

Comment C on Toxic Torts in the Restatement Third

By Eric E. Hudson



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"Comment c on toxic substances and disease is arguably the single most controversial passage in the project."¹

The Restatement (Third) of Torts is the first Restatement to include a comment directly addressing the law of causation applicable to toxic torts—comment c of section 28: Liability for Physical and Emotional Harms. Chemicals, drugs, nano-particles, and other compounds can fall into the toxic tort category, and practitioners in these fields will soon be addressing the implications of comment c. This “controversial” comment endeavors to summarize decades of precedent in a complicated and often challenging area of the law. The members and reporters of the American Law Institute should be commended, because the comment attempts to distill a wide array of issues into a manageable discussion. In applying comment c, however, practitioners and courts will have to exercise caution. Just as the “dose makes the poison,” the existing body of scientific knowledge applicable to particular agents must be carefully applied in assessing issues of causation. The body of scientific evidence for particular compounds is almost always different and unique; hence, the analysis is always in some respects different and unique. Nonetheless, comment c provides a thoughtful, initial framework for addressing issues of causation in toxic tort cases.

Overview of Comment C

Section 28 of the Restatement Third provides

Burden of Proof

- (a) Subject to Subsection (b), the plaintiff has the burden to prove

that the defendant’s tortious conduct was a factual cause of the plaintiff’s harm.

- (b) When the plaintiff sues all of multiple actors and proves that each engaged in tortious conduct that exposed the plaintiff to a risk of harm and that the tortious conduct of one or more of them caused the plaintiff’s harm but the plaintiff cannot reasonably be expected to prove which actors or actors caused the harm, the burden of proof, including both production and persuasion, on factual causation is shifted to the defendants.

Comment c is entitled “Toxic substances and disease.” There is no analogy to comment c in the Restatement (Second), and the 11 pages of text devoted to the comment in the Restatement Third and almost 30 pages devoted to the Reporters’ Notes will likely be the subject of intense scrutiny by courts addressing toxic tort claims in the near future. If the only message imparted to practitioners who address causation in cases involving toxic substances is that “this section is new, significant, and probably applicable to my practice, so I should obtain and read it,” then it will have served at least part of its purpose. What follows is an overview of comment c and some preliminary thoughts on how practitioners and courts are going to wrestle with its application.

In general, comment c reflects a significant and thoughtful effort to distill over three decades of toxic tort decisions into some general principles appropriate for a Restatement. The problem that practitioners—particularly defense practitioners—may face, however, is that attorneys are likely to pick and choose from portions of the comment to support arguments related both to causation and expert opinions

that often form the core of toxic tort cases. For example, attorneys seeking to counter a low relative risk or weak epidemiological evidence for causation may invoke the following language from comment c in an effort to defeat summary judgment: “Whether an inference of causation based on an association is appropriate is a matter of informed judgment, not scientific methodology. . . . No algorithm exists for applying the Hill guidelines to determine whether an association truly reflects a causal relationship or is spurious.”² Frankly, there are a number of literary “nuggets” from which counsel may pick and choose in connection with summary judgment motions, motions in limine, and even *Daubert* challenges. In responding to such efforts, opposing counsel must take the broader view and apply comment c as a whole—which is presumably what the drafters intended.

Comment c suggests that causation may be a difficult question in certain toxic tort cases and that there is often no hard-and-fast rule regarding the application of relative risk, epidemiological studies, or the Hill criteria in determining whether a case should survive summary judgment. But what the comment clearly does not say is that, because of the nuances of science and the informed judgment that must be applied in determining whether there is sufficient evidence of causation, any toxic tort case where evidence of an association is presented should go to a jury. Rather, the comment reiterates that, despite the special problems courts must confront in addressing toxic tort cases, “the plaintiff must [still prove causation] by a preponderance of the evidence, and the standards set forth for factual causation set forth in §§ 26–27 [of the Restatement Third] continue to apply.”³

Toxic Tort Causation

In the introductory section of comment c, the authors conclude that science does

not necessarily present an objective method of establishing answers to questions about factual causation in toxic tort cases. Rather, the comment states, “scientific standards for the sufficiency of evidence to establish a proposition may be inappropriate for the law, which itself must decide the minimum amount of evidence permitting a reasonable (and, therefore, permissible inference), as opposed to speculation that is not permitted.” The comment indicates that scientific principles about causation require judgment and interpretation that may not lend themselves to hard-and-fast legal principles regarding causation in litigation.

The comment explicitly recognizes that proof of causation often involves the admissibility of expert opinions, and this perceived intermingling of tort principles and evidentiary issues has generated at least some degree of controversy.⁴ Comment c attempts to negate the perception of intermingling substantive law with evidentiary issues in the Restatement:

Admissibility is governed by the law of evidence, and nothing in this Comment addresses that law. However, admissibility 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. This examination may occur either in the admissibility determination or in the determination whether 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. The requirements of causation, the elements of agent-disease causation that are sometimes required when group studies are employed as proof, and the sufficiency of the evidence to meet the burden of production on causation are matters of substantive tort law, and they are addressed in the Restatement.⁵

Is the comment not stating that issues of expert admissibility and causation in toxic tort cases are often inextricably intertwined? The Reporters’ Notes to comment c shed some light on this question:

Comment c recognizes that differential diagnosis is generally appropriate only when all the potential causes of a disease are unknown.

Expert-witness testimony is employed to prove agent-disease causation, and the admissibility of an expert’s opinion may be determinative as to whether the plaintiff satisfies the burden of production on agent-disease causation. Yet the emphasis on greater scrutiny of expert-witness testimony has been with regard to the basis of the expert’s opinion . . . thereby resulting in an examination of the scientific evidence that exists to support the expert’s opinion. Courts frequently assess the state of the scientific record, and only when it meets a sufficiency threshold is an expert witness permitted to testify about the evidence of agent-disease causation.⁶

Taken together, comment c and the Reporters’ Notes support the proposition that there is an independent inquiry necessary for a plaintiff to satisfy the causation requirement under part (a) of Section 28 of the Restatement Third (stating that the plaintiff has the burden to prove that the defendant’s tortious conduct was a factual cause of the plaintiff’s harm). That inquiry, which under the Restatement Third is one of substantive law rather than an evidentiary issue, requires courts to undertake an examination of the relevant science

to determine whether, based on that science, there is sufficient “room” for an expert to form the opinion that science supports an inference of causation. As recognized in the comment, courts often merge these issues, but the emphasis on the fact that there is a substantive—rather than evidentiary—aspect to the causation question is important. It is a reminder that causation in toxic tort cases can, in many cases, be addressed separately from a *Daubert* analysis.

General Causation under Comment C

This discussion in comment c then logically leads to the question of how causation is addressed in toxic tort cases. Toxic tort practitioners often speak in terms of general and specific causation—i.e., whether the substance at issue can cause a disease (general causation) and whether that substance caused the plaintiff’s condition (specific causation). Comment C concludes that general and specific causation are devices to organize a court’s analysis but that they are not formal elements of a cause of action.

In discussing general causation, comment c focuses primarily on group-based evidence typically addressed by epidemiological studies. The comment does not attempt to set forth any bright-line rules for the application of epidemiological evidence; instead, it discusses the numerous factors that can affect the question of whether epidemiology studies support a conclusion of general causation. Bias, confounding factors, sampling errors, and incorrect study design are each recognized as factors that affect the analysis in attempting to use an association identified in epidemiological studies to support a finding of causation. Interpretation of these factors requires “informed judgment,” but the Reporters’ Notes—again recognizing the intermingling of causation questions with expert proof—point out that such “informed judgment” is not typically employed by contending experts. Rather, “contending adversarial experts, because of the pressures of the adversarial system, rarely explore this uncertainty and provide the best, objective assessment of the scientific evidence.”⁷

To counter the adversarial nature of expert proof on issues of causation, the Reporters' Notes emphasize the fact that an increasing number of federal courts have employed court-appointed experts to assist in the preliminary general causation question. While such a trend may be present in the federal courts, in the world of increasing state deficits, unpaid furloughs, and mandated four-day work weeks, it seems unlikely that most courts have the resources to rely on court-appointed experts. In those instances, the onus will be on counsel to educate the court and emphasize the need for judgment to be employed by the court on general causation issues before experts are permitted to make a case to the jury.

With respect to general causation, it is also worth recognizing that the Reporters' Notes identify at least two examples that are not sufficient to support inferences of general causation. First, case reports are generally insufficient by themselves to support proof of general causation. This recognition may be particularly important in post-market adverse event reporting for prescription pharmaceuticals, where individual incidents are often used in an effort to support a general inference of causation. Second, the Reporters' Notes point out that the "vast majority of toxic agents cause a single disease or a series of biologically related diseases," and, as a result, scientific studies supporting causation for diseases other than the one from which a plaintiff suffers are not admissible to prove causation.⁸

Specific Causation

Comment c begins the discussion of specific causation by noting that the question of specific causation may sometimes be subsumed in the general causation question. The question is case-specific and depends on the facts. For example, where there are no alternative agents for a disease or there is a "signature" disease for the substance, specific causation is not an issue. Otherwise, however, specific causation must be addressed even though a plaintiff may be able to show general causation.

Although the comment points out that epidemiologists do not focus on specific causation and that there is not a scientific methodology for determining from group studies whether specific causation exists, comment c recognizes the line of cases in which courts have permitted group studies to be used as evidence of specific causation where the relative risk from such studies is greater than two.⁹ But comment c also suggests caution when the relative risk shown by group studies is attempted to be used to support specific causation:

[T]he extent to which the group-study outcome reflects the increased risk to the plaintiff depends on the plaintiff's similarity to those included in the study. Relevant differences include whether: (a) the plaintiff was exposed to comparable doses; (b) the plaintiff was not differentially exposed to other potential causes of the disease; and (c) the plaintiff has individual characteristics that might also bear on the risk of disease, such as age, gender, or general health, comparable to those in the study group.¹⁰

It is interesting (particularly for those who have been involved in expert battles over what dose may trigger a particular disease and who realize the significance that dose can sometimes impart to a toxic torts case) that this is the only discussion of dose in comment c and that there is no discussion of toxicology.

The comment then addresses the technique of differential diagnosis. Importantly, the comment recognizes that differential diagnosis, or differential etiology, is generally appropriate only when all the potential causes of a disease are known. The comment concludes that, when the causes of a particular disease are largely unknown, differential diagnosis is generally inappropriate to prove specific causation.

Ultimately, as it does with general causation, comment c instructs courts to "consider all of the evidence that bears on [specific causation] and determine,

whether in light of the general standard for sufficiency discussed in comment b, the evidence would permit a reasonable jury to find that plaintiff's disease more probably than not was caused by exposure to the agent."¹¹ In the language of comment c, courts may consider group study evidence where there is a sufficient showing of relative risk and the plaintiff's dose, and exposure and characteristics are sufficiently similar to the members of the group study. In appropriate circumstances, courts may also consider a differential diagnosis or particular biological mechanisms of a disease that link it to exposure.¹²

Conclusion

The unique and often complicated causation questions that arise in toxic tort cases have now challenged courts for more than 30 years. There is a substantial body of case law—some of it quite varied—addressing these issues, and it is hard to argue against an effort to include toxic torts in the Restatement Third. But both plaintiff and defense practitioners will disagree and struggle with different portions of comment c. Toxic torts are varied, complicated, and often tricky. Indeed, it is no wonder the concept of "science day" for courts has been proposed to educate judges about complicated scientific issues affecting questions of causation in toxic torts. For that reason alone, practitioners must ensure that the generalizations in comment c are not employed to lump all toxic torts into a single category. Toxic torts will remain complicated, and courts will continue to struggle with questions of causation in these cases. Nonetheless, comment c represents an admirable effort to collect and synthesize a disparate array of case law that has evolved over many years, and both courts and practitioners may find the comment useful in getting up to speed on causation questions. Although the comment will likely prove to be a useful tool, application of the scientific issues unique to particular cases cannot be distilled into a single and easily employed "catch-all" rule of causation. ■

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Endnotes

1. Joseph Sanders, *The Controversial Comment C: Factual Causation in Toxic-Substance and Disease Cases*, 44 WAKE FOREST L. REV. 1029 (2009) (noting that some have compared the controversy in the Restatement Third about toxic substances to the controversy surrounding the alternative feasible design requirement in the Restatement (Third) of Torts: Product Liability project in the mid 1990s).

2. RESTATEMENT (THIRD) OF TORTS § 28 cmt. c, at 406 (2010).

3. *Id.* at 402.

4. See Sanders, *supra* note 1, at 1032–33.

5. RESTATEMENT, *supra* note 2, § 28 cmt. c, at 404.

6. RESTATEMENT, *supra* note 2, Reporters' Notes, at 435–36.

7. *Id.* at 448.

8. *Id.* at 446.

9. RESTATEMENT, *supra* note 2, § 28 cmt. c, at 408. For more information related to relative risk and the implication that a relative risk greater than 2.0 supports a doubling of the incidence of disease in a group study, see the Reporters' Notes to comment c, at 450–51 (collecting cases discussing the significance of relative risk and causation). The Reporters' Notes point out that “[c]aution . . . is necessary in permitting or making inferences

about specific causation based on an increased incidence found in a group study. One must appreciate that an association . . . found in a group study does not necessarily mean a causal relationship exists.” Reporters' Notes to comment c, at 449.

10. RESTATEMENT, *supra* note 2, § 28 cmt. c, at 408.

11. *Id.* at 409. Comment b to section 28 is entitled “Reasonable inference and speculation in proving causation.” In this comment, the Restatement emphasizes the difference between a reasonable inference that may permit a case to reach a jury versus impermissible speculation. It is a distinction of great importance in toxic tort cases, and the reference to it in comment c may prove significant.

12. *Id.* at 409.

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