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SUFFICIENCY OF THE EVIDENCE DOES NOT MEET
DAUBERT STANDARDS: A CRITIQUE OF THE GREEN-
SANDERS PROPOSAL

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This is not another article about *Daubert*. The law reviews have been flooded with commentaries about this landmark case.¹ This article focuses on a proposal advocated by Professor Michael Green at a Widener University School of Law symposium on class actions and expanded on in an article by Professors Green and Sanders.² Their thesis is that what courts have been doing by purporting to follow the dictates of *Daubert* is deciding issues of admissibility with little regard for the *Daubert* criteria, but rather based on the sufficiency of the evidence to infer a causal connection and the harm alleged.³ They argue that not only are they accurately describing what courts have been doing, but normatively what they should be doing.⁴ As we shall see, the

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¹ Searching the Westlaw database for "*Daubert v. Merrell Dow Pharmaceuticals*" with the search limited to "Secondary Sources, Law Reviews and Journals," returns 3,929 results.

² Michael D. Green & Joseph Sanders, *Admissibility Versus Sufficiency: Controlling the Quality of Expert Witness Testimony in the United States* (Wake Forest Univ. Sch. of Law Legal Studies Research Paper Series, Paper No. 2016468 & Univ. of Houston Law Ctr., Pub. Law and Legal Theory Research Paper Series, Paper No. 2016468), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2016468. Professor Green presented his thesis at a *Widener Law Journal* symposium on "Perspectives on Mass Tort Litigation," April 13, 2013. See also Michael D. Green, *Pessimism About Milward*, 3 WAKE FOREST J.L. & POL'Y 41 (2013).

³ Green & Sanders, *supra* note 2, at 1-2.

⁴ *Id.*

Green and Sanders argument has some merit.⁵ However, our opinion is that Green and Sanders have misconstrued the major thrust of *Daubert*. Moreover, the change of the nomenclature to sufficiency rather than the formal structure set forth in the *Daubert* trilogy has the potential to eviscerate *Daubert*.⁶ Nomenclature exerts a powerful influence on how judges decide whether to cut off a case at an early stage or to let the case go to full trial.⁷ And, once a case has gone to full trial, the pressure on a judge not to grant a judgment N.O.V. is very strong.⁸ Green and Sanders are sensitive to the need to have pre-trial hearings that preclude full

⁵ Some courts appear, in fact, to be doing what Green and Sanders describe. See *infra* notes 17 and 34.

⁶ See Green & Sanders, *supra* note 2, at 41.

⁷ In the past decade, tort scholars have engaged in vigorous debate as to whether 'foreseeability' of harm should be dealt with under the rubric of duty or proximate cause. The position of the Restatement (Third) of Torts, section 29 is that foreseeability should be dealt with in deciding whether the defendant breached the standard of care or whether the result was within "the risks that made the actor's conduct tortious." RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 29 (2010). The no-duty formulation should be limited to high order policy issues that speak to classes of conduct that tort law immunizes from liability. The Restatement comments make clear that utilizing duty to decide fact sensitive issues of foreseeability places decision-making power in the hands of trial judges to negate liability and deprives the jury of its legitimate role in making fact-based decisions. See *id.* cmt. f. Several courts have recently adopted the Restatement view. See, e.g., *Thompson v. Kaczinski*, 774 N.W.2d 829 (Iowa 2009); *Gipson v. Kasey*, 150 P.3d 228 (Ariz. 2007). The opposite view is set forth by John C.P. Goldberg and Benjamin C. Zipursky in *The Restatement (Third) and the Place of Duty in Negligence Law*, and is exemplified in Judge Cardozo's landmark opinion in *Palsgraf v. Long Island Railroad Co.* John C.P. Goldberg & Benjamin C. Zipursky, *The Restatement (Third) and the Place of Duty in Negligence Law*, 54 VAND. L. REV. 657 (2001); *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99 (N.Y. 1928). The crux of the debate comes down to whether greater decision-making power should be placed in the hands of trial judges. Duty is traditionally an issue of law that is to be decided by the court. Whether foreseeability issues are placed in the hands of the judge or jury depends on the nomenclature. The author is, in general, sympathetic to the Restatement formulation but with some reservations. See Aaron D. Twerski, *The Cleaver, The Violin, and the Scalpel: Duty and the Restatement (Third) of Torts*, 60 HASTINGS L.J. 1 (2008).

⁸ See generally Green & Sanders, *supra* note 2, at 2 (showing that it is expected for juries to make the determination of fact, thereby making judgment N.O.V. a less than popular choice for a judge).

trials based on inadequate expert testimony,⁹ but switching from the formality of *Daubert* to a flexible sufficiency standard seriously undercuts a trial court's ability to accomplish that goal.

I. THE GREEN AND SANDERS THESIS

At the outset, Green and Sanders acknowledge two major problems that lead courts to moderate what they call the "worst consequences" of civil trials in the United States: (1) "party control of experts;" and (2) "widespread use of jury decision makers."¹⁰ These two phenomena have led American judges to monitor the reliability of expert testimony in order to avoid "junk science" from influencing decisions.¹¹ Given the constitutional right to a jury trial, courts seeking to screen ill-founded expert testimony have resorted to blocking such testimony by challenging the admissibility of the expert testimony, thus, preempting the case from reaching the jury in the first place.¹² Green and Sanders find support for their view in pre-*Daubert* cases that found expert testimony inadmissible under Rule 703 in order to avoid the mandate of *Ferebee v. Chevron Chemical Co.*,¹³ that held that as long as "experts are willing to testify" about technically complex

⁹ See *id.* at 14-15 (outlining the standards for adequate expert testimony).

¹⁰ Green & Sanders, *supra* note 2, at 2 (citing Oscar G. Chase, *American "Exceptionalism" and Comparative Procedure*, 50 AM. J. COMP. L. 277, 288 (2002)); see also David E. Bernstein, *The Misbegotten Judicial Resistance to the Daubert Revolution*, 89 NOTRE DAME L. REV. 27, 31 (2013) [hereinafter Bernstein 2013]. Professor Bernstein identifies two problems. Bernstein 2013, *supra*, at 31. The first is allowing "junk science" to go to juries. *Id.* The second is "adversarial bias" that permits juries to consider expert testimony from handpicked experts who opine without substantial reliance on objective evidence supporting their opinions. *Id.*; see also David E. Bernstein, *Expert Witnesses, Adversarial Bias, and the (Partial) Failure of the Daubert Revolution*, 93 IOWA L. REV. 451, 452-56 (2008) (illustrating a more extensive discussion of the "adversarial bias").

¹¹ Green & Sanders, *supra* note 2, at 2-3; see also Bernstein 2013, *supra* note 10, at 31.

¹² Green & Sanders, *supra* note 2, at 4.

¹³ *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984).

matters at the frontiers of scientific knowledge, then the question of credibility of the experts is for the jury.¹⁴

The history preceding the decision of the Supreme Court of the United States in *Daubert* has been recited many times over and there is no need to repeat it here.¹⁵ The case raised the question of the admissibility of expert testimony that Bendectin, an anti-nausea drug taken by women in the first trimester of pregnancy, was a teratogen.¹⁶ In setting the standard for admissibility, the Supreme Court relied on Rule 702 of the Federal Rules of Evidence, which refers to experts with "scientific knowledge."¹⁷ The Supreme Court articulated four non-exclusive factors to determine whether expert testimony met the threshold of scientific knowledge: (1) "the known or potential rate of error;" (2) whether the hypothesis of the plaintiff's theory was subject to testing; (3) peer review and publication; and (4) whether the plaintiff's premise had received general acceptance in the scientific community.¹⁸ Green and Sanders make it clear that the thrust of their argument is not to abolish pretrial hearings that screen out unreliable expert testimony.¹⁹ Rather, they believe that some of the *Daubert* factors are unhelpful,²⁰ and what the courts have actually been doing post-*Daubert* is best explained by their utilizing a traditional sufficiency of the evidence test to determine admissibility.²¹

They argue that the post-*Daubert* decisions, *General Electric Co. v. Joiner*²² and *Kumho Tire Co. Ltd. v. Carmichael*,²³ indicate that the Supreme Court of the United States has moved away "from

¹⁴ *Id.* at 1534; Green & Sanders, *supra* note 2, at 9; *see also* Bernstein 2013, *supra* note 10, at 38.

¹⁵ *See* Green & Sanders, *supra* note 2, at 5; Bernstein 2013, *supra* note 10, at 31-41 (providing an excellent review of the history).

¹⁶ Green & Sanders, *supra* note 2, at 13-14; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 582-85 (1993).

¹⁷ Green & Sanders, *supra* note 2, at 14; *Daubert*, 509 U.S. at 588-90.

¹⁸ Green & Sanders, *supra* note 2, at 14; *Daubert*, 509 U.S. at 593-95.

¹⁹ Green & Sanders, *supra* note 2, at 15.

²⁰ *Id.* at 19.

²¹ *Id.* at 20-21.

²² *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997).

²³ *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

an emphasis on the *Daubert* factors."²⁴ Green and Sanders quote from the following language in *Joiner*:

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 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. That is what the District Court did here, and we hold that it did not abuse its discretion in so doing.²⁵

They conclude that in cases post-*Joiner* and *Kumho Tire*, "the 'Daubert factors' seem to play less and less of a role, and are supplanted by an increasing focus on fit and the existence of large analytical gaps in reasoning."²⁶ They review a number of cases that they claim support their conclusion that courts have been deciding the admissibility of cutting-edge technological expert testimony on the issue of causation based on sufficiency of the evidence.²⁷ Green and Sanders then focus on the litigation involving Parlodel, a drug taken after childbirth to prevent postpartum lactation in women who could not, or elected not, to breastfeed their offspring.²⁸ Some women who took Parlodel suffered strokes,²⁹ and in a host of cases, plaintiffs alleged that Parlodel was the cause

²⁴ Green & Sanders, *supra* note 2, at 21.

²⁵ *Id.* at 22 (citations omitted) (quoting *Joiner*, 522 U.S. at 146).

²⁶ *Id.* at 24.

²⁷ *Id.* at 26-34.

²⁸ *Id.* at 34.

²⁹ *Id.* at 34-35.

of their strokes and that the drug manufacturer was at fault for not warning them about this possible side effect.³⁰ A strong majority of courts found that the evidence on causation fell short of the demanding criteria set forth in *Daubert*.³¹ Plaintiffs' evidence was inadequate because it was based on: (1) idiosyncratic adverse reaction reports; (2) animal studies; (3) challenge/rechallenge studies that did not cause strokes when the drug was reintroduced into the body of patients; and (4) inconclusive epidemiological studies.³² A few courts found that the evidence passed the *Daubert* test and that the expert testimony supported admissibility.³³

Green and Sanders are not concerned with the inconsistent results in the Parlodel cases.³⁴ They note that the Restatement (Third) of Torts acknowledges "that the line between reasonable inference and prohibited speculation is one of the more indistinct lines that exists in [the] law."³⁵ Green and Sanders give as an example two New York cases.³⁶ In the first, *Wolf v. Kaufman*,³⁷ a woman fell down a flight of unlit stairs.³⁸ The defendant was found

³⁰ See Green & Sanders, *supra* note 2, at 35-36.

³¹ See, e.g., *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 441, 577 (W.D. Pa. 2003); *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 674 (M.D.N.C. 2003); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1053 (S.D. Ill. 2001); *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1373 (N.D. Ga. 2001), *aff'd sub nom. Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1203 (11th Cir. 2002); *Glastetter v. Novartis Pharms. Corp.*, 107 F. Supp. 2d 1015, 1044-45 (E.D. Mo. 2000), *aff'd*, 252 F.3d 986, 989 (8th Cir. 2001); *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 2d 1230, 1233-34 (W.D. Okla. 2000), *aff'd*, 289 F.3d 1193, 1217 (10th Cir. 2002).

³² *Soldo*, 244 F. Supp. 2d at 464, 466, 516, 533.

³³ See *Brasher v. Sandoz Pharms. Corp.*, 160 F. Supp. 2d 1291, 1299 (N.D. Ala. 2001) (denying motion for summary judgment on grounds that expert testimony was reliable under *Daubert*); *Eve v. Sandoz Pharms. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *97-98 (S.D. Ind. March 7, 2001) (denying motion for summary judgment on grounds that expert testimony was reliable); *Globetti v. Sandoz Pharms. Corp.*, 111 F. Supp. 2d 1174, 1180 (N.D. Ala. 2000) (denying motion for summary judgment on grounds that expert testimony was reliable).

³⁴ Green & Sanders, *supra* note 2, at 37.

³⁵ *Id.* (quoting RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 28 cmt. c (2010)).

³⁶ *Id.* at 37-38.

³⁷ *Wolf v. Kaufman*, 227 A.D. 281 (N.Y. App. Div. 1929).

³⁸ Green & Sanders, *supra* note 2, at 37-38; *Wolf*, 227 A.D. at 281.

negligent for not having repaired the lights.³⁹ Justice Finch then faced the question of whether the unlit stairs were the cause of the fall.⁴⁰ He held that "it would be solely a conjecture for a jury to draw the conclusion that the deceased fell down the stairs because of the absence of light."⁴¹ Years later, after Justice Finch had been elevated to the Court of Appeals of New York, he faced a similar causation issue in *Ingersoll v. Liberty Bank of Buffalo*.⁴² This time the issue "was whether the plaintiff's decedent fell down a flight of stairs due to a heart attack or dizziness" or whether she fell on a negligently maintained step, and Justice Finch held that the question was for the jury.⁴³ The authors say:

Whether the two cases are sufficiently different[] factually to justify a different outcome is not important. Rather we think that Parlodel is a modern incarnation of rulings that courts have long made about when the evidence introduced in support of an issue is sufficient for a jury to rule on that issue.⁴⁴

II. THE STANDARDS FOR ADMISSIBILITY AND SUMMARY JUDGMENT

The standard for summary judgment is straightforward.⁴⁵ When ruling on a motion for summary judgment, all reasonable inferences drawn from the evidence must be examined in the light most favorable to the non-moving party.⁴⁶ If there is any evidence

³⁹ Green & Sanders, *supra* note 2, at 38 (citing *Wolf*, 227 A.D. at 282).

⁴⁰ *Id.* (citing *Wolf*, 227 A.D. at 281).

⁴¹ *Id.* (quoting *Wolf*, 227 A.D. at 281).

⁴² *Id.* (citing *Ingersoll v. Liberty Bank of Buffalo*, 14 N.E.2d 828, 828 (N.Y. 1938)).

⁴³ *Id.* (citing *Ingersoll*, 14 N.E.2d at 828).

⁴⁴ *Id.*

⁴⁵ See generally FED. R. CIV. P. 56(a) (stating that a motion for summary judgment will be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law").

⁴⁶ See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor."); see also *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970) (noting that the moving party has "the burden of showing the absence of a genuine issue as to any material fact," and when determining if that

from which a reasonable inference can be drawn, the issue is for the jury.⁴⁷ This is the test for sufficiency of evidence that Green and Sanders would have the courts use to make a *Daubert* determination as to whether evidence is admissible on causation.⁴⁸

The problem with the Green and Sanders thesis is that they place the cart before the horse. It is only when we determine that something qualifies as "evidence" that we can raise the issue of its sufficiency.⁴⁹ The *Daubert* trilogy was intended to set a formidable standard for admissibility before one entered the thicket of evaluating whether it was sufficient to serve as grounds for recovery.⁵⁰ If one were to ask, taking the evidence of the expert in the light most favorable to the plaintiff in *Kumho Tire*, was the evidence sufficient to sustain a motion for summary judgment, the

burden is met, evidence "must be viewed in the light most favorable to the opposing party"); *Lake Nacimiento Ranch Co. v. Cnty. of San Luis Obispo*, 841 F.2d 872, 875 (9th Cir. 1987); *Amey, Inc. v. Gulf Abstract & Title, Inc.*, 758 F.2d 1486, 1502 (11th Cir. 1985).

⁴⁷ See *Anderson*, 477 U.S. at 249, 255.

⁴⁸ See Green & Sanders, *supra* note 2, at 21.

⁴⁹ FED R. CIV. P. 56(c)(1)(B) ("A party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." (emphasis added)). The Supreme Court of the United States stated:

We observed further that "[i]t is true that the issue of material fact required by Rule 56(c) to be present to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial."

Anderson, 477 U.S. at 248-49 (quoting *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 288-89 (1968)). "Inadmissible evidence contributes nothing to a 'legally sufficient evidentiary basis.'" *Weisgram v. Marley Co.*, 528 U.S. 440, 454 (2000) (citing *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)).

⁵⁰ See generally Bernstein 2013, *supra* note 10, at 28 (explaining that the *Daubert* trilogy of cases was caused by courts relying on scientific evidence that was unsound); William L. Anderson, et al., *The "Any Exposure" Theory Round II – Court Review of Minimal Exposure Expert Testimony in Asbestos and Toxic Tort Litigation Since 2008*, 22 KAN. J.L. & PUB. POL'Y 1, 17-23 (2012).

answer must be that it was not.⁵¹ The plaintiff's theory of why the tire exploded was reasonable, and taking that evidence in the light most favorable to plaintiff, the case should have gone to the jury.⁵² That it did not go to the jury was because the court said it did not meet the threshold test of reliability.⁵³ The Court of Appeals for the Eleventh Circuit in *Joiner* had not lost its senses when it relied on animal studies to prove that PCBs cause lung cancer.⁵⁴ If the question was whether any evidence viewed in the light most favorable to plaintiff supported liability, the answer was probably yes.⁵⁵ Once again, the question was whether evidence met the high threshold of reliability demanded by *Daubert*.⁵⁶

In short, one can draw reasonable inferences from unreliable evidence. The test for reliability must stand on its own bottom.⁵⁷

⁵¹ See generally *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 146 (1999) (describing the evidence presented).

⁵² See generally *id.* at 142-46 (explaining the deposition testimony of the plaintiff's expert and showing its reasonableness).

⁵³ *Id.* at 153. The court in *Kumho Tire* makes it explicitly clear that the kind of evidence proffered by the plaintiff's expert might be admissible under different circumstances, but without proof of its reliability, it could not reach the jury. *Id.* at 141, 147, 149, 153. The Court stated:

[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience. Nor does anyone deny that, as a general matter, tire abuse may often be identified by qualified experts through visual or tactile inspection of the tire. . . . As we said before . . . the question before the trial court was specific, not general. The trial court had to decide whether this particular expert had sufficient specialized knowledge to assist the jurors "in deciding the particular issues in the case."

Id. at 156.

⁵⁴ See *Joiner v. Gen. Electric Co.*, 78 F.3d 524, 532 (11th Cir. 1996) *rev'd*, 522 U.S. 136 (1997).

⁵⁵ Justice Stevens' concurrence/dissent in *Joiner* makes this point absolutely clear: "[U]sing 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." *Joiner*, 522 U.S. at 154 (Stevens, J., concurring in part and dissenting in part). That this inference was not enough to raise the expert's evidence to the level of admissibility shows that more than a summary judgment sufficiency standard is being asked for by the Supreme Court of the United States. See *id.* at 153.

⁵⁶ *Joiner*, 78 F.3d at 532.

⁵⁷ See *supra* note 52 and accompanying text.

Green and Sanders are correct that the *Daubert* criteria in and of itself may be of lesser importance as tests of reliability.⁵⁸ But, the message from the *Daubert* trilogy is unmistakable: a court must have a high degree of confidence in the integrity of scientific evidence before it qualifies for consideration in any formal test to be utilized in litigation.⁵⁹ The reason is not only that we mistrust juries or that experts are partisan.⁶⁰ For the most part, *Daubert* has been used as a screen in toxic tort cases.⁶¹ Once it is found that a given agent is a carcinogen or affects the autoimmune system of a human being, the implication is enormous.⁶² Hundreds, often thousands, of cases ride on the outcome, and billions of dollars may be at stake.⁶³ The sufficiency standard utilized to determine

⁵⁸ Green & Sanders, *supra* note 2, at 15; see also Anderson, et al., *supra* note 50, at 18. The Supreme Court has also made this point abundantly clear:

We agree with the Solicitor General that "[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." . . . The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.

Kumho Tire, 526 U.S. at 150.

⁵⁹ "[T]he court ultimately based its decision upon Carlson's failure to satisfy either *Daubert*'s factors or any other set of reasonable reliability criteria. In light of the record as developed by the parties, that conclusion was within the District Court's lawful discretion." *Kumho Tire*, 526 U.S. at 158 (emphasis in original). "To be sure, a trial court has a range of discretion to determine whether the testimony is in fact admissible, but the court does not have discretion in whether or not to conduct a rigorous, gatekeeping inquiry into the reliability of the expert testimony." Anderson, et al., *supra* note 50, at 21.

⁶⁰ Green & Sanders, *supra* note 2, at 3. "When confronted with a 'battle of the experts' with each side claiming that his scientific judgment either does or does not support a finding of causation, lay jurors have no means by which they can determine whose judgment is superior." Bernstein 2013, *supra* note 10, at 69.

⁶¹ Green & Sanders, *supra* note 2, at 6 (quoting *In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1260 (E.D.N.Y. 1985)).

⁶² See generally *id.* at 1 (noting that the inclusion or exclusion of expert testimony can have a "profound impact" on a case and civil litigation in general).

⁶³ See *id.* at 1, 7.

whether a plaintiff has produced adequate evidence to survive summary judgment is, and always will be, minimal.⁶⁴ The *Daubert* standard is anything but minimal.⁶⁵ The four criteria set forth by the Supreme Court of the United States were a signal that they expected courts to be demanding gatekeepers and that the era that preceded *Daubert*, where experts could opine to their heart's content, was over.⁶⁶ Thus, even if the four criteria in and of themselves are of lesser formal importance, the message that the court set by engaging formal criteria was that it was establishing a high threshold for admissibility.⁶⁷ The minimalist language conjured by the term "sufficiency of the evidence" to overcome a motion for summary judgment understates by the proverbial 'country mile' what the court expects from its gatekeeper judges.⁶⁸

⁶⁴ All reasonable inferences are drawn in the opposing party's favor both where the underlying facts are undisputed and when they are in controversy. *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 456 (1992). The non-movant's version of any disputed issue of fact is presumed correct. *Id.* at 468.

⁶⁵ See Anderson, et al., *supra* note 50, at 17-23 (discussing the *Daubert* standard).

⁶⁶ The Supreme Court of the United States stated:

The objective of [the gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). "[I]n 1993, the Supreme Court's decision in [*Daubert*] expressly rejected the let-it-all-in standard in favor of a new reliability standard." Bernstein 2013, *supra* note 10, at 41.

⁶⁷ As stated previously, if all reasonable inferences had been drawn in favor of the plaintiffs and if the non-movant's facts were presumed correct in *Joiner* and *Kumho Tire*, then the Supreme Court would not have heard those cases. See, e.g., *Joiner v. Gen. Electric Co.*, 78 F.3d 524, 532 (11th Cir. 1996). That the Supreme Court did not use the Rule 56 summary judgment standard in the *Daubert* trilogy and instead created a new standard is proof that they did not want courts to rely on the familiar sufficiency standard. See *supra* note 66 and accompanying text.

⁶⁸ See Green & Sanders, *supra* note 2, at 1, 11.

III. THE PARLODEL CONTROVERSY

Green and Sanders point to the conflicting opinions as to whether plaintiffs could survive *Daubert* motions as nothing more than the standard difficulty that courts have when deciding causation cases.⁶⁹ Is the evidence sufficient to allow a jury to draw a reasonable inference, or is it so weak, or the opposing evidence so lopsided, that to give the case to the jury would result in sheer speculation.⁷⁰ They are not troubled that some courts come down on one side of the issue and some on the other.⁷¹ The authors of this article are considerably troubled by the divergent opinions.⁷²

Parlodel was a drug marketed by Sandoz Pharmaceuticals Corporation to treat a broad range of diseases, such as Parkinson's Disease.⁷³ In 1981, the FDA approved Parlodel as a preventative of physiological lactation (PPL) for women who either could not or did not want to breastfeed.⁷⁴ Over the years, there were adverse case reports that women who took Parlodel suffered seizures, strokes, and cardiovascular problems.⁷⁵ Lawsuits ensued, alleging that Sandoz did not adequately warn about the dangers attendant to the use of Parlodel for women who were taking the drug to stop

⁶⁹ *Id.* at 39-40.

⁷⁰ *Id.* at 39.

⁷¹ *See id.*

⁷² Divergent opinions in toxic torts may have profound influence on manufacturing industries, and especially pharmaceuticals. *See generally id.* at 1 (noting the profound impact the *Daubert* standard has had since its creation). A finding of liability in one district, circuit, or state based on faulty evidence and a low admission standard would lead to forum-shopping, increased insurance rates for manufacturers, and higher prices, as well as limited availability of consumer goods. Anderson, et al., *supra* note 50, at 13-14. For example:

Court acceptance/rejection of the [any exposure] theory continues to dominate what kind of and how many asbestos cases can be filed in jurisdictions where these cases are common. Perhaps as important, the decisions result in even more blatant forum shopping than otherwise might occur, because plaintiffs seek out the jurisdictions that allow this testimony to support a low dose case.

Id. at 14.

⁷³ *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 442 (W.D. Pa. 2003).

⁷⁴ *Id.*

⁷⁵ *Id.* at 445.

lactation.⁷⁶ For the purposes of this article, we shall assume that plaintiffs could establish that the warnings provided to physicians were inadequate. The difficult question in these cases concerned whether there was adequate proof that Parlodel caused strokes and cardiovascular problems.⁷⁷ In a different forum, one of the authors of this article argued that even absent such proof plaintiffs should be awarded a modicum of damages for the mental distress suffered as a result of being exposed to a lifestyle drug (for which there were safer alternatives to accomplish the desired result).⁷⁸ However, plaintiffs in the Parlodel cases were not pursuing this more modest action.⁷⁹ They were seeking high awards on the theory that Parlodel caused their serious physical ailments.⁸⁰ The defendant in each case raised a vigorous *Daubert* defense, claiming that there was no scientific evidence that met *Daubert* standards to support a finding of causation and that the cases should be dismissed on summary judgment.⁸¹

*Soldo v. Sandoz Pharmaceuticals Corp.*⁸² sets forth the most comprehensive analysis of the various arguments that plaintiffs propounded in support of their position and why the court found them woefully inadequate in meeting *Daubert* standards.⁸³ Consider the following:

I. Plaintiff's doctor prescribed a fifteen day dose of 5 mg/day to be taken in two 2.5 mg doses per day.⁸⁴ Twenty-three days after discharge she suffered a hemorrhagic stroke (ICH).⁸⁵

⁷⁶ See *supra* notes 30-31 and accompanying text.

⁷⁷ See *Soldo*, 244 F. Supp. 2d at 472.

⁷⁸ See Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257, 285 (2005).

⁷⁹ See *Soldo*, 244 F. Supp. 2d at 441 (stating that the plaintiff brought a claim for products liability).

⁸⁰ *Id.* at 442.

⁸¹ *Id.* at 525.

⁸² *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003).

⁸³ *Id.* at 526-29.

⁸⁴ *Id.* at 446.

⁸⁵ *Id.* at 447.

II. Between 1980 and 1994, ten million women were estimated to have taken Parlodel for PPL.⁸⁶ During this period of time, thirty cases of strokes and nine cases of myocardial infarction (heart attacks) were reported for women who took Parlodel for PPL.⁸⁷

III. Bromocriptine is the active ingredient in Parlodel that prevents lactation by blocking "the secretion of the hormone Prolactin, which acts on the breasts to induce secretion of milk."⁸⁸

IV. It is undisputed that all postpartum women are subject to a significant increased risk of strokes regardless of whether they had taken Parlodel.⁸⁹ One epidemiological study found that "the risk of ICH during the postpartum period [was] 28.3 times higher than in similarly aged women who [were] not postpartum."⁹⁰

V. Another study found "that women taking bromocriptine were eight times less likely than women not taking bromocriptine to develop stroke in the postpartum period."⁹¹

VI. Not a single epidemiological study demonstrated a statistically significant increase in strokes in postpartum women who had taken Parlodel.⁹²

Faced with the lack of epidemiological evidence and with the admitted significantly higher incidence of idiopathic risks of strokes for postpartum women, plaintiffs argued that both animal studies and the chemical properties of bromocriptine supported the

⁸⁶ *Id.* at 444.

⁸⁷ *Id.*

⁸⁸ *Soldo*, 244 F. Supp. 2d at 445-46.

⁸⁹ *Id.* at 450.

⁹⁰ *Id.* at 456; see also Steven J. Kittner, et al., *Pregnancy and the Risk of Stroke*, 335 NEW ENG. J. MED. 768, 772 (Sept. 12, 1996).

⁹¹ *Soldo*, 244 F. Supp. 2d at 455.

⁹² *Id.* at 450.

conclusion that Parlodel was a vasoconstrictor and was thus capable of causing a stroke.⁹³

One study conducted on humans injected Parlodel into a hand vein and found that it caused vasoconstriction.⁹⁴ However, "[a] woman would have to [have taken] 5,000 Parlodel[®] 2.5 mg tablets in a single dose to place the same amount of bromocriptine in her bloodstream as was used in the 'hand vein study.'"⁹⁵ As to animal studies, plaintiffs relied on a "hind limb" study in which Parlodel was infused into the hind limb of dogs in three doses: "1 microgram/kilogram; 5 micrograms/kilogram; and 25 micrograms/kilogram."⁹⁶ Vasoconstriction was found to have taken place only at the highest dosage.⁹⁷ Further, "a woman taking standard 2.5 mg Parlodel[®] tablets would need to take 1,250 tablets at a time to place the same amount of Parlodel[®] in her bloodstream as was used in the 25 microgram/kilogram assay of the hind limb study."⁹⁸

Plaintiffs' expert also relied on a "62-week oral toxicity study in dogs" to support the conclusion that Parlodel caused strokes.⁹⁹ In this study, animals received bromocriptine for sixty-two weeks and developed ear necrosis, suggesting that the chemical caused vasoconstriction.¹⁰⁰ "In the dog study, animals received bromocriptine for 62 weeks," whereas women would take Parlodel for two or three weeks.¹⁰¹ In this study, dogs ingested Parlodel at roughly fourteen times the daily dosage prescribed to women taking Parlodel.¹⁰² "Viewed over the full length of the study," the dogs ingested more than 280 times the Parlodel taken by a woman for PPL.¹⁰³ A similar oral toxicity study done on rats resulted in ear necrosis.¹⁰⁴ However, here too, the daily dose given to the rats did

⁹³ *Id.* at 461-62, 466-72.

⁹⁴ *Id.* at 453.

⁹⁵ *Id.*

⁹⁶ *Id.* at 467.

⁹⁷ *Soldo*, 244 F. Supp. 2d at 467.

⁹⁸ *Id.* at 468.

⁹⁹ *Id.* at 469.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Soldo*, 244 F. Supp. 2d at 469.

¹⁰⁴ *Id.* at 470.

not demonstrate necrosis until they ingested 280 times the daily dose of a plaintiff taking Parlodel for PPL.¹⁰⁵ Neither the dogs nor the rats developed ICH at even the very high dosages.¹⁰⁶

In *Soldo*, the court appointed experts pursuant to Rule 706.¹⁰⁷ Two of the experts found that there was inadequate evidence to support a finding of general causation between Parlodel and ICH strokes.¹⁰⁸ One expert, relying primarily on differential diagnosis, was prepared to find general causation between Parlodel and ICH.¹⁰⁹ The court rejected the expert's opinion for two reasons. First, the error rate in using differential diagnosis is impermissibly high.¹¹⁰ Second, given the risk of idiopathic strokes in the general population and the especially high risk of strokes in postpartum women in particular, one cannot find general causation.¹¹¹

The Parlodel cases that found the evidence of causation admissible and thus, denied summary judgment, are extremely weak, and it is difficult to see how they passed *Daubert* scrutiny.¹¹² The evidence may have passed the minimalist test for summary judgment advocated by Green and Sanders, but does not come

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 469-70. In terms of general causation, these studies would only prove that Parlodel causes stroke under the "any exposure" theory. *Id.* at 473, 530-31; Anderson, et al., *supra* note 50, at 1-2. This "*post hoc ergo propter hoc*" theory postulates that because there is evidence of the disease, any exposure to a known cause of that disease proves a causal link. David E. Bernstein, *Keeping Junk Science out of Asbestos Litigation*, 31 PEPP. L. REV. 11, 20 (2003). The theory came into prominence during asbestos litigation. *Id.* at 12. In the asbestos cases, it was known that there was a link between asbestos and mesothelioma, but the amount of asbestos that would trigger mesothelioma beyond the background risk in a plaintiff was unknown. *Id.* Some courts reasoned that any exposure to asbestos was enough to find the defendant companies liable. See Anderson, et al., *supra* note 50, at 5. This line of reasoning has fallen out of favor with most courts, which have since found it unreliable under the *Daubert* standards. *Id.*

¹⁰⁷ *Soldo*, 244 F. Supp. 2d at 503.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 516-17.

¹¹¹ *Id.* at 517; see Kittner, et al., *supra* note 90, at 772.

¹¹² See generally *supra* notes 32-33 and accompanying text (describing the evidence and showing that a minority of courts found the evidence adequate).

close to meeting *Daubert* standards.¹¹³ Thus, in *Brasher v. Sandoz Pharmaceuticals, Corp.*,¹¹⁴ the court supports admissibility primarily on the basis of animal tests and differential diagnosis.¹¹⁵ As noted earlier, the animal tests were conducted with doses at huge multiples (ranging from 280 times to 5,000 times the dosage taken by humans).¹¹⁶ Putting to one side that drawing analogies from animals to humans requires a leap of faith, the disparity in dosage is so great that it is difficult to see how animal studies can be a factor in deciding causation.¹¹⁷ As to differential diagnosis, the unquestioned fact that postpartum women have a significantly higher rate of idiopathic strokes (unrelated to ingestion of Parlodel), one wonders how one can reach any conclusion with regard to causation.¹¹⁸ Adverse reaction reports are similarly suspect.¹¹⁹ There is no way to ascertain whether the adverse reactions were from the drug or from the substantially higher background risk of stroke for postpartum women.¹²⁰ The *Brasher*

¹¹³ If all the facts are drawn in the light most favorable to the plaintiff and any reasonable inference is allowed to reach the jury, a series of studies that show Parlodel causes vasoconstriction when given to dogs and rats in incredibly high doses would allow the inference. *See Soldo*, 244 F. Supp. 2d at 469-70. But, the question under the *Daubert* standard is whether this is the kind of inference a scientist, employing the same rigor in the courtroom as they would in their relevant field, would make. *Id.* at 504. The difficulties of analogizing animal studies to humans, as well as the extremely high doses at issue, would prevent a scientist from reaching this conclusion. *Id.* at 466. "To extrapolate from the conditions of a study to more general circumstances always raises questions." DAVID L. FAIGMAN, ET AL., *MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY, STATISTICS & RESEARCH METHODS* §§ 6:8, 6:12 (2012-13 ed.).

¹¹⁴ *Brasher v. Sandoz Pharm. Corp.*, 160 F. Supp. 2d 1291 (N.D. Ala. 2001).

¹¹⁵ *Id.* at 1296.

¹¹⁶ *See supra* notes 98-106 and accompanying text.

¹¹⁷ *See Soldo*, 244 F. Supp. 2d at 466.

¹¹⁸ *Id.* at 450; Kittner, et al., *supra* note 90, at 768.

¹¹⁹ *See Parlodel, Adverse Reactions from Postmarketing Experience*, DRUGS.COM (Oct. 2012), <http://www.drugs.com/pro/parlodel.html> ("Because adverse reactions from spontaneous reports are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.").

¹²⁰ *See Soldo*, 244 F. Supp. 2d at 508-09; *see also* Kittner, et al., *supra* note 90, at 772.

court relies on the ERI study, which found an 8.4 "increase in the likelihood of stroke in postpartum women [who had taken] Parlodel."¹²¹ The court neglects to reveal that the study was done on ten postpartum women who had strokes, only *one* of which occurred in a woman who had taken Parlodel.¹²² The court simply states that the study was not statistically valid.¹²³ It is more than not statistically valid – it is utterly worthless.¹²⁴

Very simply, these cases do not require reliance on the *ipse dixit* language of *Joiner*; they do not even meet the requirement that the "reasoning or methodology underlying the testimony is scientifically valid."¹²⁵ How did the *Brasher* court, and the others who found the weak expert testimony in the Parlodel cases admissible, go so wrong? Although it paid lip service to *Daubert*,¹²⁶ it, in reality, skipped *Daubert* and went directly to the

¹²¹ *Brasher v. Sandoz Pharm. Corp.*, 160 F. Supp. 2d 1291, 1294 (N.D. Ala. 2001).

¹²² *Soldo*, 244 F. Supp. 2d at 454.

¹²³ *Brasher*, 160 F. Supp. 2d at 1294.

¹²⁴ Some courts have reasoned that statistical insignificance, especially with epidemiological studies, is not a bar to admission, and have given even more leverage when the disease/harm at issue is incredibly rare. *See Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 24 (1st Cir. 2011). But an issue being at the frontier of scientific knowledge is not a reason to allow unreliable evidence, or unreliable conclusions drawn from that evidence, to reach the jury. Bernstein 2013, *supra* note 10, at 59. "Nothing in the *Daubert* trilogy or Rule 702 suggests that the plaintiff's burden is lessened simply because the issue is on the frontier of medical knowledge or because strong contrary evidence has not been presented by the defendant." *Id.*

¹²⁵ *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592-93 (1993). Reliability is the measure by which a study can be repeated – it refers to that study's consistency or reproducibility. DAVID L. FAIGMAN, ET AL., *supra* note 113, § 5:10. Validity is "the extent to which something measures what it purports to measure. A measure can have no more validity than it has reliability." *Id.* The faults described with the studies offered in the Parlodel cases undermine those studies' reliability and validity, leaving them inadmissible under the *Daubert* standards. *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1053 (S.D. Ill. 2001).

¹²⁶ *Brasher*, 160 F. Supp. 2d at 1294-99; *Globetti v. Sandoz Pharm. Corp.*, 111 F. Supp. 2d 1174, 1176-79 (N.D. Ala. 2000); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *97-98 (S.D. Ind. Mar. 7, 2001).

test for summary judgment.¹²⁷ Summary judgment does not demand, as *Daubert* does, that expert testimony meet "exacting standards of reliability."¹²⁸ The summary judgment standard is far less demanding and allows the weakest of inferences to suffice to defeat the motion.¹²⁹

At bottom, *Brasher* relies on what has become known as the "weight of the evidence" test, advocated by Justice Stevens in *Joiner*.¹³⁰ The court admits that none of the "bits of evidence" provided by plaintiff standing alone support a finding of causation, but that taken together they "present a compelling picture" of causation.¹³¹ Putting to one side whether reliance on the Stevens' dissent is appropriate, the difficulty with the court's conclusion is that the "bits" that the court relies on are inherently incredible.¹³² The statement that experts rely on "animal studies, case reports, and pharmacological comparisons of similar classes of drugs to infer conclusions"¹³³ is of little significance unless we are told that scientists would, for example, rely on animal studies with exposure of several hundred or several thousand times that which was administered to women taking Parlodel.¹³⁴ One cannot add together five times nothing and conclude that a meaningful integer has been attained.¹³⁵

¹²⁷ *Brasher*, 160 F. Supp. 2d at 1299; *Globetti*, 111 F. Supp. 2d at 1179; *Eve*, 2001 U.S. Dist. LEXIS 4531, at *97-98.

¹²⁸ *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000).

¹²⁹ *See supra* Part II.

¹³⁰ *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 153 (1997) (Stevens, J., concurring in part and dissenting in part). Professor Green has written persuasively in support of the "weight of the evidence" approach. *See* Michael D. Green, *Pessimism About Milward*, 3 WAKE FOREST J.L. & POL'Y 41, 41 (2013) (using this approach in his most recent argument).

¹³¹ *Brasher*, 160 F. Supp. 2d at 1296.

¹³² *See id.* (acknowledging that none of the evidence is conclusive).

¹³³ *Id.*

¹³⁴ *See supra* notes 87, 90, 93, and 96.

¹³⁵ Similarly, in *Milward v. Acuity Specialty Products*, much emphasis was placed on the fact that the Court of Appeals for the First Circuit endorsed the "weight of the evidence" approach, rather than the "atomistic" approach taken by the majority in *Joiner*. Bernstein 2013, *supra* note 10, at 29. The issue in *Milward* was whether exposure to benzene caused a specific form of leukemia (APL). *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 13 (1st Cir. 2011). The assertions made by plaintiff's expert, Dr. Smith, were as follows: (1)

IV. CONCLUSION

The Green and Sanders thesis that what courts are and should be doing is testing causation utilizing a sufficiency of the evidence test is, in our opinion, simply wrong. The test for summary judgment is not demanding. *Daubert*, *Joiner*, and *Khumo Tire* are very demanding. Whether the reason is adversarial bias or the desire to eliminate "junk science," the *Daubert* trilogy seeks a high level of belief in the integrity of scientific evidence.¹³⁶ The comparison that Green and Sanders draw from run of the mill tort cases, where courts differ as to whether one can draw an inference of causation from cases very similar on their facts, is not

that benzene affects an undifferentiated stem-cell in the blood, rather than a differentiated cell with stem-cell-like self-replicating abilities; (2) that because benzene has been proven to cause some types of chromosomal damage, it is plausible that it causes the specific kind of chromosomal damage in evidence in the APL type of leukemia; (3) that because benzene has been shown to disrupt a particular enzyme (one that facilitates the replication of DNA without damage), and disruption of that enzyme has been proven to cause other types of leukemia, it is plausible that this same enzymatic disruption plays a role in the creation of APL leukemia; and finally (4) statistically insignificant epidemiological evidence showing a causal relationship between benzene and APL leukemia. *Id.* at 19-20. We have considerable difficulty with the Court of Appeals for the First Circuit's opinion. First, the most that Dr. Smith was able to conclude with each piece of evidence was that it was "plausible" that benzene was related to APL leukemia. *Id.* at 21-26. In countering evidence on the defense side, Dr. Smith did little to undercut his opinion that the relationship between benzene and APL was merely plausible. *Id.* What one comes away with from a careful reading of Dr. Smith's opinion is that he has nothing more than a guess. Whatever the *Daubert* trilogy stands for, it clearly does not endorse liability built on a guess. Second, there is nothing in Dr. Smith's opinion which demonstrates how he analyzed and combined the studies or that he engaged in a process that would pass muster under *Daubert* reliability standards. See Bernstein 2013, *supra* note 10, at 57 & n.175. Failure to do so gives an expert the freedom to engage in the kind of *ipse dixit* conclusions prohibited by *Joiner*. How one puts together a set of 'might be' pieces of evidence requires an explanation as to whether reliable scientific methods were utilized to reach his conclusion. The fact that Dr. Smith's opinion was the best that he could do with the underdeveloped state of the evidence is precisely the kind of opinion that the *Daubert* trilogy was designed to preclude. This is not merely negating weak evidence. It allows courts to consider evidence that on its own bottom says nothing more than 'maybe.'

¹³⁶ Bernstein 2013, *supra* note 10, at 31.

apposite.¹³⁷ First, those cases do not instantiate the *Daubert* criteria and do not bring to bear the concerns that are peculiar to illegitimate use of speculative science. Second, run of the mill tort cases have limited precedential value. Admittedly, a grant of directed verdict may be used as authority in other cases, but tort cases are too fact sensitive to influence results in other cases. The methodology for inferring causation in toxic tort cases has enormous precedential value. Not only will a faulty causation inference influence cases dealing with the identical drug or toxic agent, but the loosening of the standards of admissibility along the lines that Green and Sanders suggest will have enormous significance in other toxic tort cases. The issue is not whether a particular case falls on one side of the line or the other. Reasonable persons can differ even using reliable scientific evidence as to whether general or specific causation has been established. But the rigor of reliability set forth by the *Daubert* trilogy and the redrafting of the Federal Rules of Evidence should not be compromised. Unfortunately, the Green and Sanders proposal does just that.

¹³⁷ Green & Sanders, *supra* note 2, at 39-40.

