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BLOG

Courts Demand Dose-Specific Detail from General Causation Experts

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Even water can be toxic if consumed in sufficient quantities.[1] Because any chemical can be dangerous at some level of exposure, one of the "central tenets of toxicology" is that the specific dose is a key aspect of causation.[2] This principle has important implications in toxic tort and pharmaceutical products liability cases. For instance, because a substance's ability to cause injury depends on dosage, a reliable expert opinion on general causation often requires data on a substance's toxicity at the specific level experienced by the plaintiff. Without such evidence, an expert may be excluded or a case may even be dismissed.

Courts have recently excluded experts that fail to submit reliable evidence (i) of a plaintiff's level of exposure to the product or medicine and (ii) that the level of exposure experienced by plaintiff is sufficient to cause the claimed injury (i.e., general causation).

IN RE LIPITOR

In *Lipitor*, the Fourth Circuit affirmed partial exclusion of the plaintiffs' expert testimony on general causation, which played a key role in summary judgment for Pfizer, the defendant. 892 F.3d 624, 649 (4th Cir. 2018). The plaintiffs in this multi-district litigation were over three thousand women who alleged that they developed diabetes as a result of taking Pfizer's drug, Lipitor, which was indicated to prevent heart disease. *Id.* at 629–30. Their expert had strong evidence of plaintiffs' exposure levels because "Lipitor is commercially available in 10, 20, 40, and 80 mg tablets." *Id.* at 630. But he struggled to provide reliable evidence that these exposure levels could cause diabetes.

The expert's initial report "concluded that there was indeed a causal relationship between Lipitor

and diabetes" but did not opine "as to whether Lipitor causes diabetes at each of the four doses commercially available in the United States." *Id.* at 638. The district court directed him to file a supplemental report, explaining that causation required a demonstration "that particular doses of Lipitor are capable of causing diabetes." *Id.*

The expert's supplemental report applied the general causation Bradford Hill criteria to determine that there was a causal relationship between Lipitor and diabetes at each commercially available dose. *Id.* However, his causation analysis for the 10 mg dose was unsupported by studies showing a statistically significant relationship. *Id.* at 640. The district court determined that the Bradford Hill method for determining whether a relationship is causal may only be applied after a determination that the relationship is statistically significant. *Id.* The Fourth Circuit agreed, holding

that the expert's opinion regarding the 10 mg dose was not based on an accepted methodology in his field and was properly excluded under *Daubert*. *Id.* at 642.

Because the expert admitted that his opinions about the toxicity of the 20 mg and 40 mg doses were an "inference" from his opinion on the 10 mg dose, the Fourth Circuit determined that his testimony on these points should also be excluded. *Id.* Without expert testimony, summary judgment was appropriate as to all the plaintiffs who had taken only 10, 20, and 40 mg doses. *Id.* at 647. The Fourth Circuit also affirmed summary judgment as to the defendants who had taken 80 mg doses because they failed to offer sufficient proof of specific causation. *Id.* at 648–49.

The *Lipitor* Court suggested that the dosage analysis required by the district court was particularly well-suited to pharmaceutical cases because pharmaceutical products "are typically prescribed and consumed in measured and knowable quantities." *Id.* at 639. Moreover, pharmaceutical products are typically subjected to extensive testing and study, meaning that substantial data will be available for review by expert witnesses. *See id.* (noting availability of data on other patients taking identical doses).

For both these reasons, courts may be more likely to insist on evidence directly quantifying the risk associated with a specific level of exposure in a pharmaceutical case than in a toxic tort case. Thus, *Lipitor* noted that a dosage analysis was not required in *Westberry*, a case involving workplace exposure to rubber gaskets coated with talcum powder. *Id.* Although the plaintiff's precise exposure could not be quantified, causation could be inferred where, before developing a sinus condition, the plaintiff "worked in clouds" of talcum powder, which was known to irritate mucous membranes. The expert concluded that the exposure caused the sinus condition based on a differential diagnosis, a temporal relationship between the plaintiff's exposure and the onset of his symptoms, and the fact that the plaintiff's symptoms improved when he stayed away from work. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263–66 (4th Cir. 1999).

However, more recent opinions demonstrate that courts are hesitant to permit expert testimony on general causation without dose-specific evidence even in toxic tort cases.

HOSTETLER V. JOHNSON CONTROLS

In *Hostetler v. Johnson Controls, Inc.*, the court excluded general causation opinions because the experts lacked a reliable basis for opining that trichloroethylene (TCE), perchloroethylene (PCE), and asbestos were toxic at the exposures that Plaintiffs experienced. 2020 WL 5543081 (N.D. Ind. Sept. 16, 2020). Plaintiffs had offered three experts to show that they faced "increased risks of experiencing adverse health effects," including cancer and autoimmune disease, because of their exposure to these chemicals. *Id.* at *1. The experts opined on "the substances' ability to cause adverse effect in general" or "under some conditions." *Id.*

The court excluded the opinions because the experts offered no reliable evidence that TCE, PCE, and asbestos were capable of causing injury "***given [Plaintiffs'] particular exposures***." *Id.* The court noted that Plaintiffs' exposures were unquantified and no "dose-and-duration analysis" had been offered. *See id.* at *3. Although plaintiffs' experts had estimated the concentrations of TCE and PCE in the air inside their homes and noted the number of years each plaintiff lived in each home, there had been no evaluation of "the amount of time any Plaintiff spent indoors being exposed to those concentrations during those periods." *Id.* And Plaintiffs had offered "no evidence whatsoever about how much asbestos any of them were exposed to." *Id.* at *6.

Without this evidence, plaintiffs tried to establish general causation through other means. The court rejected each.

- First, the court rejected the inference that TCE and PCE are toxic at the exposure levels Plaintiffs experienced because those levels were higher than permitted by government regulation. *Hostetler*, 2020 WL 5543081 at *2–3, 6. It explained that regulatory thresholds do not reflect the concentrations that would cause injury in the general population but instead "reflect concentrations known to be safe even for the most at-risk populations, with margins built in for safety." at *3. It also noted that regulatory levels "generally assume lifetime exposure," whereas Plaintiffs had been exposed for a shorter duration that had never been quantified. *Id.*
- Second, the court rejected the inference that TCE, PCE, and asbestos are toxic at the exposure levels Plaintiffs experienced because "there is no safe level of exposure." at *4, 7. The court explained that the theoretical but

unquantified possibility of a single molecule of a substance causing injury was too speculative to be useful in the decisional process. *Id.* In doing so, the court joined "more than thirty other federal courts and state courts" in holding that the "'any exposure' theory is not reliable." *Id.*

- Third, the court rejected the inference that TCE is toxic at the exposure levels Plaintiffs experienced because of a government decision to offer health benefits to individuals diagnosed with specific diseases after exposure at a government facility. at *5. Federal Rule of Evidence 703 anticipates that an expert's testimony will be based on facts or data that experts in the field would reasonably rely on in forming an opinion on the subject at hand. But a policymaking decision to offer health benefits is not "the type of evidence a toxicologist would rely on in reaching conclusions about causation." *Id.*

Consistent with *Lipitor* and *Westberry*, the *Hostetler* Court recognized that toxicity may sometimes be inferred from evidence that: (1) the plaintiff had a high level of exposure to the substance, (2) the plaintiff subsequently developed a condition that can be caused by exposure to the substance, and (3) other potential causes of the condition have been ruled out using a differential etiology. *Id.* at *6. But it declined to recognize new exceptions from the requirement of dose-specific data, even in the toxic-tort context.

MCGILL V. BP EXPLORATION & PRODUCTION, INC.

The Fifth Circuit indicated a similar hesitance to deviate from the requirement of dose-specific data on toxicity in *McGill v. BP Exploration & Production, Inc.*, 830 F. App'x 430, 434 (5th Cir. 2020). From May to July 2010, the plaintiff in *McGill* had assisted in cleaning up the *Deepwater Horizon* oil spill. *Id.* at 431. He alleged that he was disabled by a range of conditions, including pneumonia, rhabdomyolysis, and acute respiratory failure, that he contracted as a result of his on-the-job exposure to oil and to Corexit oil dispersants. *Id.* at 431–32.

McGill's causation expert combined the weaknesses of the experts in *Hostetler* and *Lipitor*. As in *Hostetler*, the expert failed to quantify McGill's exposure level. *Id.* at 432. McGill argued that this should be unnecessary in a toxic tort case. *Id.* at 433. But the Fifth Circuit noted that the experts in the cases on which he relied had "engaged in analysis of the plaintiff's workspace to determine a probable exposure level." *Id.* In contrast, McGill's expert was "unable to answer questions regarding how much time McGill spent scooping up oil, how, where, or in what quantity Corexit was used, how exposure levels would change once substances were diluted in seawater, or how McGill's protective equipment would affect exposure." *Id.*

As in *Lipitor*, the expert "lacked critical knowledge regarding the level of [exposure] harmful to humans." *Id.* at 432. Although some of the studies on which he relied suggested that oil and Corexit could cause respiratory harm, they did not link exposure to the specific illnesses that McGill suffered. *Id.* at 433. Moreover, "none provide[d] conclusive findings on what exposure level of Corexit is hazardous to humans." *Id.* Thus, there was "a notable analytical gap between the facts he relie[d] on and the conclusions he reache[d]." *Id.*

Accordingly, the Fifth Circuit affirmed the district court's exclusion of his putative expert testimony. *Id.* at 434. The district court had concluded that, without the benefit of expert testimony, McGill could not demonstrate "scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities," making summary judgment appropriate. *Id.* The Fifth Circuit agreed, making clear that both these general causation requirements are relevant in a toxic tort case. *Id.*

STRATEGIC IMPLICATIONS

The principle that general causation requires evidence of toxicity at a plaintiff's specific dose and duration of exposure can be a powerful tool. For example, it can offer grounds to exclude an opinion, to dispute its weight, or to challenge the sufficiency of the evidence. In some circumstances, it may even offer grounds to oppose class certification or dismiss large numbers of MDL plaintiffs. Defense counsel should not allow plaintiffs to escape their general causation burden by simply assuming that a product is toxic at *any* level.

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[1] Federal Judicial Center, *Reference Manual on Scientific Evidence*, 636 (3d ed. 2011).

[2] *Id.*

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