

Challenging the Admissibility of Regulatory Findings

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The International Agency for Research on Cancer (IARC) coordinates research on the causes of human cancer and develops scientific strategies for cancer control. IARC concludes various substances and events (silica, asbestos, benzene, etc.) are known, probable or possible carcinogens. A plaintiff diagnosed with cancer files a product liability suit against the manufacturer of a product alleging the plaintiff's cancer was caused by exposure to a "carcinogenic" substance incorporated in or emitted from a particular product. To establish causation, the plaintiff relies on IARC's designation of the substance as a known, probable or possible carcinogen. In lieu of documented and scientific findings that the plaintiff was actually exposed to a "carcinogenic" substance in such a sufficient dose and that sufficient dose actually caused the plaintiff's cancer, plaintiffs are routinely relying (sometimes successfully) on these regulatory findings alone – despite well-founded and established scientific and legal principles that should thwart such efforts.

In many instances, plaintiffs invoke the findings of regulatory bodies in an attempt to prove causation, i.e. plaintiff says he was exposed to a carcinogen, plaintiff has cancer, and a regulatory body recognizes the particular product or substance is a carcinogen, therefore, the product or substance caused plaintiff's cancer. Of course, studies suggesting workers exposed to a particular product or substance might have an increased risk of cancer does not conclusively prove that a particular product or substance caused a particular worker's cancer.

Nevertheless, regulatory and agency findings are persuasive to many jurors. Jurors can easily focus on an agency's general findings that a product or substance is a known, possible or probable carcinogen instead of addressing the specific legal causation issues in a particular case – was the plaintiff exposed to a particular product or substance?, was the plaintiff exposed to a particular product or substance in sufficient amounts to have caused a particular disease?, did the defendant cause the exposure?, or did something else cause the disease? Jurors can find it difficult to discern the difference between an agency's general finding that something is a known, possible or probable carcinogen and determining that a particular product or substance was more likely than not the cause of a particular harm in a particular plaintiff.

While studies and findings of regulatory bodies concerning the potential effects of products and substances can serve a general, beneficial purpose, many courts across the country rule these findings inadmissible due to the contrary role these regulatory bodies and the legal system serve and the different manner in which these regulatory bodies and the legal system use and interpret science. Regulators use science to prevent all known and possible consequences of the use of a particular product or substance (sometimes with little regard to the actual likelihood of effects). In doing so, regulators often utilize a very low threshold of risk to invoke regulatory action. As such, many courts find the science relied upon and the ultimate conclusions of the regulators and agencies often unreliable and inadmissible in the courtroom.

In a courtroom setting, one therefore must recognize these differences and be prepared to challenge the admissibility of regulatory and agency findings.

First, one must be prepared to challenge the admissibility of regulatory and agency findings. To be successful, one must read and understand the regulatory findings. Often, regulators never reach conclusions without hundreds and hundreds of pages of analyses and comments. Regulators rarely, if ever, issue conclusions without extensive commentary on the studies, the gaps in information, the risks, the limitations in the information they reviewed, caveats, and the purpose behind their ultimate conclusion. Regulators can even admit “risk is minimal” or “risk is uncertain” despite reaching a seemingly contrary conclusion.

An example can be found in the opinion of *Rhodes v. E.I. DuPont De Nemours & Co.*, 253 F.R.D. 365 (S.D. W. Va. 2008). In *Rhodes*, plaintiffs attempted to rely on regulatory data showing government concern about C-8 in the environment. However, the Court stated:

Plaintiffs’ reliance on regulatory data is also misplaced. Though governmental agencies are concerned about the presence of C-8 in the environment, none have concluded that persons exposed to C-8 have a significantly increased risk of disease. All of the reports emphasize the lack of information about harms caused by C-8.

Id. at 377.

Second, one must understand the general concept that regulators and courts have different missions. In the courtroom, a plaintiff must establish that a particular agent or event is capable of causing a particular harm and more likely than not caused the particular harm. In another case from West Virginia, the West Virginia Supreme Court determined that in a toxic exposure case a plaintiff must establish that he or she was actually exposed to a particular substance in such quantities that the exposure more likely than not caused his or her injury. In *Tolley v. ACF Industries, Inc.*, 212 W. Va. 548, 554-55, 575 S.E.2d 158, 164-65 (2002), the West Virginia Supreme Court of Appeals held that a plaintiff must produce evidence of actual exposure levels to the toxic substance and that plaintiff was actually exposed to the toxic substance.

In the regulatory arena, regulators do not make these individual determinations. Instead, regulators focus on potential – that is, regulators desire to set standards to reduce the likelihood of exposure to potentially harmful products or substances. Thus, regulators may set artificially low standards to protect the general public against any risk. Regulators have preventative goals – regulators seek to find presumed safe levels and put precautionary measures in place to maintain those perceived safe levels. Courts, instead, determine cause and effect in a particular case. Courts seek to determine whether a particular substance or an event more likely than not caused a particular injury. A plaintiff could be exposed to a particular carcinogenic substance or to a contaminant in excess of “safe levels” – but the court’s responsibility is to determine whether the product or substance actually caused the plaintiff’s injury.

Since regulators and courts have different goals, regulatory findings that a particular product or substance is a carcinogen may be inadmissible to prove that particular product or

substance caused a particular injury to a particular individual. For example, in *Rhodes, supra*, the court explained that safe drinking water recommendations “reveal the agencies’ precautionary procedures and guidelines,” but provide no evidence of the exposure of the proposed class as compared to the general population. Defense counsel should recognize the regulator’s mission and the lower threshold for action, be prepared to explain the difference, and challenge the admissibility of these regulatory findings under *Daubert* or *Frye* – standards to which regulatory agencies are not subject. Defense counsel must be aware of the stated or statutory mission of the regulatory mission and how the regulators carry out that mission to challenge the relevancy and reliability of the regulatory findings.

Defending a product liability / toxic exposure case in the face of regulatory and agency conclusions that seem to favor the plaintiff can be a daunting task. Regulatory and agency findings, especially those sponsored by the government, are persuasive to juries and plaintiffs thus often use these findings to prove causation. Often times, plaintiffs’ experts solely rely upon these regulatory and agency findings to opine that a particular product or substance caused the plaintiffs’ injuries. Plaintiffs, in essence, attempt to introduce these general regulatory findings that, at best, suggest a general causation link between a product and a disease, in lieu of satisfying their burden of proof, specific causation, in any product liability suit. Do not simply permit the introduction of these findings without first considering their relevancy to the legal causation question. Defense counsel should be prepared to construct its defense to enable it to challenge the admissibility of these regulatory and agency findings, use the regulatory and agency findings to cross-examine plaintiffs’ experts or to use the regulatory and agency findings to disprove plaintiffs’ claims.

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