

COMMENTS OF MARY A. WELLS, IN SUPPORT OF
MOTION BY HILDY BOWBEER TO AMEND
RESTATEMENT OF TORTS:
LIABILITY FOR PHYSICAL HARM
Sec. 28, cmt c
(Proposed Final Draft No. 1, April 6, 2005)

May 13, 2005

The proposed Comment *c* to section 28 of the RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM (Basic Principles) (Tentative Draft) (April 2005 vers.) is not a focused commentary on the burden of proof or causation; it is an unnecessary and inaccurate discussion of evidence, toxicology, and epidemiology. It takes swipes at the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹ and the Supreme Court of Texas' decision² in *Merrell Dow Pharmaceuticals, Inc. v. Havner*.³ Furthermore, it collapses the standards for evidentiary sufficiency and admissibility into a single analysis and misinterprets the import of evidence addressing general causation, *i.e.*, whether exposure to a substance is capable of causing disease in humans. This approach confuses important concepts and muddles the law of causation in tort cases. Proposed Comment *c* is unnecessary to understanding the intent of section 28.

I. Admissibility and Sufficiency.

In toxic tort cases, the issue of factual causation necessarily requires litigants to focus, first, on determining what evidence is admissible to demonstrate or refute factual causation and, second, on whether the evidence is sufficient to meet a party's burden of proof. Evidence that is inadmissible because it is unreliable or does not "fit" the facts of the case is, *ipso facto*, insufficient to meet the burden of proof. That does not mean, however, that evidence that is found to be reliable and relevant by the trial court necessarily is sufficient to satisfy a plaintiff's burden of proof under section 28(a) or the defendant's burdens of proof under circumstances in which section 28(b) applies.

The questions of evidentiary admissibility and sufficiency "necessitate different inquiries and involve different stakes."⁴ An admissibility determination entails a threshold inquiry whether certain evidence ought to be admitted, while a sufficiency inquiry asks whether the collective weight of a litigant's evidence is adequate to present a jury question.⁵

The closest that *Daubert*'s admissibility analysis ever comes to the ultimate issue of sufficiency is when the trial court is considering the issue of "fit" between the proffered evidence and the issues of a given case.⁶ As part of the fit inquiry mandated by *Daubert*, the trial court "must ensure that the proposed

¹ 509 U.S. 579 (1993).

² The proposed Comment states: ". . . A few celebrated cases and case congregations, such as the Agent Orange and Bendectin litigations, led some courts to distrust juries' ability to resolve cases based on conflicting general expert-opinion evidence . . ." RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment c., at 483-84 (Proposed Final Draft No. 1, Apr. 6, 2005). This issue is discussed in greater detail *infra* at p. 3.

³ 953 S.W.2d 706, 717 (Tex. 1997), *cert. denied*, 523 U.S. 1119 (1998).

⁴ *In re Joint Eastern & Southern Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995).

⁵ *Id.*

⁶ *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 591 (1993).

expert testimony is ‘relevant to the task at hand,’ . . . *i.e.*, that it logically advances a material aspect of the proposing party’s case.”⁷ In evaluating the fit aspect of the *Daubert* analysis, the court must look to the nature of the claims and the evidence necessary to make a *prima facie* case.⁸ Evidence that does not aid a litigant in sustaining the burden of proof likewise will not “assist the trier of fact to understand the evidence or to determine a fact in issue.”⁹ This means that if expert evidence cannot support a litigant’s burden of proof, it is inadmissible under Rule 702.

Proposed Comment *c* errs in assuming that if expert testimony on causation is found admissible (by satisfying the “fit” standard as well as the relevancy standard), that testimony is necessarily *sufficient* to satisfy the burden of proof. In particular, proposed Comment *c* states that:

[A]dmissibility cannot be determined without reference to the substantive law. Moreover, courts may be required to examine scientific evidence when it is offered to prove agent-disease causation. That examination may occur either in the admissibility determination or in the determination whether the evidence is sufficient to meet the burden of production. These usually are separate issues and are subject to different legal standards. Courts, however, sometimes conflate these issues in the process of determining whether there is an adequate basis for an expert’s opinion. *When courts collapse the sufficiency determination into the question of the admissibility of an expert’s testimony no subsequent inquiry into sufficiency is necessary, and the appropriate weight to give to an expert’s opinion once it is deemed admissible is for the factfinder.*¹⁰

This assumption is unsupportable. Indeed, *Daubert*, itself, specifically recognizes that expert testimony on causation may be found admissible by the trial court and yet be insufficient to support a verdict:

[I]n 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. *Cf., e.g., Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (CA6) (holding that scientific evidence that provided foundation for expert testimony, viewed in the light most favorable to plaintiffs, was not sufficient to allow a jury to find it more probable than not that defendant caused plaintiff’s injury), *cert. denied*, 506 U.S. 826 (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (CA5 1989) (reversing judgment entered on jury verdict for plaintiffs because evidence regarding causation was insufficient), modified, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046 (1990) . . . These conventional

⁷ *Daubert v. Merrell Dow Pharms, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995).

⁸ *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1223 (D. Colo. 1998), *approved by Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005).

⁹ FED. R. EVID. 702

¹⁰ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment c. at 485 (Proposed Final Draft No. 1, Apr. 6, 2005) (emphasis added).

devices . . . are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.¹¹

In disregard of *Daubert*, the inescapable implication of Comment *c* is that case-law standards for evaluating the *admissibility* of causation evidence are interchangeable with the standards for evaluating the *sufficiency* of that evidence.

II. Plaintiff-Oriented Bias.

Section 28 relates to the relevant burdens of proof to establish causation in tort cases generally. Little in Comment *c*, after the introductory paragraphs, aids in that analysis. Instead, Comment *c* appears to be a freewheeling discussion of various concepts at issue in toxic-tort litigation, without regard to their bearing on the burden-of-proof issues that are the subject of section 28. Some early criticisms of Comment *c* by both the plaintiffs' and defense bar asserted that the Comment was biased in favor of the other. The current draft of the comment, frankly, does little to rebut either sides' criticisms, offering ready-to-cite briefing fodder for a wide array of litigation perspectives, but offering no practical assistance in understanding or applying section 28.

While bowing to both sides of the toxic-tort bar, Comment *c* appears, in my view, to sway visibly in favor of the plaintiffs' bar. For example, in the unnecessary discussion of the development of standards governing the admissibility of scientific expert testimony, the Comment states that:

. . . . A few celebrated cases and case congregations, such as the Agent Orange and Bendectin litigations, led some courts to distrust juries' ability to resolve cases based on conflicting general expert-opinion evidence. Courts began to scrutinize the scientific evidence employed and to examine carefully the bases for an expert's opinion on factual causation. Some courts then tried to develop bright-line rules based on science for adequate proof of factual causation. *The high water mark for this overreliance on scientific thresholds occurred in the Bendectin litigation when one court announced a blanket rule that a plaintiff could not make out a sufficient case without statistically significant epidemiologic evidence.*¹²

Without citing any particular case, the Comment appears to refer first to the United States Supreme Court's opinion in *Daubert* and then to the Texas Supreme Court's oft-cited opinion in *Merrell Dow Pharmaceuticals, Inc. v. Havner*. That case held that when plaintiffs intended to establish general causation through population-based studies, such evidence would support an inference of general causation only if the studies revealed a relative risk of greater than 2.0 (indicating that the risk of disease to the exposed population was more than double that of the unexposed or background population).¹³ What the Comment does not mention, however, is that *Havner* is a leading case on the standard for determining the sufficiency of scientific evidence in toxic-tort cases and that it remains the governing standard for Texas courts. The Comment also neglects to note that virtually every other court to address

¹¹ *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 596 (1993).

¹² RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment c., at 483, 484 (Proposed Final Draft No. 1, Apr. 6, 2005) (emphasis added).

¹³ *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 717 (Tex. 1997), *cert. denied*, 523 U.S. 1119 (1998).

the Bendectin litigation under some variant of the *Daubert* standard or even under the *Frye* test has excluded the plaintiffs' expert testimony, in part because the proffered testimony failed to support a *prima facie* case of causation. Indeed, that was the holding of the *Daubert* case, itself, on remand to the Ninth Circuit Court of Appeals from the Supreme Court.¹⁴ It is now generally accepted that, regardless of the outcome of a trial court's pretrial gatekeeping, trial and appellate courts have a duty to evaluate the legal sufficiency of the plaintiffs' evidence to determine whether it can sustain a jury's verdict as a matter of law.¹⁵ Yet the Comment casts these cases as aberrations in the law.

Another place where Comment *c* takes well-accepted principles and reframes them as novelties is its treatment of the concepts of "exposure," "general causation," and "specific causation," where the Comment downplays these concepts as mere "functional devices to organize a court's analysis, not as formal elements of the cause of action."¹⁶ While the Comment would have one believe that "general causation" and "specific causation" are terms of convenience, courts do not apply them that way. The Tenth Circuit Court of Appeals recently affirmed a summary-judgment ruling in a silicone gel breast implant case, observing that:

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.¹⁷

That determination effectively ended the breast implant litigation in Colorado, in much the same way that litigation had ended in many other jurisdictions. Courts have not viewed the failure to prove general causation as a failure to comply with some technical standard designed to aid the court's analysis, but as a substantive failure of proof.

The Comment also incorrectly suggests that the question of general causation can be dispensed with in any case involving traumatic-injury "because other causes that might explain the injury are absent,

¹⁴ *Daubert v. Merrell Dow Pharms, Inc.*, 43 F.3d 1311, 1322 (9th Cir. 1995) ("Plaintiffs do not quantify this possibility, or otherwise indicate how their conclusions about causation should be weighted, even though the substantive legal standard has always required proof of causation by a preponderance of the evidence. [FN19] Unlike these experts' explanation of their methodology, this is not a shortcoming that could be corrected on remand; plaintiffs' experts could augment their affidavits with independent proof that their methods were sound, but to augment the substantive testimony as to causation would require the experts to change their conclusions altogether."), *cert. denied*, 516 U.S. 869 (1995).

¹⁵ *See 3M Co. v. Johnson*, 895 So.2d 151, 165-66 (Miss. 2005) (reversing jury verdict in favor of multiple plaintiffs based on determination that testimony from expert witnesses whose testimony was admitted over *Frye* challenges did not establish product-defect or causation, thus requiring reversal); *see also Weisgram v. Marley*, 528 U.S. 440 (2000) (when plaintiff's expert testimony is erroneously admitted, and without that testimony the plaintiff cannot make a *prima facie* case, judgment should be entered in favor of the other party).

¹⁶ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment c., at 486 (Proposed Final Draft No. 1, Apr. 6, 2005).

¹⁷ *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005); *see also 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. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 875 (W.D. Tex. 1997); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1412-13 (D. Or. 1996).

and we have reasonably good understanding of the causal mechanisms involved from trauma to injury.”¹⁸ That statement *may* be true for some types of traumatic injuries, but cannot be stated with the sweeping assurance contained in proposed Comment *c*. For example, cases involving the claimed onset of fibromyalgia following a physical trauma have been held to require proof of general causation before a plaintiff can be allowed to claim that his or her disease was actually caused by a particular trauma.¹⁹

A final note on the question of perceived bias, none of the Illustrations following the text of Comment *c* address situations where a plaintiff’s proof is insufficient or where the defendant prevails. This one-sidedness, when coupled with the other statements discussed above, gives Comment *c*, the unfortunate appearance of partisan advocacy rather than of a neutral restatement of the governing legal standards.

III. Epidemiology and General and Specific Causation.

Many courts recognize epidemiology as “the best evidence of general causation in a toxic tort case.”²⁰ Hence, the Comment’s treatment of epidemiological evidence deserves special comment. First, as noted above, the discussion of epidemiology is entirely unnecessary to aid in understanding section 28, and for that reason alone should be abandoned. There is simply not enough space in the Comment to do justice to the complex scientific and medical issues involved in evaluating epidemiological evidence.²¹ Other texts do a fine, and far more complete, job of explaining epidemiology in sufficient detail to aid lay judges and lawyers in understanding these issues.²²

Proposed Comment *c* is wrong about the use of “synthesized” analyses of multiple epidemiological studies, asserting that, “[w]hen multiple studies exist, they are synthesized, either qualitatively or quantitatively with a method known as meta-analysis.”²³ While this can be done, the Comment presents the misleading impression that syntheses and meta-analyses are generally accepted procedures that are always done when multiple studies exist which address the same subject. Not so. In fact, the manipulation of epidemiologic data through “reanalysis” methodologies was the precise analytical problem being addressed in *Daubert*.²⁴ Ultimately, the epidemiological “reanalysis” at issue in

¹⁸ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment *c*., at 488 (Proposed Final Draft No. 1, Apr. 6, 2005).

¹⁹ See *Black v. Food Lion, Inc.*, 171 F.3d 308, 313-14 (5th Cir. 1999) (applying a general-causation analysis, though without specific reference to the term “general causation”).

²⁰ *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (citing *In re Breast Implant Litig.*, 11 F.Supp.2d 1217, 1224 (D.Colo.1998); *Linda A. Bailey, et al., Reference Guide on Epidemiology*, in 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)).

²¹ See Molly Treadway, *An Investigation of Juror Comprehension of Statistical Proof of Causation* (1990) (unpublished Ph.D. Dissertation, Johns Hopkins University) (discussing the difficulties encountered in presenting highly technical epidemiological evidence to lay jurors).

²² See Bert Black, James A. Jacobson, Edward W. Madeira, Jr. & Andrew See, *Guide to Epidemiology*, in EXPERT EVIDENCE: LAW, SCIENCE, AND THE FJC MANUAL 73 (Bert Black and Patrick W. Lee eds., 1997); see also Michael D. Green, D. Michael Freedman & Leon Gordis, *Reference Guide to Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333 (Fed. Judicial Center, ed., 2d ed. 2000).

²³ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment *c*., at 488 (Proposed Final Draft No. 1, Apr. 6, 2005).

²⁴ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 579 (1993) (discussing the methodology of using an unpublished “reanalysis” of previously published human statistical studies).

Daubert was held inadmissible.²⁵ Efforts to employ qualitative “syntheses” of epidemiological studies are also not without controversy when the researcher attempts to extrapolate broad conclusions from widely differing studies. That is what happened in *General Electric Co. v. Joiner*, where the Supreme Court rejected the plaintiffs’ expert’s reliance on four very different epidemiological studies because the expert sought to extrapolate from those studies certain conclusions that were unsupported by each of the studies themselves. The Supreme Court held that: “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.”²⁶ The lesson from these cases is that “synthesized” analyses, meta-analyses, or reanalyses of epidemiological studies may be fraught with methodological problems that detract from their reliability and prevent them from constituting legally sufficient evidence to support a plaintiff’s burden of proof.²⁷ The Comment, however, fails to mention these problems.

An even more serious factual error is found in the Comment’s assertion that epidemiological evidence can be used to show “specific causation,” as opposed to general causation:

[C]ourts generally hold when there is group-based evidence finding that exposure to an agent causes an incidence of disease in the exposed group that is more than twice the incidence in the unexposed group, *the evidence is sufficient to satisfy the burden of production and permit submission of specific causation to a jury*. In such a case, the factfinder may find that it is more likely than not that the substance caused the particular plaintiff’s disease. The propriety of this “doubling” reasoning depends on group studies identifying a genuine causal relationship and a reasonably reliable measure of the increased risk. Courts appropriately have permitted expert witnesses to testify to specific causation based on the logic of the effect of a doubling of the risk and other considerations explained below that modify the probability of causation for a particular individual.²⁸

This reference to the use of epidemiological evidence to establish “specific causation” is patently incorrect. The issue of “doubling of risk” refers to epidemiological concepts whereby probabilistic population-based studies evaluate the potential increased risk posed by exposure to a particular substance and the development of a particular medical condition. This is a question of *general causation*, not “specific causation” as the Comment suggests. 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

²⁵ See *Daubert v. Merrell Dow Pharms, Inc.*, 43 F.3d 1311, 1320 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995).

²⁶ *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (citing *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992), *cert. denied*, 506 U.S. 826 (1992)).

²⁷ See Michael D. Green, D. Michael Freeman & Leon Gordis, *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 380 (Fed. Judicial Center ed., 2d ed. 2000) (noting multiple problems that arise in performing meta-analyses, such as whether unpublished studies should be considered, how can the problems of differences in study quality be addressed, whether the results are capable of being reproduced, why different meta-analyses may contradict each other, and what differences in individual study outcomes may be obscured by the meta-analyses).

²⁸ RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 28, Comment c., at 491-92 (Proposed Final Draft No. 1, Apr. 6, 2005) (emphasis added).

substance caused a particular individual's injury.²⁹ *In re Hanford Nuclear Reservation Litigation*,³⁰ the lead case cited in the Reporters Notes to Comment *c* for the proposition quoted above, did not apply the doubling-of-risk analysis to the question of specific causation, as a recent District Court case explained:

Hanford[‘s] . . . rejection of the doubling of the risk standard was in the context of the court’s discussion of general causation – whether ionizing radiation is capable of causing the plaintiffs’ injuries. In *Hanford*, the 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, and the Ninth Circuit held that evidence sufficient for general causation. *Id.* at 1137. It did not discuss the sufficiency of evidence to establish specific causation.³¹

Indeed, “an agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general.”³² This distinction between general and specific causation is one of the most well settled principles in toxic-tort causation law. The fact that proposed Comment *c* contains such a significant error on such a basic point seriously undermines its credibility as an analytical tool and jeopardizes the effectiveness of the new Restatement.

IV. Conclusion.

Page-and-line correction of these errors is certainly possible. But it is preferable to simply eliminate Comment *c*, but for the first paragraph. Comment *c* bears no relation to the issues discussed in the text of section 28, and adds nothing to the reader’s understanding of that section. There is simply no reason to have this lengthy discussion of evidentiary admissibility standards interwoven into a Restatement section concerning the burden of proof. If this body of material has any place in the Restatement, it should reside in the Reporter’s Notes, where the risk of confusing and misleading the reader is far less likely. The Comments to the Restatement sections should be reserved for helpful guidelines in understanding and applying the Restatement sections, not as a repository of factually misleading legal arguments. For this reason, it is my recommendation and hope that Comment *c* be reconsidered and, ultimately, removed from the body of commentary following Restatement section 28.

²⁹ *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005); See Michael D. Green, D. Michael Freeman & Leon Gordis, *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 374-79 (Fed. Judicial Center ed., 2d ed. 2000) (containing a detailed discussion of general causation).

³⁰ 292 F.3d 1124, 1137 (9th Cir. 2002).

³¹ *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, --- (W.D. Tex. 2005).

³² Michael D. Green, D. Michael Freeman & Leon Gordis, *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 374-79 (Fed. Judicial Center ed., 2d ed. 2000) (quoting Philip Cole, *Causality in Epidemiology, Health Policy, and Law*, [1997] 27 ENVTL. L. REP. (Envtl. L. Inst.) 10284 (June 1997)).