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We are all familiar with the TV ads run by members of the plaintiffs' bar seeking plaintiffs for mass toxic tort litigation, those asking whether you or someone you know has been "exposed" to a particular substance and now suffers from one or more particular diseases. In an article earlier this year, the Wall Street Journal cited research showing that in 2023, almost 800,000 ads were broadcast at a cost of more than \$160 million, targeting matters such as the Roundup herbicide, talcum powder allegedly contaminated with asbestos, water contamination at Camp Lejeune, and drugs like Ozempic now being used to treat obesity.

Albeit not likely to appear in a comparable TV ad, there are many issues and developments that bear watching from the perspective of product manufacturers and their counsel on the defense side of these matters.

First, the ads themselves highlight one of the primary issues in any toxic tort claim – was there sufficient exposure to cause harm? If not, it cannot be said that the substance caused the harm. As the adage goes, "The dose makes the poison" (a phrase derived from the basic principle of toxicology expressed by Paracelsus: "All things are poison and nothing is without poison; only the dose makes a thing not a poison.)" Indeed,

even pure water can be toxic if you drink too much in a short period of time as your kidneys cannot process the excess water, potentially leading to a life-threatening dilution of the sodium content of your blood.

Exposure is a critical but difficult factual issue in many toxic tort contexts because it calls for reconstructing how the plaintiff has allegedly interacted with a substance perhaps over the course of decades. While exposure and its counterpart dose (whether and to what degree the substance was ingested, inhaled or absorbed into the body) are really matters of amount, there is typically little or no data or measurement to support such

an analysis, just anecdotal recollections of using a product, such as accounts of taking 3-5 minutes to apply talcum powder after a shower amid clouds of dust.

In a litigation, at this stage, an expert will be presented to provide an opinion regarding exposure, but is it sufficient for the expert to opine merely that exposure was sufficient to be harmful or must the expert quantify the exposure (which, again, typically involves extrapolation from some limited evidence)? And how will the quantification be assessed?

There have been some court decisions calling for quantification evidence and requiring it to conform to accepted methodologies. For example, a New Jersey appellate court recently found the lower court had failed to properly consider the methodology behind a plaintiff's expert evidence in a talcum powder case offered to extrapolate lifetime exposure from the number of containers of defendants' products that each plaintiff claimed to have used in their lifetime. (Barden v. Brenntag North Am., Inc.) One of the problems in trying to reconstruct exposure is that the analysis will rely on a number of presumptions rather than data for its calculations, e.g., the number of times the product was used and the length of time it was encountered, how often the plaintiff bought and replenished the product, and incomplete data measuring the concentration of the suspect contaminant in the product.

Not long ago, the New York Court of Appeals reiterated the need to quantify exposure and dose, i.e., "[t]he requirement that plaintiff establish, using expert testimony based on generally accepted methodologies, sufficient exposure to a toxin to cause the claimed illness," while rejecting plaintiff's simulation of asbestos exposure due to "flaws" in the test. (Nemeth v. Brenntag North Am., Inc.) Another New York court later focused on the element of "dose," as opposed to exposure, noting that "exposure simulation studies must account for the amount of respirable asbestos fibers released from the toxic product . . . Simply quantifying the magnitude of asbestos fibers released into the environment is insufficient." (Dyer v. Amchem Prods. Inc.) That is, as alluded above, how many asbestos fibers would enter the body via inhalation and thus potentially cause harm.

These sorts of rulings emphasize the role of the courts as "gatekeepers" of reliable scientific evidence. The gatekeeping role is reemphasized under the 2023 amendments of Federal Rule of Evidence 702, which clarify that a court must review expert testimony as a preliminary question, finding whether its proponent has

established the testimony's admissibility by a preponderance of the evidence and the expert's "opinion reflects a reliable application of the principles and methods to the facts of the case." (Fed. R. Evid. 702) While the gatekeeping concept to preclude unreliable expert testimony, including so-called "junk science," from being presented at trial is not new, many courts had foregone their gatekeeping role, increasingly deferring the consideration of expert evidence to the jury as a matter of its strength or weight. The amendments clarify that the burden is on the courts to determine reliability as a question of admissibility.

We will watch to see if the federal courts' gatekeeping role is reinvigorated. In the mass toxic tort area, there have been notable pretrial exclusions of experts in cases involving the pesticide paraquat and an alleged link between acetaminophen and autism.

The battle over science in the courtroom is being waged on another front as well, as some plaintiff-side science is coming under scrutiny, a counterpunch to usual attacks on "industry-sponsored" science.

For example, in a case involving a claim for mesothelioma allegedly arising from exposure to a cosmetic talc product, for proof of causation, plaintiff relied on a published study, "Malignant mesothelioma following repeated exposures to cosmetic talc: A case series of 75 patients." (Peninsula Pathology Assocs. v. American Int'l Indus.) The paper was not derived from some epidemiological study, however; it consisted of cases "selected from [a] medical-legal consultation practice," and the authors identified exposures based on deposition testimony and interrogatory answers. Defendants argued that the publication would merely be a vehicle to put 75 other plaintiffs in other cases before the jury under the guise of a scientific study and sought discovery regarding the basis for the study on which they might base a Rule 702 challenge. The district court denied the discovery, which ruling is on appeal to the Fourth Circuit.

In an amicus brief to the Fourth Circuit, the American Tort Reform Association explains that "[t]he ability to test scientific claims is particularly critical when made-for-litigation science is at issue," and parties must be able "through discovery, to probe the basis of a proposed expert's testimony and present significant flaws or misrepresentations" on a Rule 702 motion, if the courts are "to diligently exercise their gatekeeping responsibility."

We can expect wrangling to continue from both sides, accusing the other of either made-for-litigation/junk science or industry-sponsored science.

As a final topic for our discussion of mass toxic tort developments to watch, corollary to traditional toxic tort cases discussed above are claims attacking a product's alleged toxic hazards under various consumer protection statutes and causes of action. These sorts of claims can typically be pled as class actions and the science component is not as rigorous as having to prove actual exposure and causation. The gravamen of these cases is that the consumer has been misled because some undisclosed, potentially hazardous substance is in the product.

For instance, as a corollary to the cases alleging cancer from using the Roundup herbicide, consumer class actions were brought based on the purported presence of glyphosate in breakfast cereal (used on the wheat crops), which would be allegedly misleading insofar as the product is advertised as "natural."

Similarly, while PFAS (per-/polyfluoroalkyl substances) have been the subject of many claims for direct exposure (these are the firefighting foam commercials) as well as groundwater contamination, the substances are also found in various consumer products, prompting consumer lawsuits. For example, suits have been filed against cosmetics manufacturers based on the presence of PFAS in their products. (PFAS would be used in cosmetics to enhance the product's durability, spreadability, etc., given the substances' water-resistant properties and film-forming capabilities.) PFAS are man-made and known as "forever chemicals." Thus, cosmetics suits have alleged, for example, that a cosmetic maker's claims of "open, inclusive and sustainable beauty" is contradicted and misleading if the product contains forever chemicals.

So, as discussed above, there is plenty to watch for in mass toxic tort area – what will be the next alleged toxin highlighted on TV; greater judicial focus on quantifying exposure; increased gatekeeping of expert testimony; battles over whose science is legitimate; and which products on our shelves also present toxic concerns. Make sure to tune in.



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