to the general acceptance of RFLP analysis: (1) the FBI has chosen an improper matching window for determining whether there is a match between the defendant and the unknown sample; (2) the lack of objective criteria used in the FBI's matching process in which the examiner conducts a two-step analysis of the autorad; and (3) the FBI's environmental insult validation studies were insufficient. These issues all involve consideration of the reliability of particular test results and not whether the FBI's techniques are generally accepted as capable of producing reliable results. As we noted above, such considerations normally go to either the admissibility or the weight to be given the evidence in **493 a particular case, not admissibility under *Frye*. See *Ford*, 301 S.C. at 490, 392 S.E.2d at 784 (particular techniques used in specific test or reliability of test results may be impeached by expert testimony).

2. General Acceptance of Population Frequency Calculation

[6] At the *Frye* hearing, Drs. Daiger and Goldman testified that, in the field of human population genetics, the methodology by which the *380 FBI calculates population frequency estimates was generally accepted. Additionally, Dr. Conneally testified as to the general acceptance of the FBI's fixed bin methodology for calculating population frequencies in the field of human population genetics and the FBI's use of a randomly selected data base. In its pretrial order, the court concluded that "[t]he science of population frequency projections—be they the allele patterns of mice, fruit flies or humans—has been accepted for decades.... [W]hat is important is that the FBI, as well as the commercial laboratories, do establish a population data base and follow widely accepted *methods* for making a population frequency calculation." (Emphasis added.) Additionally, the court noted that the "statistical equation or formula has been in existence and used by scientists in the field for most of this century."

In challenging the general acceptance of population frequency calculations, the defendant specifically attacks the reliability of the FBI's data base. The defendant's most important challenge is to the possible existence of population substructure in the Caucasian data base that the FBI used. Drs. Shields and Nadeau testified for the defense that they recognized the possibility of population substructure. Dr. Shields testi-

fied that due to substructure, the FBI cannot reliably use the product rule in their calculations, and that he was aware of population geneticists who disagreed with the FBI's method of calculating population frequencies. Dr. Nadeau testified that population substructure would compromise the FBI's method for calculating the probability of a random match.

Recently, the National Research Council (NRC), an organization administered jointly by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine, appointed a committee to address the issues surrounding forensic DNA testing. In April 1992, the committee released a report entitled "DNA Technology in Forensic Science." Although the NRC's exhaustive report supports the general acceptance of most of the FBI's methodology, its discussion of the debate regarding the existence of population substructure is particularly relevant to population frequency calculation.

As described above, the FBI applies the product rule by multiplying the individual allele frequencies together to calculate the frequency of the complete DNA pattern. The product rule is a basic statistical tool used in estimating the probability of a random match. According to the NRC report and the defendant's expert witnesses, because the product rule is based on the assumption that each individual's alleles constitute statistically independent evidence, its *381 validity rests on the absence of population substructure. *National Research Council, DNA Technology in Forensic Science* at 3-4, -6 (1992) [hereinafter *NRC Report*]. Thus, the most important question underlying the validity of using the product rule is whether significant population substructure exists. *Id.* at 3-6.

On this issue, the report recognizes that a considerable debate exists among population geneticists. On the one hand, some population geneticists contend that population genetics studies show some substructuring within racial groups and that the absence of substructuring for any particular genetic marker cannot be predicted, but must be determined empirically. There are population geneticists, however, who acknowledge the possibility of population substructure, but argue that current data suggests that its effect on population frequency calculations is minimal. Although in its report the NRC does not commit itself to either side of this debate, it "assumes for the sake of discussion that population substructure may ex-

ist...." *Id.*

**494 In light of the conflicting expert testimony at the *Frye* hearing and the NRC's recognition of considerable debate among population geneticists concerning the possibility of significant population substructure, we conclude that the FBI's method for estimating population frequencies, which relies on the product rule, has not found general acceptance in the field of population genetics. *See Commonwealth v. Lanigan*, 413 Mass. 154, 162-63, 596 N.E.2d 311, 316 (1992) (finding FBI's method for calculating frequency of defendant's DNA profiles not generally accepted because of lively and current debate regarding existence of population substructure). Thus, we hold that the trial court's decision to admit the population frequency estimates was error.

III. Conclusion

After considering the findings of the trial court and carefully reviewing the record, we hold that: (1) the theory underlying DNA profiling analysis is generally accepted in the relevant scientific community; (2) the technology that the FBI presently uses to conduct RFLP analysis and declare a match is generally accepted in the relevant scientific community as capable of producing reliable results; but, (3) the statistical techniques that the FBI used to estimate population frequencies is not generally accepted among population and human population geneticists because of the debate concerning population substructure. A match is virtually meaningless without a statistical*382 probability expressing the frequency with which a match could occur. *NRC Report, supra* at 3-1; *see People v. Barney*, 8 Cal.App.4th 798, 10 Cal.Rptr.2d 731, 742 (1992) (describing statistical calculation as "pivotal element" of DNA analysis). Thus, evidence of a match will not be admissible if it is not accompanied by a population frequency estimate that has been produced from a generally accepted method.

We are mindful that forensic DNA testing is an evolving science and that future discoveries or technological advances might lead us to reach a different conclusion than we have reached today. Currently, two approaches offer great promise for addressing the issue of population substructure. The NRC recommends immediate empirical studies of ethnic subgroups to determine the extent of population sub-

structure. Possibly, such studies will confirm that substructure does not exist or is minimal, thereby leading to general acceptance among population geneticists of the FBI's method of calculating population frequencies. More important in the short term, perhaps, is the NRC's suggested method for conservatively estimating population frequencies in order to account for population substructure. The report recommends using the "ceiling principle."

The ceiling principle requires insertion of a "ceiling frequency," or upper bound, for each allele at each locus when employing the product rule. *Id.* at 3-10 to 3-11. The NRC urges that population geneticists conduct population studies of ethnic subgroups in order to provide for valid estimation of ceiling frequencies. The report describes this approach in detail.

"The ceiling principle yields the same frequency for a genotype, regardless of the suspect's ethnic background, because the reported [ceiling] frequency represents a maximum for any possible ethnic heritage. Accordingly, the ethnic background of an individual suspect should be ignored in estimating the likelihood of a random match. The calculation is fair to suspects, because the estimated probabilities are likely to be conservative in their incriminating power."

Id. at 3-13.

The NRC asserts that the ceiling principle can account for any error caused by possible population substructure. Therefore, the admissibility of population frequency estimates does not necessarily await resolution of the population substructure issue, as long as the relevant scientific community generally accepts a method for calculating*383 statistical probabilities. For instance, the State may be able to demonstrate general acceptance of the NRC's recommended ceiling principle, which embraces the possibility of population substructure and thus yields a conservative **495 estimate resolving all uncertainties in favor of the defendant. *See Lanigan*, 413 Mass. at 163, 596 N.E.2d at 316 (citing *Curnin*, 409 Mass. at 226-27, 565 N.E.2d at 445).

In light of our holding in this bifurcated appeal, we remand this case to the trial court. The trial court must conduct a hearing in order to determine whether the NRC's recommended ceiling principle is a gener-

ally accepted technique. If the ceiling principle has gained general acceptance in the relevant scientific community, then the trial court must decide whether admission of the population frequency statistic in this case was harmless error. Resolution of the remaining questions raised on appeal are therefore stayed pending the trial court's expedited determination of the remanded issues.

Reversed and remanded for further proceedings consistent with this opinion.

All concurred.
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UNPUBLISHED OPINION. CHECK COURT
RULES BEFORE CITING.

Superior Court of Delaware,
Kent County.
Ellen H. WARREN, Plaintiff,
v.
Justin TOPOLSKI, Defendant.
C.A. No. 06C-06-030 (RBY).

Submitted: April 15, 2009.
Decided: April 30, 2009.

West KeySummary

Evidence 157  555.10

157 Evidence

157XII Opinion Evidence

157XII(D) Examination of Experts

157k555 Basis of Opinion

157k555.10 k. Medical Testimony.

Most Cited Cases

Rheumatologist's conclusion that an accident triggered the patient's fibromyalgia based on a temporal elimination of other known triggering factors failed to show a causal relationship sufficient to elevate causation evidence for a jury and therefore failed the Daubert standard. The other triggering factors were ruled out by the expert as causing the fibromyalgia because they existed long before the diagnosis of the disease. The expert did not provide any scientific basis as to why those other factors were not considered. Rules of Evid., Rule 702.

Upon Consideration of Defendant's Motion in Limine to Exclude Expert Testimony. **GRANTED**

John C. Andrade, Esq., Parkowski, Guerke & Swayze, P.A., Dover, Delaware for Plaintiff.

Brian E. Lutness, Esq., Silverman, McDonald & Friedman, Wilmington, Delaware for Defendant.

ORDER AND OPINION

YOUNG, J.

I. DECISION

*1 This decision follows Plaintiff's request to revisit the prior decision of this Court on the basis that Plaintiff had obtained a medical expert in a field different from the specialist whose testimony had previously been rejected. For the following reasons, and based upon the same *Daubert* consideration, and journal authority materials as reviewed in the prior decision, Defendant's Motion is, again, **GRANTED**.

II. ANALYSIS

Plaintiff's new medical expert is Dr. Maged I. Hosny, a licensed rheumatologist. He is board certified, and has an impressive curriculum vitae. His knowledge of rheumatology is extensive. Dr. Hosny, however, cannot state definitively whether the accident caused Plaintiff's fibromyalgia. Dr. Hosny offered intelligent opinions concerning various "triggering" factors for fibromyalgia. He also offered his belief that the "triggering" factors that Plaintiff had prior to the accident (admitted by the parties, and referred to on p. 2, item (e), in the Court's Opinion of March 20, 2008) could be ruled out in his causal analysis. Dr. Hosny reasoned that, because Plaintiff suffered from those various other maladies long before the accident, and because those "triggers" did not lead (within an undetermined period of time) to the onset of Plaintiff's fibromyalgia, the accident was the only relevant event that could have "triggered" Plaintiff's fibromyalgia. When questioned about whether Plaintiff's fibromyalgia was *caused* by the accident, however, Dr. Hosny could not respond relevantly.

As was the case in the earlier consideration, the appropriate standard to analyze this question is that set forth in D.R.E. 702. Rule 702 allows expert testimony if that testimony (1) "is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." In the Rule 702 analysis, the Court must determine whether Dr. Hosny's testimony will

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be reliable and relevant.

In March 2008, the Court granted a similar motion excluding the testimony of Plaintiff's anesthesiologist. The decision then was that, because Plaintiff's witness could not testify about the *cause* of Plaintiff's fibromyalgia, the testimony was insufficient to present to the jury. The same analysis applies, and the same conclusion must be reached here, even though now the Court considers the testimony of a rheumatologist.

The same obstacles that prevented the Court from allowing the anesthesiologist's testimony one year ago are still present. Of all the material presented to the Court, including Dr. Hosny's testimony, the underlying matter of fact is that the medical community does not know what causes fibromyalgia.^{FN1} The research and experiments that scientists and doctors have conducted have expanded the general information available about fibromyalgia, but none states decisively any known causes. According to the materials presented to the Court, it is "difficult to diagnose [fibromyalgia] because it produces no objective physical changes that can be used to identify the syndrome."^{FN2}

FN1. Johns Hopkins Guide to Fibromyalgia, at 3, available at http://www.johnshopkinshealthalerts.com/ppc/arthritis/fibromyalgiar_reg_landing.html; FibroAction-Fibromyalgia Syndrome and Physical Trauma, <http://www.fibroaction.org/articles/fibromyalgia-syndrome-and-physical-trauma.aspx>.

FN2. Johns Hopkins Guide to Fibromyalgia, Pg. 5.

*2 Directly on point is the Delaware Superior Court's decision in *Minner v. American Mortgage & Guaranty Co.*^{FN3} The *Minner* court refused to allow a doctor to offer testimony concerning her speculation about what caused the plaintiff's fibromyalgia.^{FN4} The crux of that Court's reasoning was that the doctor's testimony was speculative, and did not exclude other causative factors.^{FN5} The court held that this speculation "is precisely the type of testimony that should be kept from the jury under the principles of *Daubert*."^{FN6} Further, she did "not follow a logical, scientific,

and deductive process to exclude other possible causative factors."^{FN7}

FN3. *Minner*, 791 A.2d 826.

FN4. *Id.* at 872.

FN5. *Id.* at 855.

FN6. *Id.*

FN7. *Id.*

Dr. Hosny's testimony was similar to that excluded in *Minner*. Dr. Hosny thoroughly addressed the "triggering" factors. He opined that since the factors or symptoms that Plaintiff had before the accident did not lead, directly, in his view, to the onset of her fibromyalgia, he ruled out those factors as the potential causes. Notably, he could not define how much time between a symptom's appearance or some event and the onset of fibromyalgia complaints ruled one thing in and another out. After he ruled out the several other symptoms Plaintiff had, Dr. Hosny concluded, based exclusively on temporal circumstances, that the accident alone was the "triggering" factor of Plaintiff's fibromyalgia. Dr. Hosny did not, however, provide any scientific basis as to why those other symptoms were not considered. His sole reasoning was that Plaintiff suffered from the symptoms before the accident, but had not described an onset of fibromyalgia. This conclusion alone is insufficient to present it to a jury under *Minner* and *Daubert*. As stated in *Minner*:

It is well settled that a causation opinion that is based solely on a temporal relationship is not derived from the scientific method, and is therefore insufficient to satisfy the requirements of Rule 702.

Plaintiff argues that, regardless of the *Minner* decision, Dr. Hosny's testimony is sufficient for purposes of D.R.E. 702. Plaintiff contends that Dr. Hosny's testimony is the result of two studies that have been peer reviewed and are accepted in the rheumatology community. Plaintiff continues that, because of these critiques and acceptances, the materials Dr. Hosny relied upon are reliable, and therefore satisfy the D.R.E. 702 criteria.

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Plaintiff also relies on the cases of *Marsh* and *Epp*.^{FN8} Those cases, Plaintiff argues, stand for the premise that experts may present their arguments regarding fibromyalgia causation to a jury under the *Daubert* analysis. The Court is constrained to disagree.

FN8. *Marsh*, 977 So.2d 543; *Epp*, 271 Neb. 640, 715 N.W.2d 501.

In the *Marsh* case, that court addressed our issue under the *Frye* test.^{FN9} While it may be argued whether *Frye* may be more or less demanding than *Daubert*,^{FN10} in this instance it is of no consequence. Delaware recognizes the *Daubert* test.^{FN11} Therefore, any analysis pertaining to expert testimony must suffice under *Daubert*. Even in the *Marsh* decision under *Frye*, the dissent convincingly stated the impropriety of the majority's decision, noting the absence of general acceptance of the expert's opinion. Because general acceptance is one consideration this Court makes under *Daubert*, the obvious presence of all of the debate within the scientific community about the association between physical trauma and fibromyalgia precludes satisfactory evidence for jury consideration.

FN9. *Marsh*, 977 So.2d at 550.

FN10. *Id.* at 546 (internal citations omitted).

FN11. *See MG Bancorporation Inc. v. Le Beau*, 737 A.2d 513, 523 (Del.1999).

*3 Further, Plaintiff's reliance on *Epp* is not convincing.^{FN12} In *Epp*, the court ruled that the trial court's exclusion of a doctor's testimony was an abuse of discretion.^{FN13} The court, however, reviewed what the doctor's examination and diagnosis consisted of, finding it to be reliable.^{FN14} The doctor in *Epp* not only ruled in the accident as a possible cause of the plaintiff's fibromyalgia, but also ruled out other possible causes by a "differential diagnosis" process, which the *Epp* court considered a reliable scientific method.^{FN15} Dr. Hosny, on the other hand, testified that his basis for excluding Plaintiff's sleep deprivation and emotional distress and musculoskeletal problems was that she had those symptoms before the accident. Dr. Hosny reasoned that because those symptoms existed prior to the accident, yet did not, by complaint, lead to an onset of fibromyalgia, they must not have factored into her diagnosis for a "trig-

ger" when fibromyalgia was diagnosed. This, really quite vague, temporal approach cannot rule out the other, myriad causative conditions.

FN12. *Epp*, 271 Neb. 640, 715 N.W.2d 501.

FN13. *Id.* at 511.

FN14. *Id.* at 508-11.

FN15. *Id.* at 511.

Dr. Hosny, again, did not and could not testify that Plaintiff's injury was **caused** by the accident. Rather, his opinion, again, was that the accident was the "triggering" factor. That is insufficient, in this case, to elevate to causation evidence for a jury.

Dr. Hosny attempted to distinguish cause in a medical sense from cause in a legal sense to bolster his opinion. Dr. Hosny identified that "cause" from his perspective referring to pathophysiology. Here we deal with legal requirements. In the legal sense, cause is interpreted in a "but-for" situation. "But-for the accident", would Plaintiff have been free of fibromyalgia? That is the relevant question for trial. Did Plaintiff's accident, aside from the sleep deprivation, emotional distress, physical ailments etc., bring about the fibromyalgia? Dr. Hosny's testimony to that effect was deficient. The medical science that he relied upon certainly does not say definitively.

As specifically stated in *Daubert*:

Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final and binding legal judgment-often of great consequence-about a particular set of events in the past.^{FN16}

FN16. *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579, 596-97-(1993).

The gate-keeping role may result in precluding the

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jury from hearing certain evidence.^{FN17} That may prevent admission of cutting edge scientific discovery. It conceivably has prevented admission of evidence that is now considered household knowledge. In any event, the Court's function is to allow the jury to hear evidence that suffices, in this moment in time, under the *Daubert* standard and D.R.E. 702. At this point, Dr. Hosny's opinion is insufficient for a final legal determination sufficient to go to a jury for consideration.

FN17. *Id.*

*4 Speculation is insufficient for *Daubert* purposes. Because that is the situation here, Dr. Hosny's testimony is not medically sufficiently reliable. It must, therefore, be excluded.

III. CONCLUSION

For the foregoing reasons, Defendant's Motion to exclude from jury consideration the testimony of Dr. Hosny is **GRANTED: SO ORDERED.**

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Warren v. Topolski
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Symposium: Beyond Collective Bargaining and Employment at Will

***397 THE FUTURE OF WRONGFUL DISMISSAL CLAIMS: WHERE DOES EMPLOYER SELF INTEREST LIE?**

Henry H. Perritt, Jr. [FN1]

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I. INTRODUCTION

The most significant employment law development in the last quarter of the 20th century has been the erosion of the employment-at-will rule [FN1] and the recognition of a family of common law rights protecting individual employees against wrongful dismissal. [FN2] Under these wrongful dismissal doctrines, terminated employees may be able to recover damages when they can show that their terminations violated employer promises, jeopardized clear public policies, or, sometimes, when the terminations did not comport with good faith and fair dealing. The wrongful dismissal common law doctrines have substantially eroded the operation of the employment-at-will rule.

Nevertheless, the employment-at-will rule is not altogether dead. The law in no American jurisdiction requires private employers to demonstrate "just cause" for terminating an employee. The employment-at-will rule continues to provide a presumption, however circumscribed, that a dismissal is legal; it is up to the dismissed employee to rebut that presumption by showing violation of a common law wrongful dismissal doctrine or violation of a statute.

This article considers the current state of the common law of wrongful dismissal and suggests that the employer community would be well served by participating in the drafting and promotion of state wrongful dismissal statutes to codify and integrate the law of employee dismissal. Common law contract doctrines eventually will evolve to permit employees to recover substantial front pay awards on implied contract theories based on employer representations, and public policy tort doctrines logically may expand to protect a variety of rights modeled on constitutional free speech and substantive due process rights.

The author has followed the evolution of the employment-at-will rule and the common law of wrongful dismissal closely since the *398 early 1980s. The author wrote one of the first books on the subject and has monitored case developments closely in order to prepare twice-annual supplements to the book and its second edition. [FN3] Parts of this article are adapted from the book.

This article first reviews the three basic wrongful dismissal doctrines, emphasizing recent developments and likely trends for the further evolution of each. Then, the article surveys legislative developments, emphasizing the political calculus that will determine the fate of any statutory proposal. Finally, the article explains why employers would be better off participating in framing wrongful dismissal legislation than letting near-term legis-

lative opportunities pass by until the common law has evolved further.

II. THE STATE OF WRONGFUL DISMISSAL LAW AND THE EMPLOYMENT-AT-WILL RULE

Three basic common law doctrines permit recovery of damages for wrongful dismissal despite the employment-at-will rule. The first permits a plaintiff to recover for breach of contract when the employer dismisses the employee in violation of promises of employment tenure made orally, or implied from a course of conduct or from employee policies or handbooks. [FN4] This *implied-in-fact contract theory* requires a plaintiff to plead and prove the following elements:

1. The employer made a promise of employment security.
2. The employee gave consideration for the promise, in the form of detrimental reliance by continuing employment or otherwise.
3. The employer breached the promise by dismissing the employee.
4. The employee suffered damages.

The second common law doctrine allows an employee to recover in tort when the dismissal offends some identifiable public policy. [FN5] This *public policy tort theory* requires the plaintiff to plead and prove the following elements:

1. That a clear public policy existed and was manifested in a state or federal constitution, statute or administrative regulation, or in the common law (the *clarity* element). *399
2. That dismissing employees under circumstances like those involved in the plaintiff's dismissal would jeopardize the public policy (the *jeopardy* element).
3. The plaintiff's dismissal was motivated by conduct related to the public policy (the *causation* element).
4. The employer lacked overriding legitimate business justification for the dismissal (the *overriding justification* element).

The third common law doctrine enables an employee to recover for breach of contract [FN6] when the employer has violated a "covenant of good faith and fair dealing," implied in all contracts as a matter of law. [FN7] Conceptually, the *covenant theory* requires that contract rights be exercised in a manner that does not violate the covenant. Thus, even though an employer has the right to terminate an at-will contract for any reason, good or bad, or for no reason at all, the employer also has a duty not to exercise this right in bad faith or unfairly.

Under the broadest view of this doctrine, a dismissed employee need only show:

1. An employment relationship existed.
2. The employment was terminated.
3. Some aspect of the termination was unfair or in bad faith.

Upon such a showing, a jury is entitled to decide, with only the most general instructions, [FN8] whether the termination was fair and in good faith.

The trend of wrongful dismissal cases demonstrates a strong convergence of judicial opinion on the elements of the implied-in-fact contract, a majority public policy tort rule more favorable to employees and a minority rule less favorable to employees. Substantial differences of opinion exist respecting the implied covenant of good faith and fair dealing.

A. Public Policy Tort

Two dimensions influence how favorable to employees a particular variant of the public policy tort doctrine is: (1) the respective roles of judge and jury, and (2) the flexibility of the substantive public policy analysis. Most favorable to the employee on judge and *400 jury roles is *Cloutier v. Great Atlantic & Pacific Tea Co.* [FN9] In *Cloutier*, the court declined to restrict tort recovery to instances in which the dismissal contravened clear public policy pronouncements in statutes. Rather, the court decided it “best to allow the citizenry, through the institution of the American jury, to strike the appropriate balance in these difficult cases,” [FN10] in other words, to decide the clarity and jeopardy elements. Giving juries more flexibility benefits employees because juries notoriously are sympathetic to employees and hostile to employers.

Most favorable to employees on the substantive analytical framework is *Novosel v. Nationwide Insurance Co.*, [FN11] in which the United States Court of Appeals for the Third Circuit, applying Pennsylvania law, held that a public policy tort claim could be premised on private employer conduct that infringes rights recognized in the United States Constitution. [FN12] The Third Circuit held that an employee who was dismissed for refusing to participate in an employer-directed lobbying campaign had a legitimate claim upon which relief could be granted. [FN13] The court reasoned that the public policy tort concept as recognized in *Nees v. Hocks* included dismissals that chilled rights embodied in the federal and state constitutions. [FN14] *Novosel* benefits employees because it greatly expands the range of public policies on which public policy tort claims can be based.

At the opposite pole from *Novosel* are *Murphy v. American Home Products*, [FN15] and *Phung v. Waste Management, Inc.* [FN16] In *Murphy*, the New York Court of Appeals refused to recognize a tort of “abusive discharge.” [FN17] The court reviewed the trend in other states toward tempering “what is perceived as the unfairness of the traditional rule by allowing a cause of action in tort to redress abusive discharges.” [FN18]

*401 It concluded that changes in the traditional rule should be left to legislatures. [FN19] In the court's view, the legislature was better equipped than the courts to consider the competing policy positions of various groups as to whom liability was appropriate. [FN20] *Phung* also appears to reject the public policy tort doctrine, suggesting that courts should defer to legislatures for modifications of the employment-at-will rule. [FN21] *Phung*, however, is not as broad as *Murphy*. In *Phung* the Ohio Supreme Court did not state that it would never recognize a public policy tort. Rather, the court noted that “the allegations herein failed to state a violation of a sufficiently clear public policy to warrant creation of a cause of action in favor of Phung. No jurisdiction has allowed a cause of action to proceed based only on vaguely alleged violations of ‘societal obligations.’” [FN22]

Few states have followed either the *Cloutier* view of the jury role, or the *Novosel*, [FN23] the *Murphy* or *Phung* doctrinal extremes. The *Cloutier* view of the jury's role in public policy tort cases seems to be an aberration. Judges, not juries, decide what is public policy and what kind of jeopardy can occur if specific types of employee conduct are chilled by the threat of dismissal. The judge ought to decide the clarity and jeopardy elements, both of which involve relatively pure law and policy questions in the abstract. [FN24] The jury decides factual issues relating to causation and overriding justification. Most courts considering the matter since *Cloutier* have adopted the view that the judge decides what public policy is and what kind of conduct is necessary to realize the public policy. In performing their roles, judges can consider a variety of sources of public policy: well recognized common law concepts as well as specific statutory or administrative announcements. The jury decides only the actual questions of what *402 conduct the employee engaged in and what the employer's motivation was. [FN25]

Many courts recognize that *Murphy* and *Phung* are too narrow. While legislatures may be more appropriate institutions than courts in making basic policy judgments, there is a long tradition of courts relying on public policy to control the evolution of the common law. [FN26]

1. Potential for Constitutionalizing Private Employment: *Novosel*

The *Novosel* doctrine has attracted few supporters, but it is an important model for possible future expansion of the public policy tort into a constitutionalization of private employment. Even when *Novosel* is read to encompass dismissals that offend public policy only in that they jeopardize the exercise of “free speech” rights, and even if free speech rights were limited, as they have been in the public sector to matters of public concern, [FN27] the expansion would be significant.

But free speech is not the only constitutionally recognized right. Due process is also constitutionally recognized. Part of substantive due process is the rationality idea: the idea that injury must be justified by some good cause. It is a relatively short logical step from *Novosel* to transform the public policy tort into a legally imposed just cause standard. Because of this potential, it is worth considering the *Novosel* analysis in greater depth.

The public policy tort concept logically extended applies to wrongful dismissal lawsuits in which the employment termination offends policies embodied in the United States Constitution or state constitutions. The precedent for such an application is mixed, *403 largely because it generally is agreed that the Constitution does not protect persons against purely private conduct. [FN28] There is no logical reason, however, why the Bill of Rights [FN29] cannot be used as a foundation for public policy to permit tort recovery. Indeed its guarantee of a jury trial was used for this purpose in *Nees v. Hocks*. [FN30]

The first element of the analytical structure for a public policy tort, clarity of the policy, was met in *Novosel* because “the protection of an employee's freedom of political expression would appear to involve no less compelling a societal interest than the fulfillment of jury service or the filing of a workers' compensation claim.” [FN31] The second element, jeopardy, was met because of the chilling effect that the threat of employment termination can have on expression. [FN32] On the record before the court of appeals, the employer had suggested no particular justification for the dismissal, permitting an inference that it was solely motivated by *Novosel*'s political expression. It is not too difficult to apply this reasoning to other constitutionally recognized rights, including substantive due process.

*404 2. Backlash Represented by *Bushko v. Miller Brewing Co.*, *Adler v. American Standard Corp.*, and *Gryzb v. Evans*

The majority rule regarding the public policy tort involves a flexible interest balancing approach basically similar to that outlined in the introduction. A considerably narrower approach also has emerged as a kind of minority rule. The narrower approach, less favorable to employees, denies recovery unless the employee can show that he was dismissed for exercising an explicit statutory right, [FN33] or for refusing to violate an explicit statutory prohibition. [FN34] The narrower approach involves less judicial activism and greater deference to the legislature. It declines to afford a theory of recovery to a dismissed employee unless the legislature explicitly has declared public policy in connection with the particular type of conduct engaged in by the employee.

Bushko v. Miller Brewing Co. [FN35] exemplifies the refusal-to-violate-positive-law formulation of the pub-

lic policy tort. Mr. Bushko claimed he was fired because he told his employer a machine was in an unsafe condition and violated state law. [FN36] The majority reversed the intermediate court of appeals because it “incorrectly held that activity merely consistent with a public policy provides a basis for a wrongful discharge cause of action.” [FN37] Bushko's counsel conceded at oral argument that “Bushko was not ordered by his employers . . . to do anything that violates the positive law of the State of Wisconsin,” [FN38] so the Supreme Court concluded he had no claim. The majority opinion strains to construe earlier Wisconsin public policy tort cases as adopting the refusal-to-violate formula, expressing a concern that, without narrow limitations, a Pandora's box would be opened, out of which due process or equal protection concepts would emerge to swallow the distinction between private and governmental employment. [FN39]

Three justices concurred, emphasizing that Mr. Bushko's evidence, but not his legal theory, was deficient. [FN40] The concurrence disagreed with the majority's characterization of Wisconsin case law, and with the majority's preoccupation with the refusal-to-violate *405 branch of the public policy tort concept. In many cases, as the *Bushko* concurrence pointed out, the dispute between employer and employee can be recharacterized as a refusal-to-violate rather than actions-consistent-with-public-policy. [FN41] Inherent in the state machine safety statute involved in *Bushko* was an employee's duty to report safety violations to an employer. By dismissing an employee for making such reports, the employer arguably was retaliating for the employee's refusal to violate his reporting duty. [FN42]

The concurrence embraced two “guidelines” for applying a public policy tort concept anchored in the idea that employer power to dismiss should not be used to undermine fundamental public policies. “Not only employees but also the public would suffer if the discharge power enhanced the ability of employers to violate public policy.” [FN43] One suggested guideline was applicable when an employee was dismissed for refusing to violate a statutory or constitutional provision; the second was when an employee was dismissed for “actions consistent with a clear and compelling public policy embodied in a statute or constitution.” [FN44]

In *Adler v. American Standard Corp.*, the court of appeals embraced a two-prong public policy tort formula similar to that advocated by the *Bushko* concurrence. [FN45] In *Adler*, the disagreement between the panel majority and the dissenter was whether Mr. Adler's insistence on reporting corporate bribes to higher employer authority satisfied either prong of the formula. The majority noted the traditional reluctance of legislatures “to impose affirmative obligations on citizens to report or prevent crimes,” and concluded that Mr. Adler had no duty to report the corporate misconduct. [FN46] Following the refusal-to-violate or compliance-with-duty formulations strictly, the majority thought, was necessary to “tie abusive discharge claims down to a manageable and clear standard.” [FN47] The dissent characterized Adler's conduct as a refusal to perform an illegal act: soliciting business through bribes, [FN48] illustrating the characterization point of the *Bushko* concurrence.

*406 The second branch of the *Adler* formula permits recovery only when the employee is dismissed for insisting on performing a duty, while the second branch of the *Bushko* concurrence formula would permit recovery when an employee is dismissed for “actions consistent with . . . public policy . . .” [FN49] Conceptually, many employee actions could be consistent with public policy without falling within a positive duty imposed on the employee.

The Kentucky Supreme Court, in *Gryzb v. Evans*, similarly concluded that recovery is permitted only when rights specifically granted to employees are violated, declining to recognize a public policy tort based on constitutional rights. [FN50] It held, however, that a claim based on the public policy contained in anti-discrimination statutes was not cognizable because of the availability of administrative remedies. [FN51]

For ease of exposition it is useful to call the *Bushko* majority test and the first prong of the *Adler* test the “refusal-to-violate” requirement; the second prong of the *Adler* test the “compliance-with-duty” requirement; and the second prong of the *Bushko* concurrence formula the “actions-consistent” test.

Refusing to violate an explicit statutory prohibition and exercising an explicit statutory right are two sides of the same coin, with an important difference. In both circumstances, an employee is engaging in conduct that the legislature has decided is socially desirable: conduct clothed with a right and conduct promoted by a prohibition against acting otherwise. The difference is that a prohibition reflects stronger policy. When the legislature prohibits conduct, it intends to leave those regulated no choice; they must comply with the prohibition or face sanction. When the legislature creates a right, it affords a greater range of choice; the person possessing the right has the legal power either to exercise it or not. Arguably, the policy reflected by creation of a right is weaker.

There is, however, another consideration. Rights have correlative duties. Usually, when the legislature creates a right possessed by employees, qua employees, the correlative duty is imposed on their employers. When the legislature creates a prohibition applicable to employees, the prohibition is a duty imposed on the employees. The correlative right is possessed by someone else, frequently the public at large. Another way to look at the underlying interest analysis is to view the public policy tort as a means of enforcing duties *407 rather than a means of protecting rights. Under this view, it is easier to conclude that an employer should be liable for violating a duty to the employee than to be liable for coercing someone else to violate his or her duty to the public. Under this view the public policy tort is applicable only when an employee is dismissed for exercising an explicit statutory right and not when an employee is dismissed for refusing to violate a statutory prohibition. This explains the Seventh Circuit approach, [FN52] but it does not fully explain the *Bushko* approach.

3. An Appropriate Middle Ground

The public policy tort can become an amorphous source of just cause litigation, unless standards exist for principled decision-making, especially at the summary judgment and pleadings stages. But the refusal-to-violate and compliance-with-duty requirements do not represent appropriate standards. They are not faithful to the underlying concept of the public policy tort, and they do not eliminate the ability of a litigant or judge to manipulate results by artful characterization. The potential for alternative characterizations of employment dismissal disputes so as to meet the refusal-to-violate and compliance-with-duty requirements is adequately illustrated by the *Bushko* concurrence and the *Adler* dissent.

A brief review of the landmark public policy tort cases exposes the lack of harmony between the “refusal-to-violate” and “compliance-with-duty” tests and the underlying concept of the public policy tort. In some of the landmark cases, to be sure, the result is predicted by these two tests. In *Petermann v. International Brotherhood of Teamsters*, the employee was fired for refusing to perjure himself, a clear refusal-to-violate case. [FN53] Cases in which an employee is dismissed for refusing to dispose of hazardous wastes improperly or for refusing to operate unsafe or overweight vehicles similarly would satisfy the refusal-to-violate test. But other seminal cases do not satisfy the tests. In *Palmateer v. International Harvester Co.*, the plaintiff had no duty to report criminal violations, so he satisfied neither the refusal-to-violate nor the compliance-with-duty tests. [FN54] Employees dismissed for filing workers' compensation claims satisfy neither the refusal-to-violate nor the compliance-with-duty tests. *408 The plaintiff in *Sheets v. Teddy's Frosted Foods, Inc.*, in reporting product labeling violations, satisfied neither test. Indeed, no whistle blower case would satisfy the tests, in the absence of a statute—unlikely to be enacted—that imposes an obligation to blow the whistle. [FN55]

Judge Posner's alternative test, permitting recovery only for dismissals motivated by employee exercise of a statutory right, [FN56] may explain the workers' compensation cases, but it does not predict the results in a large number of other cases in which the interests jeopardized by the dismissal belong not to the employee, but to the public. A much better way to make public policy tort analysis principled than the *Bushko* and *Adler* formulations is to use the three steps identified in the introduction to this article and advocated elsewhere by the author: [FN57] (1) requiring clarity of public policy; (2) identifying jeopardy to realization of the policy if the employer escapes liability; and, (3) requiring the employee to demonstrate a causal link between the policy-promoting conduct and the dismissal.

The jeopardy analysis can be subdivided. The first jeopardy step is to decide what kind of conduct is necessary to further the public policy. [FN58] A class of conduct thus identified can be considered analogous to the "protected conduct" concept under Section 7 of the National Labor Relations Act [FN59] and other statutes protecting employees in engaging in defined conduct. [FN60] The second substep under the jeopardy analysis is to decide if the employee's actual conduct fell within the protected conduct. The third substep is to decide if the threat of dismissal is likely in the future to discourage the employees from engaging in similar conduct. The answer to the third question almost always will be "yes."

Bushko and *Adler* follow the clarity and causation steps, so the disagreement between the author of this article and the authors of the *Bushko* and *Adler* majority opinions must relate to the jeopardy analysis. The important point to accept is that many dismissals can jeopardize clear public policies without involving refusal-to-violate or compliance-with-duty. Whistle blowing in cases where violations of law or employer conduct jeopardizing public safety and health are *409 likely to go undetected without employee whistle-blowing are clear examples; rarely are employees obligated to turn their employers in to enforcement agencies. Nearly the entire universe of external public policy tort cases fails to satisfy the refusal-to-violate or compliance-with-duty tests; yet it is reasonable that some fundamental aspects of employees' private lives should be protected from employer coercion lest fundamental policies enshrined in constitutional and tort doctrines be jeopardized.

The Nebraska Supreme Court found these ideas persuasive when it adopted a reading of the public policy tort that permitted recovery for good faith reports by employees of employer violations of criminal statutes to the criminal authorities. It considered and rejected the line of cases limiting the public policy tort to instances in which the employee was dismissed for refusing to commit a crime. [FN61] The Kansas Supreme Court similarly extended public policy tort protection to employees fired for reporting serious employer violations of state or federal rules or statutes to employer officials or to governmental agencies. The Kansas Supreme Court rejected an argument that public policy tort recovery should be limited to circumstances in which an employee is dismissed in contravention of a right specifically granted to employees, reasoning that the public interest requires the voluntary disclosure of employer wrongdoing. [FN62] Similarly, the Illinois intermediate appellate court reasoned that employee reports of nursing home violations to nursing home personnel promote public policy just as much as reports to enforcement agencies. [FN63]

Indeed, another approach to limiting the public policy tort proceeds from essentially opposite principles from *Gryzb*, *Bushko*, and *Adler*: from the idea that it is the public who is to be protected by the theory, not persons within the workplace. In *Foley v. Interactive Data Corp.*, [FN64] the California Supreme Court held that a public policy tort requires that the policy concerns implicated by the employer-employee controversy implicate some policy related to the general *410 public's interest rather than management of the particular enterprise. [FN65]

4. Implications of *Lingle v. Norge Division*

There is a strong trend toward rejecting public policy tort claims based on policies in statutes that provide administrative remedies. The reasoning is central to the jeopardy analysis. If administrative channels exist for enforcing the public policy or for protecting employees against dismissal and retaliation for public policy-serving conduct, the public policy will not be jeopardized in the absence of a public policy tort remedy. This idea is not applied strongly to preclude public policy tort recovery for dismissals also covered by anti-discrimination statutes, but anti-discrimination statutes have especially strong cumulative and supplementary remedial policies. [FN66]

In contrast, one would have thought that employees covered by “collectively bargained just cause protection” present the paradigmatic case in which the jeopardy analysis militates against the availability of public policy tort relief. Nevertheless, the Supreme Court of the United States has decided that public policy tort claims by employees protected by collectively bargained just cause and arbitration provisions are not preempted by Section 301 of the Labor Management Relations Act, and a growing number of state supreme courts have decided that collective bargaining employees may maintain parallel public policy tort actions.

In *Lingle v. Norge Division*, [FN67] the Supreme Court of the United States held that a public policy tort claim for worker's compensation retaliation was not preempted by Section 301 of the LMRA, [FN68] although the employee plaintiff arbitrated her claim of dismissal without just cause and won reinstatement. The unanimous Court reasoned that the tort claim was independent of the collective bargaining agreement, and therefore could be decided without interpreting the collective agreement. Thus the state claim was not “inextricably intertwined” with contract questions that could be *411 presented to the arbitrator—the test articulated by the Court in *Allis-Chalmers Corp. v. Lueck*. [FN69]

The *Lingle* decision does not resolve the question of what preclusive effect an arbitration might be entitled to receive. [FN70] Nor does it decide how, as a matter of substantive state law, the availability of collectively bargained just cause protection ought to affect the jeopardy component of public policy tort analysis.

The Kansas Supreme Court, overruling earlier Kansas Supreme Court precedent, [FN71] held in *Coleman v. Safeway Stores, Inc.* [FN72] that an employee covered by collectively bargained just cause and arbitration provisions nevertheless was entitled to assert public policy tort claims. The court reasoned that the arbitration remedy was not aimed at protecting the individual rights and public interests implicated in the public policy tort concept, and that the majoritarian principles of collective bargaining were inappropriate mechanisms to waive rights embodied in the tort law. The court also utilized *Alexander v. Gardner-Denver Co.* to characterize arbitration as a potentially inferior procedural system for hearing public policy tort claims. [FN73]

Maryland's highest court also has decided that public policy tort claims are available to employees covered by collective bargaining agreements. [FN74] These cases are just the most recent in a trend that began with the Illinois Supreme Court in *Midgett v. Sackett-Chicago, Inc.* [FN75]

B. Implied-in-Fact Contract

As the introduction noted, virtually all states have accepted the proposition that the employment-at-will presumption can be overcome by proof of an informal contract to dismiss only for certain reasons or only through certain procedures. There is growing acceptance of the proposition that consideration for an informal employer

promise can be found in the employee's continuing to work *412 and performing normal duties after knowing of the employer's promise. This section reviews the consideration analysis, explains that disclaimers generally have been given effect, explores the front pay issue, and notes that some of the implied-in-fact contract ideas developed in the context of wrongful dismissal cases are being extended to support employee claims for other terms of employment such as particular pay rates, or promotions.

1. Continuing Employment as Consideration for an Employer's Promise of Employment Security

Nearly all states allow consideration for an informal employer promise of employment security to be shown by proof of conduct above and beyond performing the ordinary job duties, such as quitting another job or turning down alternative job offers. If such "special consideration" is established, the promise of employment security is enforced even in the most conservative states. [FN76]. In a growing number of states, continuation of employment after knowing of a promise of employment security is consideration for the employer's promise. The rationale is that the continued performance of service is a detriment suffered by the employee which was bargained for by the employer. Even when the "bargained-for" aspect cannot be met, the employer's promise can be enforced under the promissory estoppel doctrine, contained in Section 90 of the Restatement (Second) of Contracts, if the employee's conduct in reliance on the promise was reasonable, and reasonably should have been expected by the employer. [FN77]

The idea of the "bargained-for-exchange" is important to grasp before analysis of the consideration requirement [FN78] in wrongful dismissal*413 actions makes sense. Intuitively, the bargained-for idea is an easy idea when two parties sit down at a table and say to each other, "If I give you this what will you give to me in return?" and eventually reach a deal. For example, if there is a specific agreement evidencing a meeting of the minds between employer and employee regarding compliance with personnel policies, there is little need for other manifestations of assent. [FN79] It is a harder idea to grasp when one party makes a promise without saying anything explicit to the other about what is expected in return, and then the other engages in some sort of conduct in reliance on the promise. Yet, that is precisely the circumstance found in most implied-in-fact contract cases involving wrongful dismissal allegations.

When one party makes a promise and the other party responds with conduct, a unilateral contract may have arisen. In the unilateral contract context, the bargained-for question is the following: did the party making the promise make it *for the purpose of inducing* a certain kind of conduct. If such a purpose was present, one says the reliance was "bargained for." [FN80]

*414 Even when conduct is not bargained for in this sense, it nevertheless may have legal effect as a validation device, [FN81] under the promissory estoppel idea embraced in Section 90 of the Restatement (Second) of Contracts. Promissory estoppel does not contemplate that the conduct be bargained for, only that it should have been anticipated by a reasonable promisor and that the conduct itself be a reasonable response to the promise.

The special consideration requirement for employment security promises provided a means of insisting upon obvious validation for unusual types of employment promises. [FN82] Because most employers did not make promises of employment security, or did not intend to be bound by such promises, in order for an allegation of such a promise to be taken seriously, an especially credible validation device was required. The most obvious such device was special consideration: paying money, or doing something out of the ordinary beyond merely undertaking or continuing the employment relationship. Some courts misunderstood this special consideration requirement and transformed it into a substantive rule. Until relatively recently, most states accepting the im-

plied-in-fact contract theory required a showing of special consideration in the form of quitting another job or turning down job offers to validate an employer promise of job security. Several recent cases, however, clearly say that the employer's promise can be validated merely by continuing employment.

In *Woolley v. Hoffman-La Roche, Inc.*, [FN83] the New Jersey Supreme Court concluded that consideration to support a handbook promise to dismiss only for cause was inherent in the nature of the handbook, which apparently was intended to discourage unionization. [FN84] The court held that reliance by employees in general should be presumed, and need not be shown in individual cases. [FN85] The *Woolley* analysis is unexceptional in one respect and unusual in another. The unexceptional part of *Woolley* is acceptance of the premise that a bargained-for exchange in the unilateral contract context can be *415 shown by a general promise of employment security in an employee handbook on one side, and mere continuation of employment on the other. The unusual part is dispensing with the need to show knowledge of the promise (because the terms in the policy manual applied to employees who had not received it). As explained earlier, the most likely motive for an employer to make a promise of employment security to the work force in general is that the promise will encourage employees to continue their employment. Thus the bargained-for-exchange idea for this kind of reliance on the promise is logical.

Other courts before *Woolley* found continuation of employment sufficient to satisfy the bargained-for detriment requirement. *Pine River State Bank v. Mettelle* [FN86] involved an employee handbook distributed to the plaintiff employee after he was on the job. [FN87] The Supreme Court of Minnesota held that the employee, by continuing his employment thereafter, furnished consideration sufficient to support the handbook promises of employment tenure. [FN88]

Woolley has crystallized the distinction between special consideration and merely continuing employment. The courts in other states, including California, [FN89] Connecticut, [FN90] Idaho, [FN91] Iowa, [FN92] Massachusetts, [FN93] Minnesota, [FN94] Nebraska, [FN95] New Hampshire, [FN96] Virginia, [FN97] and Massachusetts, [FN93] Minnesota, [FN94] Nebraska, [FN95] New Hampshire, [FN96] Virginia, [FN97] and *416 West Virginia [FN98] have followed the *Woolley* conclusion that mere continuation of employment is sufficient to support a promise. Courts have been less enthusiastic about that aspect of *Woolley* suggesting that the employee need not even know about the employer's promise. [FN99]

2. The Proper Role of the Consideration Requirement

Because of the function of consideration as a validation device for promises, there is theoretical justification for linking the consideration requirement to the clarity of the promise. If the promise of employment security is relatively specific, there is less reason to insist on special consideration, and continuation of employment should serve to validate the promise. Conversely, if the promise is ambiguous, it may be appropriate to insist on special consideration such as quitting another job or giving up a specific job offer. The Connecticut Supreme Court, reviewing recent cases from other jurisdictions, has explained that the proper role of special consideration is evidentiary: to strengthen an inference that the parties intended for promises of employment security to be enforceable. [FN100]

*417 3. Disclaimers are Effective

Disclaimers are one way employers attempt to preclude promises of employment security being enforce-

able. Disclaimers are express statements, usually in employment applications or in employee handbooks, that put employees on notice that general statements or conduct suggesting a commitment of employment security should not be relied upon by the employees. Most courts would agree with the federal court in *Novosel v. Sears, Roebuck & Co.*, [FN101] that an employment application expressly reserving the employer's right to terminate with or without cause, and precluding informal agreements to the contrary, negates any possibility of an implied agreement to dismiss only on certain grounds. [FN102] Written or oral assurances of continued employment, however, may vitiate the effect of a disclaimer. Also, it may be a jury question whether informal assurances of employment security override a letter from the employer expressly reserving the right to terminate at any time. [FN103] In *Ohanian v. Avis Rent a Car System, Inc.*, [FN104] the court affirmed a jury finding that a written disclaimer executed after an oral promise of employment security was made did not constitute a contract. Obviously the content and timing of both the promise and the disclaimer are important. [FN105]

*418 4. Extension to Other Terms of Employment

In a growing number of cases, employees have recovered damages for termination of disability benefits or for other changes in employment terms not involving dismissal. [FN106] *Woolley* has been used to validate employee benefit promises. [FN107] The Montana Supreme Court has held, however, that the implied covenant theory is unavailable to enforce employer promises of promotions and raises. It is available only to contest employment terminations. [FN108]

5. Front Pay

Compensation in the form of money damages for disappointed expectations is the usual remedy for breach of contract. [FN109] Expectation damages are measured by the financial position the plaintiff would have occupied had the contract been performed fully. [FN110] Expectation damages in a wrongful dismissal case require the fact finder to project how long the employee would have been employed but for the employer's breach. This is an inherently speculative undertaking. [FN111]

*419 The uncertainty problem when a plaintiff avoids the employment-at-will rule by establishing an implied-in-fact contract of employment security is not uncertainty with respect to earnings, but uncertainty with respect to the duration of the contract. This source of uncertainty is unique to informal contract for indefinite employment; when breach of an express contract for a definite term is involved, the duration of the contract is clear.

The tension between the expectation damage principle and the uncertainty proviso is illustrated by two recent implied contract cases: *Ohanian v. Avis Rent a Car System, Inc.*, [FN112] and *Sepanske v. Bendix Corp.* [FN113] In *Ohanian*, the Second Circuit, applying New York law, affirmed a jury award of \$304,393 to an Avis regional vice-president, based on breach of a contract for lifetime employment. The contract arose from negotiations over a transfer in which an employer representative said, "unless he screwed up badly, there is no way he was going to get fired . . . he would never get hurt here in this company." When the plaintiff was fired, his annual salary was \$68,400. The jury found that the present value of the plaintiff's lost wages was \$245,409. The Second Circuit approved instructing the jury that it was to compute the amount plaintiff would have received until the natural end of the plaintiff's contract, subtracting from this amount anything Ohanian would receive from other employment. *Ohanian*, therefore, is a paradigmatic illustration of the expectation-damages principle in an implied-in-fact contract case.

The uncertainty issue was involved directly in *Sepanske*. The plaintiff had been promised employment in an equivalent job after he returned from a leave of absence. The jury found that the job offered on his return was not equivalent. The appellate court reversed an award of \$75,206 in damages. It held that the plaintiff was entitled to an award of only nominal damages for breach of the employment contract:

Plaintiff's expectation under the contract was to be restored to his old job or to an at-will position which was equivalent to or better than his [old] position . . . but he had no actionable expectation that any such restoration would be permanent. The position was still at will—one which the employer was free to alter or terminate without consequence The jury's damage assessment in such a situation amounts to pure speculation. There is no tangible basis upon which damages may be assessed where plaintiff's expectation was for an at-will position*420 which could have been changed or from which he could have been terminated without consequence. [FN114]

The difference between *Sepanske* and *Ohanian* is the difference between assessing damages for termination of an at-will employment contract and assessing damages for breach of a conditional promise of employment security. In *Sepanske*, the jury was in the position of estimating when *Sepanske's* employer might wish to exercise its unilateral right to terminate *Sepanske*. That was too speculative an undertaking to pass muster. In *Ohanian* the jury was in the position of estimating the likelihood—or the timing—that *Ohanian* might “screw up,” permitting the employer to terminate the employment. That was not too speculative an undertaking.

The point is not that there is a special rule for computing damages for breach of an implied-in-fact contract of employment, as compared with breach of a contract for a definite term; on the contrary, the rule is the same. But most implied-in-fact contracts are based on rather general assurances of employment until a contingency occurs—frequently the existence of “just cause” for termination, or the completion of certain procedures. Evaluating the probability of the contingency occurring and its timing is inherently more uncertain than determining when a certain number of years or months will elapse.

Some courts deny front pay. [FN115] In *Brockmeyer v. Dun & Bradstreet*, [FN116] the court concluded that reinstatement and backpay were the most appropriate remedies for wrongful dismissal in violation of a public policy. [FN117] There is a trend, however, in implied contract cases, like statutory employment discrimination cases, to award front pay. [FN118]

C. Implied Covenant of Good Faith and Fair Dealing

The implied covenant doctrine enjoyed brief popularity and was used by the earliest courts that relaxed the employment-at-will rule. But as the more traditional and circumscribed implied-in-fact contract and public policy tort doctrines were developed, the implied covenant doctrine declined in importance. The early implied covenant*421 cases, *Petermann v. Brotherhood of Teamsters*, [FN119] and *Monge v. Beebe Rubber Co.*, [FN120] suggested no real limits to the scope of the implied covenant of good faith and fair dealing. Juries apparently were to be allowed to decide for themselves what constituted good faith and to decide if the employer's actions met the standard thus derived by them. [FN121] Under this approach, the implied covenant doctrine would give employees very broad protection.

Courts willing to relax the employment-at-will rule began to raise doubts about the implied covenant theory in the early 1980s. The New York Court of Appeals disfavored implying a promise in a breach of contract action that was inconsistent with the manifest intent of the parties, in *Murphy v. American Home Products Corp.* [FN122] The Wisconsin Supreme Court recognized the implied covenant doctrine, but limited it greatly in

Brockmeyer v. Dun & Bradstreet [FN123] The *Brockmeyer* court concluded that implied covenant recovery should be limited to dismissals “contrary to a fundamental and well-defined public policy as evidenced by existing law.” [FN124] In effect, it used the implied covenant theory to limit damages available under the public policy tort theory. [FN125]

Now, California, Massachusetts, and Montana are the only states that rely heavily on the implied covenant as the primary wrongful dismissal doctrine. Two impose important limitations on its use. [FN126] Quite recently, the California Supreme Court, in *Foley v. Interactive Data Corp.* held that tort damages are not recoverable in implied covenant cases. [FN127] The Montana courts have been aggressive in using the implied covenant doctrine to impose something close to a just cause requirement. In Montana an employer has the burden of showing a “fair and honest reason” for a dismissal in order to escape*422 liability under the covenant. [FN128] Otherwise the implied covenant theory is hedged about with various restrictions.

III. THE FUTURE

Most of the major changes in employment law in this century, except for wrongful dismissal, have been made through state or federal legislation. Accordingly, it is natural for employers and advocates for employee interests to consider legislative alternatives to the continued evolution of common law. Indeed, part of the genesis of the common law revolution in wrongful dismissal was a 1976 law review article proposing a wrongful dismissal statute because of pessimism about the capacity of the common law to effect needed changes in the employment-at-will doctrine. [FN129] Interest in legislation is either increased or diminished by the likelihood, reviewed in the preceding sections, that the common law will continue to evolve to offer employees more chances of recovering substantial damages in defined classes of cases.

A. Basic Alternatives

The author has explained elsewhere that there are two basic approaches to defining wrongful dismissal in a statute: prohibiting dismissals except for just cause, and enumerating the reasons for which dismissal is not permitted. [FN130] The latter approach is less revolutionary and essentially codifies common law doctrines.

In addition, and perhaps of greater significance, two approaches to employee dismissal law integration are conceivable. The first approach simply would add a new statutory prohibition to existing statutory and common law rights and duties affecting employment terminations. The second approach would integrate a new, more comprehensive protection against wrongful dismissal with existing legal regimes, supplanting existing statutes and forums to a substantial degree. Most statutory additions to employment law have been cumulative: they simply define a new employee right, such as the right not to be dismissed for reporting false claims to the federal government, and leave intact existing rights, such as the right not to *423 be dismissed because of race, sex, religion or national origin, the right not to be dismissed for filing an OSHA complaint, the right not to be dismissed for engaging in collective bargaining, and so on. The more integrated approach would recognize that the more general the statutory protection the less the need for separate grants of narrow rights. If, for example, a statute grants the right not to be dismissed without good cause, it logically encompasses the rights identified in the previous sentence and other similar rights. There is some conflict between an enumerated prohibitions approach and the most complete integration. If a new statute covers only terminations for the enumerated prohibited reasons, it is difficult to support preemption of rights and remedies associated with reasons not enumerated in the statute. Accordingly, across the board preemption and integration is much easier with a just cause statute

than with an enumerated prohibition statute.

The major risk to the employer community is that rigid opposition to any form of legislation, resulting in nonparticipation in drafting efforts, will result in just cause legislation which is not integrated with the common law or other statutory rights. An independent risk is that legislation actually may be preferable to employer interests than continued evolution of the common law. If this is so, employers ought to take the initiative to promote the enactment of wrongful dismissal statutes.

The following sections review the outlines of major legislative proposals, including the only state statute enacted that addresses wrongful dismissal in a broad way. Then it assesses the political climate for wrongful dismissal legislation and concludes with a summary of the arguments why the employer community should get involved and should favor wrongful dismissal legislation providing an integration of the fragmented set of common law and statutory employee protections.

B. Legislative Proposals

The most significant development at the state level has been the enactment by the Montana legislature of a "Wrongful Discharge From Employment Act." [FN131] The statute follows the suggestions made by the author of this article for an enumerated prohibitions approach. [FN132]

*424 The Montana statute authorizes damages actions for dismissals which are in retaliation for an employee's refusal to violate public policy, [FN133] are not for good cause after employees complete probationary periods, [FN134] or which violate express written employer personnel policies. [FN135] Compensatory damages for lost wages and benefits for up to four years are available, but no other form of damages are available unless the employee can establish actual fraud or actual malice by the employer. [FN136] The statute expressly preempts common law tort and implied contract claims, [FN137] and excludes employment terminations that are subject to state and federal whistle-blower and discrimination statutes, [FN138] or are covered by collective bargaining agreements. [FN139] Arbitration of claims arising under the statute is optional, but attorney's fee awards are provided for against the party declining to arbitrate. [FN140]

The Montana statute is a peculiar combination of just cause and enumerated reasons legislation. It is not entirely clear why the specific provisions relating to public policy dismissals or dismissals contravening employer personnel policies are included, given the broad prohibition against dismissals without just cause, unless the narrower prohibitions are intended to protect only probationary employees.

A trial court in Montana held the Montana statute unconstitutional, essentially on equal protection grounds, although the court's opinion does not provide much analytical support for its conclusion. The Supreme Court of Montana reversed. [FN141]

The possibilities for wrongful dismissal legislation have been focused by an initiative of the Commissioners on Uniform State Laws to develop a model state statute. Early drafts of the statute reflect an approach similar in many ways to the Montana statute and to this author's proposals. The draft statute enumerates reasons for which employees may not be dismissed including also, as an option, a provision restricting dismissals to just cause. Claims of violation of the statute must be presented to an administrative agency for a preliminary probable cause determination. If probable cause is found, mediation and arbitration may ensue. The draft statute provides for *425 limited judicial review of arbitral determinations. It also preempts common law causes of ac-

tion pertaining to dismissal. Employees must elect between making claims under the statute or making claims under other federal or state statutes for a single termination. The draft statute limits damages and provides for attorney's fee awards to the prevailing party. The plaintiff bar actively opposes the damages limitation and the preclusion of common law theories.

An intriguing idea that deserves more detailed development is the one advanced by University of Pennsylvania Professor Janice Bellace for integrating wrongful dismissal protection with the existing unemployment compensation system. This would avoid the need for erecting a new set of institutions, would avoid to some extent constitutional challenges to the appropriateness of the dispute resolution forum (although unemployment compensation does not reduce or supplant any common law right) and permit an intuitively appealing integration of remedies.

The legal attack on the Montana statute also illustrates one of the most difficult legal issues in drafting an appropriate statute. This legal issue constrains the policy choices that can be made and alters the political debate because of the possibility that some approaches advanced for policy reasons would be unconstitutional.

The problem is that limitations on damages, channeling wrongful dismissal controversies into alternative dispute resolution forms like arbitration, and integrating wrongful dismissal protections by abolishing common law rights of action all arguably infringe the right to a civil jury trial, preserved by the Seventh Amendment to the United States Constitution and similar provisions of all but two state constitutions. [FN142] The state constitutional protections are more important to the wrongful dismissal legislative debate than the Seventh Amendment protection. The Seventh Amendment has not been incorporated into the Fourteenth Amendment due process clause and therefore only affects federal court decision-making over cases presenting federal questions or involving diversity jurisdiction.

There is little doubt about the capacity of a legislature to change the common law. Otherwise there would be little function for legislatures. So, to the extent that a legislature considering wrongful dismissal legislation explicitly extinguishes a common law right, there should not be a constitutional jury trial problem. The right to jury trial in a civil case depends upon there being a civil case. [FN143]

*426 Some courts, however, have used equal protection analysis to conclude in nonemployment law areas that when the legislature takes away a common law right it must substitute some reasonable alternative. [FN144] Such an analytical framework, of course, puts a court in the position of judging whether the alternative provided is "reasonable." These concerns constrain mainly the authority of a legislature to integrate new wrongful dismissal protection with existing common law and statutory rights.

There are other difficulties. Most commentators have thought that some form of arbitration would be a desirable way to adjudicate wrongful dismissal claims. But forcing wrongful dismissal claims into an arbitration process centrally confronts the jury trial right. If a legislature expressly extinguishes all of the common law wrongful dismissal rights and then substitutes a new statutory right that must be presented to an arbitrator, it theoretically avoids the constitutional jury trial guarantee but invites a court to decide whether the new legislatively substituted mechanism is "reasonable."

In addition, arbitration has some shortcomings as a dispute resolution process in this context. Most commentators have concluded too quickly that the success of collectively bargained arbitration recommends it for use in the wrongful dismissal area. But the legal and practical environment in which arbitration would function is different between collective bargaining and individual wrongful dismissal claims. In the collective bargaining

environment, the union and the employer exercise continuing control over the arbitration process. They pick the arbitrators and develop institutional memories of arbitrator performance. If the arbitrator makes decisions they do not like, they can easily change the language of the collective bargaining agreement which the arbitrator must apply. These controls are absent when arbitration is used as a means of deciding individual wrongful dismissal claims. A wrongful dismissal arbitrator is interpreting the law, not a collective bargaining agreement.

Accordingly, the need for some controls over arbitrator decision-making suggests that a more intrusive form of judicial review would be appropriate, and perhaps constitutionally required, for wrongful dismissal arbitration. Yet a more intrusive kind of judicial review mitigates many of the advantages of arbitration as a dispute resolution process. For instance, judicial review is meaningful only if *427 there is some kind of record to review. Yet requiring arbitrators to create records makes the process more expensive and more formal. In this context, creating a record means not only making a transcript of the evidence and testimony, but also requiring that the arbitrator issue a written opinion logically justifying his decision.

In addition, the likelihood of constitutional challenges to a legislative overhaul means not only the jury trial guarantee but also separation of power concepts would be brought to bear. Although state courts apply separation of powers concepts differently in detail, the basic ideas articulated by the United States Supreme Court under the United States Constitution are reasonable rules of thumb. These concepts say that it violates separation of powers for a legislature to force private common law rights to be adjudicated finally by an institution that is not a court, thus reinforcing the jury trial guarantee. It is permissible, however, for the legislature to create new rights and to provide for their adjudication by institutions lacking some attributes of a court. Under the "public right" or congressionally created "private right" doctrine, a legislature could create a new right not to be dismissed wrongfully and set up arbitration-like tribunals to adjudicate claims. Nevertheless, the adequacy of the adjudicatory mechanism thus set up would be subject to scrutiny under equal protection, separation of powers, and procedural due process concepts.

The foregoing discussion does not support an inference that the only constitutional wrongful dismissal statute is one that simply adds to the universe of employee rights and provides for litigation in the regular common law courts. It is possible and constitutional to draft a wrongful dismissal statute that integrates employee rights and provides for their adjudication in an appropriate administrative or arbitrary tribunal. The point is that drafters of statutes must be careful to understand the constitutional risks of particular approaches and to draft language carefully to avoid the difficulties.

C. Political Factors

I have reviewed the basic political calculus of wrongful dismissal legislative reform elsewhere. [FN145] Four changes are occurring that shift this calculus.

First, organized labor has endorsed in principle the concept of comprehensive legislative protection against dismissal without just cause. In a statement adopted by the AFL-CIO Executive Council in 1987, organized labor strongly rejected the alternative of enumerated*428 prohibitions legislation. [FN146] Second, the plaintiff bar, at least in some states, has become sufficiently satisfied with common law wrongful dismissal developments and is beginning to resist the idea of wrongful dismissal legislation that limits in any major way common law theories or damages recoverable under those theories. Third, congressional activism is limiting further the reasons for which employees may be terminated. Within the last few years, Congress has enacted legislation requiring notification before facilities are closed, [FN147] granting private rights of action for dis-

missals associated with polygraph examinations [FN148] and granting a private right of action for dismissals in retaliation for reporting false claims under government contracts. [FN149] All of these new rights can be asserted in court.

Fourth, the academic community is beginning to perceive the problems associated with fragmentation. Clyde W. Summers, Professor of Law at the University of Pennsylvania and arguably the original stimulus for common law modification of the employment-at-will rule, has written recently about the fragmentation in labor law. [FN150] Professor Summers observes that the purpose of labor law always has been to redress an imbalance in bargaining power between employee and employer. Collective bargaining was the original policy instrument chosen to meet this goal, but collective bargaining largely has been abandoned as the policy instrument of choice because of its limited coverage. Although collective bargaining has a number of theoretical advantages, including flexibility to meet localized concerns, capacity to create adjudicatory institutions to enforce rights, and reduction of the need for detailed government intervention, it is not likely to return as the dominant regulatory approach. Rather, the policy emphasis has shifted fundamentally toward programs such as OSHA and ERISA that define individual employee rights and provide governmental institutional mechanisms to enforce them. Common law wrongful dismissal is a further example of this trend.

*429 Professor Summers believes that the major challenge for the new century is integrating forums and rights so that neither employees nor employers face the necessity of litigating the same employment decision many different times and in many different forums under many different legal theories. [FN151] He fears, however, that solutions to the fragmentation problems inevitably will be piecemeal and incomplete. [FN152] He urges that a rough consensus could be arrived at, using minimum effort, regarding the appropriate remedies and measures of damages so that they will not vary according to the form of the action or the chosen forum. [FN153] Further, he urges "reduc ing multiple litigation by requiring that all of the rights growing out of the same transaction be adjudicated in the same forum and that the judgment be collateral estoppel on those rights." [FN154] He observes that statutes can be drafted with more careful attention to preemption problems. [FN155] These all are important and sound ideas.

Professor Summers also encourages more attention to effective remedies, recognizing that, "[m]ost workers do not have the price of admission to the legal system. They cannot afford a lawyer, and the claims are too small to produce a viable contingent fee." [FN156] Explaining why attorney's fee awards, and double damages do not provide sufficient incentives for adequate legal representation, he observes that, " f ew neutral observers would characterize the NLRB, EEOC, OSHA, or the Department of Labor as effective guardians of employee rights." [FN157] He also notes that large punitive and emotional distress damage awards in public policy tort cases really represent only a lottery with a few big winners and many losers. He urges that the industrial democracy premise underlying the policy preference for collective bargaining is still valid and that we should search for new ways to fulfill it. [FN158]

The California Supreme Court's decision in *Foley* apparently is perceived by many plaintiff lawyers as sharply curtailing the opportunities for wrongful dismissal plaintiffs and their counsel. Regardless of whether this is an accurate characterization of *Foley*, the perception may cause the plaintiff bar to view wrongful dismissal *430 legislation (similar to that being developed by the commissioners on state laws) more favorably.

My original calculus suggested that wrongful dismissal legislation might be feasible if it contained the following elements: (1) grant of attorney's fees (for plaintiff lawyers); (2) enumerated reasons for which dismissal is not permitted, essentially codifying the three major common law theories (for employers); and,

(3) limiting damages to back pay with the possibility of double back pay or triple back pay liquidated damages provision in some cases (as a compromise between employer and plaintiff lawyers). The trends, however, make enactment of such legislation increasingly unlikely as time passes. The addition of more prohibited motive statutes narrows the gap somewhat conceptually between just cause protection and enumerated prohibitions protection. Satisfaction by the plaintiff bar with the status quo removes a potential ally in any movement for legislative reform. Additionally, the labor movement has taken sides between the two basic types of wrongful dismissal legislation.

D. Employer Interests

The right kind of wrongful dismissal legislation is in the economic interest in the employer community. The employer community, however, risks being excluded from the process of developing and implementing wrongful dismissal legislation unless it recognizes its economic interests more clearly and becomes more active in promoting legislative reform. The essential danger remains that just cause legislation will be enacted on top of existing piecemeal protections with no provisions which might be desired by employers, or alternatively that the common law will evolve in a way so favorable to employees that the political opportunity for reform legislation will be lost entirely.

Serious employer involvement in exploring the options for wrongful dismissal legislation need not be limited to the proposal emerging from the Uniform State Law Commissioners' effort, nor to the enumerated prohibitions approach. A third alternative with a number of attractive features would be to integrate wrongful dismissal protection with the existing unemployment compensation system. Such integration could eliminate the need for developing new forums and processes and also would match conceptually with some kind of standard, and limited, liquidated damages for wrongful dismissal. Employers ought to help rationalize employment law instead of letting other interests superimpose yet another program restricting employer autonomy.

[FN_a] B.S. 1966, M.S. 1970, Massachusetts Institute of Technology; J.D. Georgetown 1975; Professor of Law, Villanova Law School; member of the bar, Virginia, Pennsylvania, District of Columbia, United States Supreme Court.

[FN1]. The employment-at-will rule can be summarized like this: An employer may dismiss an at-will employee for a good reason, a bad reason, or for no reason at all.

[FN2]. See *Wandry v. Bull's Eye Credit Union*, 129 Wis. 2d 37, 40 n.2, 384 N.W.2d 325, 326 n.2 (1986) (noting erosion of employment-at-will rule, citing author's treatise).

[FN3]. H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* (1984); H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* (2d ed. 1987 & Supp. 1 1989).

[FN4]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* §§ 4.1-4.28 (2d ed. 1987).

[FN5]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* §§ 5.1-5.33 (2d ed. 1987).

[FN6]. Some courts treat breach of the implied covenant as a tort. *But see* *Foley v. Interactive Data*, 47 Cal. 3d 654, —, 765 P.2d 373, 395-96, 254 Cal. Rptr. 211, 233-34 (1989) (en banc) (covenant is essentially a contract

theory).

[FN7]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 4.11 (2d ed. 1987).

[FN8]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 7.28 (2d ed. 1987) (example of implied covenant jury instructions).

[FN9]. 121 N.H. 915, 436 A.2d 1140 (1981).

[FN10]. *Id.* at 924, 436 A.2d at 1145.

[FN11]. 721 F.2d 894 (3d Cir. 1983). See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 5.12 (2d ed. 1987) for analysis of public policy tort claims based on Constitutional policies.

[FN12]. *Id.* at 898-99. The *Novosel* case was settled after the district court, on remand, denied the employer's motion for summary judgment on all counts except plaintiff's punitive damage claim for breach of contract. *Novosel v. Nationwide Mutual Ins. Co.*, 118 L.R.R.M. (BNA) 2779, 2782 (W.D. Pa. 1985). Interestingly, the employer argued that it dismissed Mr. Novosel for pro-union remarks made to non-management personnel, which might have raised additional public policy and preemption issues. *Id.* at 2780.

[FN13]. *Novosel*, 721 F.2d at 897.

[FN14]. *Id.* at 899.

[FN15]. 58 N.Y.2d 293, 448 N.E.2d 86, 461 N.Y.S.2d 232 (1983).

[FN16]. 23 Ohio St. 3d 100, 491 N.E.2d 1114 (1986).

[FN17]. 58 N.Y.2d at 297, 448 N.E.2d at 87, 461 N.Y.S.2d at 233.

[FN18]. *Id.* at 301, 448 N.E.2d at 89, 461 N.Y.S.2d at 235.

[FN19]. *Id.*

[FN20]. *Id.* at 302, 448 N.E.2d at 89-90, 461 N.Y.S.2d at 235-36.

[FN21]. 23 Ohio St. 3d at 103, 491 N.E.2d at 1117.

[FN22]. *Id.* at 102, 491 N.E.2d at 1116-17. The membership of the *Phung* court was unusual. Justice Dahling, author of the majority opinion, was not a regular member of the Supreme Court. He replaced Justice Douglas, who wrote the *Phung* court of appeals decision finding a cause of action. *Id.* at 103, 491 N.E.2d at 1117. So when Justice Dahling is subtracted from the majority, and Justice Douglas added to the dissenters, one obtains a four-three majority in *Phung*, suggesting that the court might reach a different result in another public policy tort case, either because of different facts, or because of minor changes in the court's membership.

[FN23]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 5.12 (2d ed. 1987 & Supp. 1 1989) (characterizing authority supporting *Novosel* approach "sparse").

[FN24]. H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 7.11 (2d ed. 1987); *Mello v. Stop*

& Shop Co., 402 Mass. 555, — n.7, 524 N.E.2d 105, 108 n.7 (1988) (reversing judgment for employee and noting that jury does not define public policy; judge decides clarity element, then instructs jury on how to decide if causation element was present).

[FN25]. See H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* §§ 7.10, 7.16 (2d ed. 1987).

[FN26]. See *Lucas v. Brown & Root, Inc.*, 736 F.2d 1202, 1205 (8th Cir. 1984) (court competent to decide public policy; legislature not only source of public policy); *Wagenseller v. Scottsdale Memorial Hosp.*, 147 Ariz. 370, 378-79, 710 P.2d 1025, 1033-34 (1985) (en banc) (quoting *Lucas v. Brown & Root, Inc.*, 736 F.2d 1202, 1205 (8th Cir. 1984) (court decisions, as well as statutes and constitutions are sources of public policy); *Dabbs v. Cardiopulmonary Management Serv.*, 188 Cal. App. 3d 1437, 1443-45, 234 Cal. Rptr. 129, 133-34 (1987) (public policy need not be based on statutory right or on refusal to perform illegal act but may also be derived from decisional law; reversing trial court and finding public policy based tort remedies for therapist who refused to work under conditions that endanger patients). Professors Ronald Dworkin and Melvin Eisenberg are particularly articulate in explaining how judges must consider policy in deciding difficult cases. See generally, R. DWORKIN, *TAKING RIGHTS SERIOUSLY* 81-130 (1977); M. EISENBERG, *THE NATURE OF THE COMMON LAW* (1988) (fairness dictates consideration of public policy).

[FN27]. See *Connick v. Myers*, 461 U.S. 138, 146-47 (1983) (First Amendment protection does not extend to public employee expression related to private matters).

[FN28]. *United Bhd. of Carpenters & Joiners v. Scott*, 463 U.S. 825, 830 (1983) (violation of First Amendment rights cannot be shown under 42 U.S.C. § 1985(3) unless the state was involved in the deprivation); see *Barr v. Kelso-Burnett Co.*, 106 Ill. 2d 520, 526, 478 N.E.2d 1354, 1357 (1985) (free-speech provisions of state and federal constitutions cannot support public policy tort because they reflect public policy only against governmental interference); Annotation, *Discharge From Private Employment on Ground of Political Views or Conduct*, 51 A.L.R.2d 742 (1957).

[FN29]. U.S. CONST. amends. I-X.

[FN30]. 272 Or. 210, 536 P.2d 512 (1975) (tort recovery permitted for discharge in retaliation for jury service). However, in *Chin v. American Tel. & Tel. Co.*, 410 N.Y.S.2d 737, 741, 96 Misc. 2d 1070, 1075 (Sup. Ct. 1978), the court declined to find public policy support for a tort action based on first amendment interests. For early dicta that a tort remedy does exist for dismissals based on constitutionally protected acts, see *Boniuk v. New York Medical College*, 535 F. Supp. 1353, 1356 n.1, 1358 n.2 (S.D.N.Y. 1982) (only lower state courts have recognized the tort of abusive discharge; not appropriate for federal court to recognize it); *Brink's Inc. v. City of New York*, 533 F. Supp. 1123, 1125 (S.D.N.Y. 1982) (while wrongful discharge action not recognized for at will employees in New York, it is possible that it would be recognized if discharge violated public policy). It is not clear what vitality these New York cases have since the New York Court of Appeals has rejected the concept of a public policy tort in *Murphy v. American Home Prods.*, 58 N.Y.2d 293, 301, 448 N.E.2d 86, 89, 461 N.Y.S.2d 232, 235 (1983). Cf. *Gil v. Metal Serv. Corp.*, 412 So. 2d 706, 708, (La. App. 1982) (dicta that a "whistle-blower" might be constitutionally protected from dismissal under the free speech clause.)

[FN31]. *Novosel v. Nationwide Ins. Co.*, 721 F.2d 894, 899 (3rd Cir. 1983).

[FN32]. See *id.* at 900 (threat of employment termination infringes "the individual rights of the employees and the ability of the lone political actor to be heard").

[FN33]. *Buethe v. Britt Airlines, Inc.*, 787 F.2d 1194 (7th Cir. 1986).

[FN34]. *See Adler v. American Standard Corp.*, 830 F.2d 1303 (4th Cir. 1987); *Bushko v. Miller Brewing Co.*, 134 Wis. 2d 136, 141, 396 N.W.2d 167, 170 (1986).

[FN35]. 134 Wis. 2d at 136, 396 N.W.2d at 167.

[FN36]. *Id.* at 137-140, 396 N.W.2d at 168-69.

[FN37]. *Id.* at 141, 396 N.W.2d at 170.

[FN38]. *Id.* at 142, 396 N.W.2d at 170.

[FN39]. *Id.* at 146, 396 N.W.2d at 172. This possibility is addressed *infra* in this article in the text accompanying notes 141 to 143.

[FN40]. *Id.* at 147, 396 N.W.2d at 172 (Abrahamson, J., concurring).

[FN41]. *Id.* at 155 n.6, 396 N.W.2d at 176 n.6 (Abrahamson, J., concurring).

[FN42]. *Id.* (Abrahamson, J., concurring).

[FN43]. *Id.* at 151, 396 N.W.2d at 174 (Abrahamson, J., concurring).

[FN44]. *Id.* at 149, 396 N.W.2d at 173 (Abrahamson, J., concurring).

[FN45]. 830 F.2d 1303, 1306-07 (4th Cir. 1987) (quoting Maryland cases as embracing theory covering either dismissals for refusal to act unlawfully or dismissals for attempt to perform duty).

[FN46]. *Id.* at 1307.

[FN47]. *Id.*

[FN48]. *Id.* at 1308.

[FN49]. *Compare id.* at 1307 with *Bushko*, 134 Wis. 2d at 149, 396 N.W.2d at 173.

[FN50]. 700 S.W.2d 399 (Ky. 1985).

[FN51]. *Id.* at 401.

[FN52]. *See Buethe v. Britt Airlines, Inc.* 787 F.2d 1194 (7th Cir. 1986) (Posner, J.) (Indiana public policy tort doctrine provides cause of action for whistle-blowers only when statute creates right to “blow a particular whistle”—presumably to report particular type of violation to particular agency).

[FN53]. 174 Cal. App. 2d 184, 344 P.2d 25 (1959).

[FN54]. 85 Ill. 3d 124, 421 N.E.2d 876 (1981).

[FN55]. 179 Conn. 471, 427 A.2d 385 (1980).

[FN56]. *See Buethe*, 787 F.2d at 1194.

[FN57]. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 5.1 (2d ed. 1987).

[FN58]. *See* *Guy v. Travenol Laboratories, Inc.*, 812 F.2d 911, 916 (4th Cir. 1987) (comprehensive enforcement scheme of Federal Food, Drug and Cosmetic Act makes it unnecessary to recognize public policy tort to further policy of Act).

[FN59]. 29 U.S.C. § 157 (1970).

[FN60]. *See* 29 U.S.C. § 215 (a)(3) (1982) (FLSA retaliation); *id* at § 1140 (ERISA retaliation).

[FN61]. *See* *Schriner v. Meginnis Ford Co.*, 228 Neb. 85, 93, 421 N.W.2d 755, 759 (1988) (affirming summary judgment for employer because employee lacked sufficient basis for good faith belief employer was violating state odometer statute when he reported employer to state attorney general's office).

[FN62]. *Palmer v. Brown*, 242 Kan. 893, 897, 752 P.2d 685, 688 (1988) (recognizing public policy tort claim for employee dismissed for reporting medicare fraud).

[FN63]. *Shores v. Senior Manor Nursing Center, Inc.*, 164 Ill. App. 3d 503, 509, 518 N.E.2d 471, 475 (1988) (reversing dismissal of complaint and finding employment termination for reporting nursing home violations to nursing home supervisory personnel covered by public policy tort).

[FN64]. 47 Cal. 3d 654, 765 P.2d 373, 254 Cal. Rptr. 211 (1988).

[FN65]. *Id.*, 765 P.2d at 379, 254 Cal. Rptr. at 217. (" . . . whether the discharge is against public policy and affects a duty which inures to the benefit of the public at large rather than to a particular employer or employee."). *See also* *Mello v. Stop & Shop Co.*, 402 Mass. 555, 560-61, 524 N.E.2d 105, 108 (1988) (dismissal for complaining about purely internal false claims and false reports does not implicate public policy).

[FN66]. *See, e.g.,* *Johnson v. Railway Express Agency*, 421 U.S. 454, 459 (1975); *Alexander v. Gardner-Denver Co.*, 415 U.S. 36, 48 (1974).

[FN67]. 108 S. Ct. 1877 (1988).

[FN68]. 29 U.S.C. § 185 (1970).

[FN69]. 471 U.S. 202 (1985).

[FN70]. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 7.31 (2d ed. 1987).

[FN71]. The precedent overruled explicitly included *Armstrong v. Goldblatt Tool Co.*, 242 Kan. 164, 169-70, 747 P.2d 119, 123-24 (1987), decided only three months earlier.

[FN72]. 242 Kan. 804, 813-15, 752 P.2d 645, 651-52 (1988) (reversing summary judgment for employer).

[FN73]. 415 U.S. 36 (1974).

[FN74]. *Ewing v. Koppers Co.*, 312 Md. 45, 50-51, 537 A.2d 1173, 1175 (1988) (public policy tort claim for re-

taliatory discharge for filing worker's compensation claim is available to employee covered by collective agreement, but preempted by 29 U.S.C. § 185 where arbitrator already had decided that just cause existed). *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 5.20 (2d ed. 1987) for other cases.

[FN75]. 105 Ill. 2d 143, 473 N.E.2d 1280 (1984).

[FN76]. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* §§ 1.12, 4.15 (2d ed. 1987).

[FN77]. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 4.14 (2d ed. 1987).

[FN78]. Part of the idea of offer and acceptance or "meeting of the minds" in contract theory is to require that a promise be supported by some sort of validation device before the law enforces it. The most common validation device is *consideration*: something given in return for a promise. This may be a return promise or it may be conduct. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 4.13 (2d ed. 1987) for analysis of the difference between bilateral (promise given in return for a promise) and unilateral (conduct given in return for a promise) contracts. It may be any benefit or detriment that is given in exchange for a promise. There must be a promise, or finding consideration is of no avail to the plaintiff. *See* *Walker v. Modern Realty of Mo., Inc.*, 675 F.2d 1002, 1004 (8th Cir. 1982) (recognizing promissory estoppel theory, but denying recovery because no promise of continued employment). The benefit may be a promise to pay a sum of money or may be the performance of an act, for example repairing an automobile. The detriment can be forbearance to do anything that one has a legal right to do, for example refraining from using tobacco. The motive for the consideration requirement, as for alternative validation devices, is essentially evidentiary. If a party has given something in return for a promise it is more likely that both parties meant for the promise to be enforced. *See* *Darlington v. General Electric*, 350 Pa. Super. 183, 203, 504 A.2d 306, 311, 316 (1986) (analysis of role of consideration in evidencing party intent to be bound; quoting this author's treatise on order of proof in implied contract case). When something has been given in return for a promise, it also seems fairer to enforce the promise. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 4.12 (2d ed. 1987) (discussing the history of the consideration requirement).

[FN79]. *See* *Lukoski v. Sandia Indian Management Co.*, 106 N.M. 664, —, 748 P.2d 507, 509-510 (1988) (affirming judgment for employee based on handbook distributed after employment began with signed receipt by employee). Another good example is the Pennsylvania case of *Robertson v. Atlantic Richfield Petrol. Prod. Co.*, 371 Pa. Super. 49, 537 A.2d 814 (1987) (affirming jury verdict of \$200,000 for employee), where employee and employer had an explicit conversation about the employee's concern that accepting a new assignment for which he was underqualified might jeopardize his employment. The employer agreed to reassign him if the new assignment did not work out. It was reasonable for the jury to infer an explicit bargain giving rise to employment security in these circumstances. *Id.* at —, 537 A.2d at 818-19.

[FN80]. If, for example, I am concerned that my employees may defect to another employer who pays higher salaries and offers more secure employment, I may make a general commitment to the work force that no one will be laid off. In such circumstances, it is reasonable to infer that my promise was made for the purpose of inducing employees to refuse offers to go to the competitor and to remain in my employ. In contrast, I might make the same commitment to the work force and one employee might rely on it by passing up a scholarship for post-graduate education. In this circumstance, it would not be reasonable to infer that I made the general commitment to induce the refusal of the scholarship. In the first hypothetical the bargained for conduct was the refusal of other job offers. In the second hypothetical the conduct of passing up the scholarship would not be bargained for.

[FN81]. See RESTATEMENT (SECOND) OF CONTRACTS § 18 (1979) (manifestation of mutual assent); *id.* § 19 (conduct as manifestation of assent); *id.* § 24 (offer defined). See also, A. CORBIN, CORBIN ON CONTRACTS § 13 (1963) (describing a promise as an “expression of intention” that need not be expressed with words); *id.* § 34 (rejecting idea that for a contract to be enforceable, the parties must have intended to affect their legal relations).

[FN82]. See *Albert v. Davenport Osteopathic Hosp.*, 385 N.W.2d 237, 238-39 (Iowa 1986) (at-will presumption can be overcome by additional consideration such as quitting another job, but in this case employee did not give additional consideration so contract was terminable-at-will).

[FN83]. 99 N.J. 284, 491 A.2d 1257 (1985).

[FN84]. *Id.* at 302, 491 A.2d at 1267.

[FN85]. *Id.* at 307, 491 A.2d at 1270.

[FN86]. 333 N.W.2d 622 (Minn. 1983).

[FN87]. *Id.* at 624.

[FN88]. *Id.* at 629.

[FN89]. See *Foley v. Interactive Data Corp.*, 47 Cal. 3d 654, —, 765 P.2d 373, 384, 254 Cal. Rptr. 211, 222 (1988) (ordinary rules of contract interpretation permit proof of implied terms; no basis for requiring special consideration).

[FN90]. See *Coelho v. Posi-Seal Int'l, Inc.*, 208 Conn. 106, 118-19, 544 A.2d 170, 176 (1988) (promise of employment security becomes enforceable as soon as employee enters employment; no reliance beyond performance of regular services legally required as consideration).

[FN91]. See *Watson v. Idaho Falls Consol. Hosp., Inc.*, 111 Idaho 44, 48, 720 P.2d 632, 636 (1986) (employee handbook creates binding unilateral contract) (quoting *Woolley v. Hoffman-LaRoche*, 99 N.J. 284, 491 A.2d 1257 (1985)).

[FN92]. See *Cannon v. National By-Products, Inc.*, 422 N.W.2d 638, 641 (Iowa 1988) (rejecting requirement for special consideration to support promise to dismiss only for good cause or to support post-employment incorporation of personnel policies).

[FN93]. See *Jackson v. Action for Boston Community Dev.*, 403 Mass. 8, 14, 525 N.E.2d 411, 415 (1988) (“remaining with an employer after, or commencing employment upon, receiving an employee manual can . . . supply the necessary consideration to incorporate the manual's terms into employment contract”).

[FN94]. See *Brookshaw v. South St. Paul Feed, Inc.*, 381 N.W.2d 33, 36 (Minn. Ct. App. 1986) (employee accepts an offer of a disciplinary procedure contained in a handbook by remaining on the job despite disclaimer printed in handbook); *Hunt v. IBM Mid Am. Employees Fed. Credit Union*, 384 N.W.2d 853, 856-58 (Minn. 1986) (distinguishing special consideration case from implied contract case like *Pine River State Bank*, 333 N.W.2d 622 (Minn. 1983)) (implying nothing more than performance of services is necessary when promise was sufficiently specific) (reversing denial of summary judgment for employer because handbook promise too vague).

to constitute enforceable covenant of good faith and fair dealing).

[FN95]. *Stratton v. Chevrolet Motor Div., Gen. Motors Corp.*, 229 Neb. 771, 775-77, 428 N.W.2d 910, 913-14 (1988) (employee can “accept” written or oral limitations on at-will termination right by continuing employment after knowing of them; no knowledge and no breach in instant case).

[FN96]. *See Panto v. Moore Business Forms, Inc.*, 130 N.H. 730, 735-38, 547 A.2d 260, 264-66 (1988) (adopting general principle that employee accepts employer offer by continuing normal work; characterizing *Woolley*, 99 N.J. 284, 491 A.2d 1257 (1985), as relaxing traditional contract principles; applying traditional unilateral contract principles in layoff compensation case).

[FN97]. *See Thompson v. American Motor Inns, Inc.*, 623 F. Supp. 409, 414-15 (W.D. Va. 1985) (consideration for handbook promises supplied by continued work after reading handbook; citing *Woolley*, 99 N.J. 284, 491 A.2d 1257 (1985) with approval).

[FN98]. *See Cook v. Heck's Inc.*, 342 S.E.2d 453, 458-59 (W. Va. 1986) (handbook statements regarding employment security can be offers of unilateral contract, accepted by employee continuing to work, citing *Woolley*, 99 N.J. 284, 491 A.2d (1985)).

[FN99]. *See Sabetay v. Sterling Drug, Inc.*, 114 A.D.2d 6, 9-10, 497 N.Y.S.2d 655, 657 (N.Y. App. Div. 1986) (lack of knowledge of handbook precludes implied contract claim because both “inducement” and reliance must be shown), *aff'd*, 69 N.Y.2d 329, 506 N.E.2d 209 (1987).

[FN100]. *Coelho v. Posi-Seal Int'l, Inc.*, 208 Conn. 106, 118, 544 A.2d 170, 176 (1988) (affirming judgment on jury verdict for employee). *See also Scott v. Extracorporeal, Inc.*, 376 Pa. Super. 90, —, 545 A.2d 334, 338-40 (1988) (role of special consideration is essentially evidentiary, strengthening inference that parties intended employment security; but general promises do not necessarily go to jury even when special consideration present).

[FN101]. 495 F. Supp. 344 (E.D. Mich. 1980).

[FN102]. *See id.* at 346. *See also Thompson v. St. Regis Paper Co.*, 102 Wash. 2d 219, 230-31, 685 P.2d 1081, 1088 (1984) (employers can avoid enforceability of handbooks by stating conspicuously that they are not intended to be enforceable); *Cutter v. Lincoln Nat'l Life Ins. Co.*, 794 F.2d 352, 355-56 (8th Cir. 1986) (affirming j.n.o.v. for employer under South Dakota law; written employment agreement provided for termination with or without cause).

[FN103]. *Schipani v. Ford Motor Co.*, 102 Mich. App. 606, 302 N.W.2d 307 (Ct. App. 1981) (affirming denial of motion for summary judgment with respect to breach of implied contract). The agreement said, “I understand that my employment is not for any definite term, and may be terminated at any time, without advance notice by either myself or Ford Motor Company” *Id.* at 610, 302 N.W.2d at 309. *But see Longley v. Blue Cross & Blue Shield*, 136 Mich. App. 336, 339-41, 356 N.W.2d 20, 21-22 (Ct. App. 1984) (plaintiff's deposition testimony that she read and believed statement that employer could dismiss with or without cause precluded trial on implied contract theory); *Reid v. Sears, Roebuck & Co.*, 790 F.2d 453, 461 (6th Cir. 1986) (giving effect, under Michigan law, to disclaimer in employment application); *Ringwelkski v. Sears, Roebuck & Co.*, 636 F. Supp. 519, 520 (E.D. Mich. 1985) (giving effect to disclaimer in employment application); *Ledl v. Quik Pik Food Stores, Inc.*, 133 Mich. App. 583, 586-88, 349 N.W.2d 529, 531-32 (Ct. App. 1984) (agreement acknowledging unenforceability of employer's promises of employment security made seven years earlier precluded recovery

for termination based on breach of implied promise). *See also* Stiver v. Texas Instruments, Inc., 750 S.W.2d 843, 846 (Tex. Ct. App. 1988) (giving effect to disclaimer limiting authority to modify express at-will provision to officer of employer).

[FN104]. 779 F.2d 101, 108 (2d Cir. 1985).

[FN105]. *See* Murray v. Kaiser Aluminum & Chem. Corp., 591 F. Supp. 1550, 1553-54 (S.D. W. Va. 1984) (written contract providing for continued employment as long as "mutually agreeable" permitted unilateral termination by employer for any reason), *aff'd*, 767 F.2d 912 (4th Cir. 1985).

[FN106]. DeFosse v. Cherry Elec. Prod. Corp., 156 Ill. App. 3d 1030, 1031-32, 510 N.E.2d 145, 145 (App. Ct. 1987) (ordering j.n.o.v. on claim for breach of handbook promise to pay disability benefits; employee testified he read provisions and that they influenced his decision to take job); *see generally* Boynton v. TRW, Inc., 858 F.2d 1178, 1183 (6th Cir. 1988) (reviewing cases applying implied-in-fact theory to employer decisions not involving employment termination; reversing judgment finding employee failed to state a claim based on his layoff); Panto v. Moore Business Forms, Inc., 130 N.H. 730, 731, 547 A.2d 260, 261-62 (1988) (on certification from federal court, holding that employee could enforce layoff compensation promise on unilateral contract theory, consideration provided from mere continuation of employment). Bower v. AT&T Technologies, Inc., 852 F.2d 361, 366 (8th Cir. 1988) (reversing district court for refusing to enforce detailed promises of reemployment; implied contract analysis permitted employees a trial on their claim of reemployment rights after a layoff).

[FN107]. *See* Grigoletti v. Ortho Pharmaceutical Corp., 226 N.J. Super. 518, 545 A.2d 185 (1988) (benefits promise an offer of a unilateral contract; consideration is employee reliance, which is to be presumed; discussing *Wooley*, 99 N.J. 284, 491 A.2d 1257 (1985)).

[FN108]. Frigon v. Morrison-Maierle, Inc., 760 P.2d 57, 60 (Mont. 1988) (affirming summary judgment for employer).

[FN109]. J. MURRAY, MURRAY ON CONTRACTS § 221 (2nd rev. ed. 1974).

[FN110]. *Id.* *Reliance* damages are available as an alternative in some cases. *See* J. MURRAY, MURRAY ON CONTRACTS § 223 (2nd rev. ed. 1974); RESTATEMENT (SECOND) OF CONTRACTS § 90 comments a-f (1979).

[FN111]. *Compare* Washington Welfare Ass'n, Inc. v. Wheeler, 496 A.2d 613, 617 (D.C. Cir. 1985) (\$26,000 jury award for future earnings under contract terminable only for just cause allowed to stand) *with* Gram v. Liberty Mutual Ins. Co., 391 Mass. 333, 334-35, 461 N.E.2d 796, 798 (1984) (reversing \$325,000 judgment for dismissed employee on grounds that proper measure is not same as earnings for lifetime employment).

[FN112]. 779 F.2d 101, 109-10 (2d Cir. 1985).

[FN113]. 147 Mich. App. 819, 826-27, 384 N.W.2d 54, 58 (1985).

[FN114]. *Id.* at 829, 384 N.W.2d at 59.

[FN115]. *See* Sterling Drug, Inc. v. Oxford, 294 Ark. 239, 251-52, 743 S.W.2d 380, 386-87 (1988) (reviewing cases; rejecting front pay as too speculative).

[FN116]. 113 Wis. 2d 561, 575, 335 N.W.2d 834, 841 (1983).

[FN117]. *Id.* at 573, 335 N.W.2d at 840-41.

[FN118]. *See Ritchie v. Michigan Consol. Gas Co.*, 163 Mich. App. 358, 374, 413 N.W.2d 796, 803-04 (1987) (approving front pay in implied contract case); H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 4.28 (2d ed. 1987 & Supp. 1 1989).

[FN119]. 174 Cal. App. 2d 184, 344 P.2d 25 (1959).

[FN120]. 114 N.H. 130, 316 A.2d 549 (1974).

[FN121]. *Petermann*, 174 Cal. App. 2d at 189, 344 P.2d at 28; *Monge*, 114 N.H. at 133-34, 316 A.2d at 552.

[FN122]. 58 N.Y.2d 293, 304-05, 448 N.E.2d 86, 91, 461 N.Y.S.2d 232, 237-388 (1982) (accepting implied-in-fact contract theory but rejecting implied covenant and public policy tort).

[FN123]. 113 Wis. 2d 561, 335 N.W.2d 834 (1983).

[FN124]. *Id.* at 573, 335 N.W.2d at 840.

[FN125]. *See also Melnick v. State Farm Manual Auto. Ins. Co.*, 106 N.M. 726, —, 749 P.2d 1105, 1111 (1988) (rejecting implied covenant as theory applicable to employment terminable at-will—at least where no “improper motivation” shown).

[FN126]. For a discussion of the limitations placed on the implied covenant, see *supra* notes 105-07 and accompanying text.

[FN127]. 47 Cal. 3d 654, 698 n.39, 765 P.2d 373, 400 n.39, 254 Cal. Rptr. 211, 238 n.39 (1988) (implied covenant does not, without more, impose duty to dismiss only for good cause).

[FN128]. *See Stark v. Circle K Corp.*, 751 P.2d 162, 167 (Mont. 1988) (affirming \$270,000 jury verdict for employee who refused to sign probationary notice the accuracy of which he contested).

[FN129]. Summers, *Individual Protection Against Unjust Dismissal: Time for a Statute*, 62 VA. L. REV. 481 (1976).

[FN130]. *See* H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* § 9.20-9.24 (2d ed. 1987); Perritt, *Wrongful Dismissal Legislation*, 35 UCLA L. REV. 65 (1987); Perritt, *Employee Dismissals: An Opportunity for Legal Simplification*, 35 LAB. L.J. 407 (1984).

[FN131]. MONT. CODE ANN. §§ 39-2-901 to 39-2-914 (1989) (enacted 1987).

[FN132]. *Compare id.* (Montana statute encompassing wrongful discharge) with H. PERRITT, *EMPLOYEE DISMISSAL LAW AND PRACTICE* app. C (2d ed. 1987) (draft statutes for wrongful discharge).

[FN133]. MONT. CODE ANN. § 39-2-904(1).

[FN134]. *Id.* § 39-2-904(2).

[FN135]. *Id.* § 39-2-904(3).

[FN136]. *Id.* § 39-2-905(1).

[FN137]. *Id.* § 39-2-913.

[FN138]. *Id.* § 39-2-912(1).

[FN139]. *Id.* § 39-2-912(2).

[FN140]. *Id.* § 39-2-914.

[FN141]. *Meech v. Hillhaven West, Inc.*, 776 P.2d 488 (Mont. 1989).

[FN142]. *See James, Right to a Jury Trial in Civil Actions*, 72 YALE L.J. 655 (1963).

[FN143]. *See id.*

[FN144]. *See Kluger v. White*, 281 So.2d 1 (Fla. 1973) (invalidating auto insurance reform); *Wright v. Central Du Page Hosp. Ass'n*, 63 Ill. 2d 313, 347 N.E.2d 736 (1976) (invalidating medical malpractice reform); *Keyes v. Humana Hosp. Alaska, Inc.*, 750 P.2d 343 (Alaska 1988) (rejecting jury trial, substantive due process, and separation of powers attack on malpractice screening panel).

[FN145]. *See Perritt, Wrongful Dismissal Legislation*, 35 UCLA L. REV. 65, 68-72 (1987).

[FN146]. The AFL-CIO Executive Council issue a "Statement on the Employment-at-Will Doctrine" on February 20, 1987, generally expressing support for broad just-cause legislation, and criticizing proposals for enumerated prohibitions statutes. *See generally* Gould, *Job Security in the United States: Some Reflections on Unfair Dismissal and Plant Closure Legislation from a Comparative Perspective*, 67 NEB. L. REV. 28, 41 n.73 (1988) (labor unions may realize various benefits from wrongful discharge statute).

[FN147]. 29 U.S.C. §§ 2101-2102 (1982 & Supp. 1989).

[FN148]. 29 U.S.C. § 2005 (1982 & Supp. 1989).

[FN149]. 31 U.S.C. § 3730(h) (1982 & Supp. V. 1987).

[FN150]. Summers, *Labor Law as the Century Turns: A changing of the Guard*, 67 NEB. L. REV. 7 (1988).

[FN151]. *Id.* at 24-25.

[FN152]. *Id.*

[FN153]. *Id.* at 24.

[FN154]. *Id.*

[FN155]. *Id.* at 25.

[FN156]. *Id.*

[FN157]. *Id.*

[FN158]. *Id.* at 27.
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