An Association Does Not Equal Causation

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A recurring area of dispute in toxic tort litigation is plaintiffs' reliance on governmental findings made for regulatory or other purposes, such as risk assessments and standards established for government disability benefit schemes, to establish the element of causation. Such findings generally cannot satisfy the causation requirement of a tort action because they are predicated on different considerations and a much lower threshold of proof than that required for legal causation. Professor Margaret Berger noted the following distinction:

> Proof of risk and proof of causation entail somewhat different questions because risk assessment frequently calls for a cost-benefit analysis . . . risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not.[1]

While use of regulatory findings as evidence of causation is not especially novel, it seems likely to increase in light of current government initiatives to revamp chemical regulations. For example, the Environmental Protection Agency (EPA) has announced plans to establish a list of "chemicals of concern" in which the EPA, using its authority under the Toxic Substances Control Act, will "list chemicals that 'may present an unreasonable risk of injury to health and the environment.'"[2] In announcing the initiative, EPA Administrator Lisa P. Jackson stated:

> The American people are understandably concerned about the chemicals making their way into our products, our environment and our bodies. . . . We will continue to use our authority under existing law to protect Americans from exposure to harmful chemicals and to highlight chemicals we believe warrant concern. At the same time, I will continue to fight for comprehensive reform of the nation's outdated chemical management laws that ensures a full assessment of the safety of chemicals on the market today and effective actions to reduce risks where chemicals do not meet the safety standard. Chemical safety is an issue of utmost importance, especially for children, and this will remain a top priority for me and our agency going forward.[3]

As one commentator notes, the EPA's action is unprecedented and "is a big deal," because "the 'chemicals of concern' listings indicate EPA thinking that these chemicals are potentially dangerous and that further regulatory action is warranted."[4] This process will generate regulatory findings, such as risk assessment studies, which will undoubtedly be asserted to constitute proof of causation in toxic tort lawsuits.

The United States District Court for the Northern District of Ohio, in *Mann v. CSX Transportation, Inc.*,[5] rejected the use of regulatory findings and standards used for governmental presumptive disability schemes to establish causation of alleged dioxin-related injuries. The court's rulings on motions and its decision illustrate the issues raised in this context.

The Allegedly Toxic Incident

Mann v. CSX Transportation, Inc., arose out of the derailment of a freight train and ensuing fire in Painesville, Ohio, on October 10, 2007.[6] The National Transportation Safety Board determined that the probable cause of the accident was a broken rail, which occurred because a track inspector installed an incorrect type of rail joint bar.

Thirty-one cars of the 112-car train derailed. Nine of them were tank cars that contained hazardous materials (ethanol, liquefied petroleum, and phthalic anhydride); other derailed cars carried flammable but nontoxic materials.[7] The derailment caused a fire that burned for almost 60 hours and consumed 2,800 tons of material, including ethanol, plywood, polyethylene, creosote-treated railroad ties, cornstarch, biodiesel, feed, glycerin, and phthalic anhydride. Authorities evacuated some 1,300 residents within a half-mile radius of the derailment for about three days. There were no reported injuries.

Mann's Claims

The day after the accident, one plaintiff resident filed a class action complaint in state court, alleging injuries resulting from exposure to "black smoke and fumes," which were "hazardous to life, health and property."[8] One week after the incident, another set of plaintiffs filed a separate class action lawsuit in federal court, similarly alleging, among other things, "exposure to hazardous materials . . . as a proximate result of the October 10, 2007 explosion and fire of Defendant CSX's train and the resulting release of toxic fumes, odors and hazardous substances from the time of the explosion and continuing thereafter."[9] The state court action was removed, and the cases were consolidated in the federal district court. A second amended complaint in the consolidated action specified allegations concerning exposure to denatured ethanol, as a source of hydrocarbons and benzene, which the complaint alleged "is a known carcinogen associated with leukemia," and exposure to phthalic anhydride, which the complaint alleged to be a cause of various eye, skin, and

respiratory irritations, as well as liver and kidney damage.[10]

By order dated October 22, 2008, the court dismissed the plaintiffs' claims sounding in an independent cause of action for medical monitoring and in strict liability, allowing the plaintiffs to proceed on their negligence claims, including seeking medical monitoring as part of their alleged damages.[11]

In their expert reports, the plaintiffs eventually defined their theory of the case as exposure to dioxin and asserted a medical monitoring program covering 11 diseases, including several cancers.[12] The diseases claimed by the plaintiffs resembled the diseases for which the U.S. government provides benefits to veterans for presumed exposure to the Vietnam War–era defoliant Agent Orange, although the basis for those benefits, as the *Mann* court correctly recognized, is not a finding of causation between exposure to dioxin and disease, and the benefit program cannot be used as such evidence. It should also be noted that, as a general matter, dioxins are produced in almost any fire, e.g., fireplaces, home furnaces, barbeques, and most combustion involving natural substances. Consequently, individuals are ordinarily exposed to background levels of dioxin in their daily lives, and in a causation analysis, dioxin exposure that results from such normal emissions must be accounted for.[13]

Motion for Summary Judgment

CSX conceded the duty and breach elements of the plaintiffs' negligence claims. The issue on summary judgment was whether the breach had caused the plaintiffs' alleged injuries and need for medical monitoring. In this regard, the court recognized that, to survive summary judgment, the plaintiffs were required to demonstrate a genuine issue of material fact that "(1) the dioxins released into the air by the fire are known causes of human disease; and (2) that the named Plaintiffs were exposed to the dioxins in an amount sufficient to cause a significantly increased risk of disease such that a reasonable physician would order medical monitoring."[14] While the court expressed

Insufficient Evidence of Causation

The association/causation distinction has been recognized by the courts. For example, in *Nelson v. Tennessee Gas Pipeline Co.*, a case that involved allegations of exposure to polychlorinated biphenyls (PCBs), the plaintiffs sought to show causation by comparing statistical values assigned by their expert to one group of 98 residents of the area in which the PCBs were released and to a second group of 56 unexposed individuals based on questionnaires and testing intended to detect neurological and pulmonary abnormalities.[1] Based on higher "scores" in the exposed group, the plaintiffs' expert opined that the effects seen in that group were probably not caused by PCB exposure.

The court rejected this evidence, concluding that "[t]his kind of cohort epidemiological study hopes to establish an association between exposure and disease, *but an association does not mean there is a cause and effect relationship*."[2] The court further explained:

> Before any inferences are drawn about causation, the possibility of other reasons for the association must be examined, including chance, biases such as selection or informational bias, and confounding causes.

Even if this methodology validly showed that plaintiffs were impaired (which defendants do not concede), it did not provide a valid scientific basis for the opinion on causation.

The court observed that, instead, there were a number of possible causes of plaintiffs' impairments, such as alcohol, tobacco, and drug use; exposure to chemicals in solvents and spray paints; and working with textiles. Given that the record was replete with evidence of other factors or agents that may have been responsible for symptoms claimed by the plaintiffs, there was no basis for the expert's opinion that PCB exposure "was the cause of plaintiffs' reported maladies."

In *Henricksen v. ConocoPhillips Co.*, the court considered the plaintiff's theory and evidence supporting the claim that the plaintiff's leukemia had been caused by exposure to gasoline in the course of his work as a tanker truck driver.[3] The court granted summary judgment to the defendant on the ground, *inter alia*, that the plaintiff had not adduced sufficient evidence of general causation in relying on certain epidemiological studies that showed positive associations between the benzene content of gasoline and acute myelogenous leukemia. The court pointedly acknowledged

> *[A]n association does not equal causation* and it is the duty of scientists to rigorously analyze the data to determine whether or not such an association is causal. This means considering such factors as strength of association, consistency of association, specificity of association, and biological plausibility.
>
> None of the studies relied upon have concluded that gasoline has the same toxic effect as benzene, and none have concluded that the benzene component of gasoline is capable of *causing* [acute myelogenous leukemia] AML.[4]

Endnotes
1. 243 F.3d 244 (6th Cir. 2001).
2. *Id.* at 253 (emphasis added).
3. 605 F. Supp. 2d 1142 (E.D. Wash. 2009).
4. *Id.* at 1175–76 (first emphasis added, second emphasis in original).

the latter element in terms similar to a medical monitoring claim, its formulation of the issue was essentially the same as the typical two-prong inquiry for toxic tort causation: general causation and individual causation. The court found the plaintiffs' evidence to be lacking in both respects and granted summary judgment to defendants.

Veteran Administration Benefits

In opposing summary judgment, the plaintiffs in *Mann* relied on two types of evidence. First, they contended that causation of a number of diseases was established because the U.S. government, under a program administered by the Veterans Administration (VA), provides benefits to Vietnam veterans who were presumed to have been exposed to the chemical herbicide Agent Orange, which contained trace amounts of dioxin. Plaintiffs argued that "it is well established by governmental agencies that dioxin causes cancer in humans" and that "[t]he VA program provides a reference for additional diseases that are 'presumptively link [sic] to dioxin exposure."[15] It should be noted that no U.S. court has ever found that, as a matter of law, Agent Orange caused injury.[16]

The court resoundingly rejected as "groundless" the plaintiffs' efforts to rely on the VA program to establish the requisite causal link between dioxin and disease.

> Additionally, Plaintiffs' reliance on the VA Agent Orange Program as evidence that dioxins are "presumptively linked" to cancer is groundless. "VA/IOM classifications are not in themselves sufficient evidence from which a jury could conclude that exposure to the defendants' chemicals caused the bellwether Plaintiffs' diseases." *Adams*, 2007 WL 1075647, at *3. The VA Program was specifically designed to measure association between dioxins and endpoint diseases, not causation. Pub. L. No. 102-4, 105 Stat 11, 13 (1991). Courts have consistently held that association does not satisfy the element of causation. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) ("This kind of cohort epidemiological study hopes to establish an association between exposure and disease, but an association does not mean there is a cause and effect relationship."); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1175 (E.D. Wash. 2009); *Nehmer v. United States Veterans' Admin.*, 712 F. Supp. 1404, 1416 (N.D. Cal. 1989). Accordingly, Plaintiffs have not demonstrated a causal link between dioxins and cancer.[17]

A "one in a million risk" used for regulatory purposes did not satisfy the plaintiffs' burden to demonstrate a level of exposure that warranted medical monitoring.

As the court correctly observed, association does not equal causation, which, as noted above, is the problem underlying the use of these various types of governmental and regulatory findings and schemes as surrogates for causation, because the purposes for which the findings are rendered and the methodologies on which they are based do not fulfill the rigors of a legal causation analysis.

That association does not equal causation is not necessarily a novel concept (or admonition); yet, the proposition must be emphasized, particularly where the association at issue supposedly has a governmental imprimatur, as is the case with the VA program for Agent Orange or regulatory findings, such as those that can be expected from the current round of initiatives like the EPA's Chemicals of Concern list.

EPA Cleanup Standard C

In *Mann*, in addition to finding that the plaintiffs had failed to establish general causation, the court also determined that the plaintiffs "failed to establish that they were exposed to dioxins in an amount warranting a reasonable physician to order medical monitoring."[18] The plaintiffs sought to satisfy this "specific causation" element by purportedly modeling dioxin levels in the "impact zone" through reliance on only a few measurements and asserting that the levels generated from this modeling exceeded EPA's soil cleanup level for dioxin. EPA's soil cleanup levels are predicated on the risk of there being one additional cancer case among one million persons exposed to the conditions being assessed. As the Third Circuit has noted,

> No one points to any demographic, epidemiologic or any other type of scientific data, nor to any risk-utility analysis that supports EPA's million-fold regulatory factor as demonstrating the presence of a hazard, nor does this threshold appear in the regulatory or statutory history. Nevertheless, the million-fold factor seems ubiquitous in regulatory risk-utility determinations despite its indeterminate pedigree.[19]

The court in *Mann* found that such a "one in a million risk" used for regulatory purposes did not satisfy the plaintiffs' burden to demonstrate a level of exposure that warranted medical monitoring.

More generally, the *Mann* court observed that "demonstrating why regulatory guidelines are often not useful in the tort litigation context . . . the EPA soil cleanup level represents a threshold for the cleanup of contaminated soil, not a danger point above which individuals require medical monitoring."[20] Furthermore, the court recognized the impropriety of using government regulations for purposes of establishing the causation element of a tort, because such governmental determinations are necessarily "conservative" by nature and, thus, "should not be used in place of a medically-based risk assessment or evidence of the actual dose level at which dioxin truly causes cancer—the danger point critical

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of individual and corporate depositions:

- Listen to the question. Pause and think before you answer.
- Make sure you understand the question; if not, ask that the question be repeated or rephrased.
- To the extent possible, keep your responses short and succinct.

It's essential to remind the representative that he or she is acting as the voice of the corporation and, for that reason, should withhold any personal opinions, commentary, or characterizations. I was recently involved in a commercial insurance dispute in which the defendant insurer's Rule 30(b)(6) representative unwittingly characterized language in the insurance policy at issue as a "mistake" on the part of the insurer. Although inaccurate and seemingly insignificant at the time, the representative's reference to a "mistake" in the policy was subsequently used by opposing counsel as support for bad-faith claims against the insurer.

It can also be helpful to conduct a practice question-and-answer session using the Rule 30(b)(6) deposition notice as your outline. Doing so provides a preview of the actual deposition, which is likely to increase the representative's comfort level, and it also refreshes the representative's substantive knowledge of the case while highlighting any potential problematic areas that may require additional review and preparation.

Remember to take care of the logistical and housekeeping details. For example, you should notify the representative if the deposition will be videotaped, and make recommendations regarding attire as you feel appropriate and necessary. Make sure the representative knows how to get to the deposition location and, if necessary, has access to safe and convenient parking.

Above all, don't hesitate to spend as much time as you need preparing. The Rule 30(b)(6) representative is a significant figure in any corporate litigation, and a knowledgeable and articulate representative plays an important role in ensuring a favorable outcome for the corporation. ■

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to a medical monitoring determination."[21] As another court has similarly explained, "the basic goal underlying risk assessments . . . is to determine a level that will protect the most sensitive members of the population."[22] Moreover, inasmuch as these assessments rely on "a number of protective, often 'worst case' assumptions . . . the resulting regulatory levels . . . generally overestimate potential toxicity levels for nearly all individuals."[23] Accordingly, regulatory levels and findings are sufficient as evidence for a causation analysis.

Conclusion

We can expect that more chemicals will be placed on government lists and that they will increasingly be the subject of governmental regulations and findings. As this occurs, we can likewise expect to see such materials finding their way into the courtroom to be used for purposes for which they are not intended and are ill-suited. Such usage should be resisted based on the fundamental proposition that "association does not equal causation" and on a showing that the genesis of such regulatory findings is wholly dissimilar from a proper causation analysis. ■

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Endnotes

1. Margaret A. Berger, *The Supreme Court's Trilogy on the Admissibility of Expert Testimony*, *in* Reference Manual on Scientific Evidence 33 (Fed. Jud. Ctr. 2d ed. 2000).

2. Press Release, U.S. Envtl. Prot. Agency, EPA Announces Actions to Address Chemicals of Concern, Including Phthalates: Agency Continues Efforts to Work for Comprehensive Reform of Toxic Substance Laws (Dec. 30, 2009).

3. *Id.*

4. Elizabeth Grossman, *What the EPA's "Chemicals of Concern" Plans Really Mean*, Sci. Am., Jan. 11, 2010.

5. Case No. 1:07-Cv-3512, 2009 U.S. Dist. Lexis 106433 (N.D. Ohio Nov. 10, 2009).

6. *Id.* at *6.

7. *Id.*

8. Hirsch Complaint at 20–22.

9. Mann Complaint at 15, Mann v. CSX Transportation, Inc, U.S. Dist. Lexis 106433.

10. Second Amended Complaint at 27–28, *Mann*, U.S. Dist. Lexis 106433.

11. *Mann* (order dated Oct. 22, 2008).

12. *Mann*, 2009 U.S. Dist. Lexis 106433, at *4–5.

13. CSX Transp., Inc.'s Memorandum in Support of its Motion for Summary Judgment based on the Absence of Necessary Expert Evidence and to Stay Class Proceedings at 7 (Jul. 31, 2009), *Mann*, U.S. Dist. Lexis 106433.

14. *Mann*, 2009 U.S. Dist. Lexis 106433, at *8.

15. Plaintiffs' Memorandum in Opposition to CSX Transp., Inc.'s Motion for Summary Judgment at 21 (Sept. 8, 2009), *Mann*, U.S. Dist. Lexis 106433.

16. *See In re* Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (granting summary judgment dismissing claims of plaintiffs who had opted out of class settlement on grounds of lack of causality, as "[n]o acceptable study to date . . . concludes that there is a causal connection between exposure to Agent Orange and the serious health effects claimed by plaintiffs"), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom.* Lombardi v. Dow Chem. Co., 487 U.S. 1234 (1988).

17. *Mann*, 2009 U.S. Dist. Lexis 106433, at *11 (emphasis added).

18. *Mann*, 2009 U.S. Dist. Lexis 106433, at *12.

19. Redland Soccer Club, Inc. v. Dep't of Army, 55 F.3d 827, 840 n.7 (3d Cir. 1995).

20. *Mann*, 2009 U.S. Dist. Lexis 106433, at *14–15.

21. *Id.* at *15.

22. Rowe v. E.I. DuPont de Nemours & Co., Civ. No. 06-1810 (RMB), 2008 U.S. Dist. LEXIS 103528, *46 (D.N.J. Dec. 23, 2008).

23. *Id.* at *47 (quoting David E. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 34 (2003)).