Exposure Assessment in Personal Injury Litigation: Challenging the Data

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Although much has been written about evidence that may be used to demonstrate causation in toxic tort litigation, relatively little attention has been focused on the types of evidence that may be used to prove that a plaintiff had the level and duration of exposure to an alleged toxin necessary even to develop the injury he or she claims. Yet the sufficiency of exposure data is often as important as the causation evidence.

Indeed, either a court, in deciding pretrial motions, or a finder of fact, in post-trial deliberations, may conclude that enough evidence exists to find that a particular chemical or physical agent is capable of causing a certain adverse outcome, but the evidence is simply not sufficient to conclude that the plaintiff was exposed to a dose of that material high enough to have caused the claimed effect.

In federal cases, under Federal Rule of Evidence 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), and its progeny, exposure must be proven—through expert testimony—with the same degree of reliability and "fit" as causation. State courts have reached the same conclusion. Under these circumstances, it may be useful to consider how some parties have attempted to prove exposure and how courts have treated that evidence. As an initial matter, however, it is probably useful to discuss some of the ways in which exposure might be established.

EXPOSURE ASSESSMENT METHODOLOGIES

Personal Testimony. A plaintiff may simply say, "I ate it," "I drank it," or "I breathed it." This bare evidence may suffice for some types of exposures, such as when the potential toxicant at issue is a pharmaceutical product and the concentration or other dosage level is known. However, under most circumstances, the information that a person took something into his or her body, without more data, does not provide sufficient information for a finder of fact to reach any real conclusion as to what level of exposure the person experienced. Although precise measurement has not typically been required, *some* sort of quantifiable finding is important because most courts insist on an evidentiary showing that: (1) the material alleged to have caused an adverse effect has the relevant toxicological properties; and (2) the plaintiff has received a dose of that material consistent with such an effect.

Biological Measurements/Biomarkers. A plaintiff may have measurable quantities of the allegedly harmful material, or some metabolite of the material, present in his or her body. Lead in blood and arsenic in hair are good examples of

this type of exposure measurement. Although the presence of the material is not in doubt, methodological shortcomings remain. First, the source of exposure generally cannot be identified, because many materials are not unique to a single source. Second, depending on the tissue sampled, the measurement may reflect only recent or very old exposures. The exposure pathway can be even more attenuated if the toxin—such as mercury in fish—is present only in a "vector" that passes alleged exposure to a human plaintiff.

Similarly, some materials have generally accepted biological effects, even if direct levels in the body are not measured. For example, long-term asbestos exposure can produce lung-function abnormalities. Radiation may cause certain cancers or DNA mutations. Based on these "biomarker" relationships, if a particular individual had particular deficits in lung function or specific DNA changes, one might argue that it was the result of a certain exposure. However, it is seldom possible to "fingerprint" an exposure: few biomarker effects are uniquely caused by a particular exposure. Moreover, even if a particular biomarker effect can be isolated to a certain type of exposure, the source of that exposure can rarely be identified with certainty. Finally, for many biomarker effects, detection does not necessarily signal an adverse health event, now or in the future.

Industrial Hygiene Sampling. There are essentially two types of industrial hygiene sampling utilized in personal injury litigation: personal sampling and area sampling. In personal monitoring for potential chemical exposure, the sampling device is placed on an individual, and its readings measure inhalation exposure, in that individual's breathing zone, of the chemical material being sampled. In area monitoring, the sampling device is placed at a set location, and a measurement of airborne chemical levels—again, only for the material being sampled—is achieved for the area and time frame sampled.

Although such devices—along with similar devices measuring exposure to physical agents, such as radiation or noise—do not directly measure those chemicals or agents within the body, if personal monitoring devices are placed and interpreted correctly, the devices generally provide reliable information about the exposure of that individual. So, for example, if a monitoring device, calibrated to identify and quantify a particular chemical, is properly placed in a person's breathing zone, the resulting measurement may be considered good evidence of exposure to that chemical for that person.

However, there are numerous evidentiary shortcomings to the use of industrial hygiene monitoring as "proof" of exposure. First, exposures can be measured only when the devices are properly placed, calibrated, and operated. Second, even if the devices are correctly utilized, interpretation of the data gathered may not reflect actual exposure. For example, some industrial hygienists will interpret a "nondetect" value for a particular chemical as one-half the limit of detection, when there is no evidence that the material was present at all. Third, the instruments are not designed to identify a source of exposure, only the level measured in a breathing zone or the area monitored. Fourth, even if some chemical concentration is measured, the sampling presented may not be representative of the plaintiff's actual exposure, such as when area monitoring measurements are sought to be used as a proxy for personal monitoring data.

Computer Modeling. Computer modeling has been used to try to estimate exposures to various chemicals and physical agents. The modeling can be simple or complex, and it can attempt to simulate indoor or outdoor environments. All modeling, however, is based on inputs to the model that reflect assumptions, and complex models can have many assumptions that undercut their reliability—*i.e.*, "Garbage in, garbage out."

Modeling has historically been used in the risk assessment paradigm, but not as proof of exposure in an individual toxic tort or product liability case. In a risk assessment or regulatory context, of course, assumptions in the model can be driven by policy decisions, such as the "precautionary principle," that are not appropriate for use in a personal injury lawsuit. Models presented in court must scrupulously adhere to the facts of the case, and each interpretation or assumption made by the modeler—or by the internal working of the model itself—must be exhaustively documented and consistent with the facts.

JUDICIAL APPROACHES

Courts grappling with exposure assessment issues have evaluated evidence presented under each of the biomarker, industrial hygiene, and modeling methodologies, and they have

identified potential flaws in each approach. The cases discussed provide useful examples of the principles at issue but do not represent an exhaustive survey of the many complex issues inherent in litigation regarding exposure assessment.

Biomarkers/Subcellular Damage. Courts addressing biomarker issues have been careful to note that the existence of a biomarker in a plaintiff does not inevitably lead to a causation finding. For example, in *Cotroneo v. Shaw Environmental & Infrastructure, Inc.*, No. Civ. A. H-05-1250, 2007 WL 3145791 (S.D. Tex. Oct. 25, 2007), the court reviewed claims that cleanup contractors had been exposed to radioactive materials, including Americium-241 ("Am-241") and Cesium-137, and found it "undisputed that some level of this toxin [Am-241] is present in each plaintiff's urine." *Id.* at *1. The court further recognized that "[t]he Dose Report indicating the presence of Am-241 in plaintiffs' bodies is evidence of exposure; it is not evidence of causation." *Id.* at *5 n.19. The plaintiffs could not make the required causation showing, and summary judgment ultimately was granted to the defendants. *See also In re Hanford Nuclear Reservation Litig.*, 497 F.3d 1005, 1016 (9th Cir. 2007) (noting that plaintiff exposure to radioactive Iodine-131 had been shown but that epidemiological studies had not established any causative relationship between Iodine-131 and the plaintiffs' illnesses at the dose levels received).

Other courts have found that the presence of a biomarker in a plaintiff may not even rise to the level of a cognizable claim. For example, the Sixth Circuit in *Rainer v. Union Carbide Corp.*, 402 F.3d 608 (6th Cir. 2005), found that demonstrated DNA damage from plutonium and neptunium exposure (but no clinical symptoms of any associated disease) would not be accepted, under Kentucky state law, as a "bodily injury" on which a claim under the Price-Anderson Act could be predicated. *Id*. at 618. In so ruling, the court looked to medical monitoring jurisprudence to hold that the Kentucky Supreme Court would find "a claim of an enhanced risk of illness or disease [ ] insufficient to establish a 'present physical injury.' " *Id.* at 619.

Although recognizing that the plaintiffs in the earlier medical monitoring cases "did not (and perhaps could not) point to any concrete physical damage," *id.*, while the *Rainier* plaintiffs did have proven subcellular effects, the court nonetheless found that Kentucky law would not provide a basis for their claims. The court reasoned that the Kentucky Supreme Court had addressed asbestos-exposure claims in its prior jurisprudence and "was presumably aware that asbestos inhalation causes subclinical tissue damage to the lungs. Yet it did not recognize this damage as sufficient to constitute a 'present physical injury.' " *Id.* Accordingly, the Sixth Circuit found that the district court properly rejected these claims.

The court further noted that its decision reflected sound public policy, because a ruling to the contrary would "throw open the possibility of litigation by any person experiencing even the most benign subcellular damage," a potentially immense class of claimants. *Id.* at 621. Moreover, the court said, its ruling perhaps would inure to the plaintiffs' benefit in the future, because Kentucky has a "one claim" rule that would permit the plaintiffs only "nominal recovery" for their DNA damage claims and would preclude their subsequent recovery "should they later develop a truly debilitating disease." *Id.*

Industrial Hygiene Data. A Delaware court hearing the W.R. Grace bankruptcy proceedings undertook analysis of various sources of air-sampling data to determine whether claimants had shown exposure to asbestos fibers that would substantiate their claims in the bankruptcy. *In re W.R. Grace & Co.*, 355 B.R. 462 (Bankr. D. Del. 2006). The court first rejected historical testing from the 1970s, because the methodology utilized could not be documented and, more importantly, because the testing was not representative of homeowner exposure. *Id.* at 488–89. Second, the court similarly found that additional data collected during drywall installation and insulation removal were "not consistent with domestic exposure" to asbestos fibers and accordingly could not support claimants' exposure allegations because the sampling sought to be presented did not "fit" the facts of the case. *Id.* at 489–90.

Finally, the Delaware court compared the data-collection efforts undertaken by experts for the claimants and for W.R. Grace, holding that the claimants' expert had erred in conducting industrial hygiene studies that included only 30-minute testing for "excursion limits"—*i.e.*, the maximum short-term exposure—and did not utilize eight-hour time-weighted averages ("TWAs"), which would have been more representative and consistent with applicable exposure standards. The court ultimately rejected these claimant-collected data, like the other data sets, because the claimants' expert report did "not

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support unreasonable risk of harm due to typical homeowner activities." *Id.* at 490.

In contrast, the court found that exposure assessment experts for W.R. Grace appropriately accounted for potential lifetime average exposure of the claimants, "used exposure assessment data and dose response to calculate risk," and appropriately calculated an excess mortality risk from the presence of asbestos in claimant homes of 0.01 to 0.0001 percent. *Id.* at 491–92 (footnotes omitted). The court found that this level did "not establish an unreasonable risk of harm" and accordingly could not support the relief that claimants sought. *Id.* at 493.

Computer Modeling. As already noted, the key issue in garnering judicial acceptance of a computer model is demonstrating that factually correct inputs have been made and no inappropriate assumptions have undercut the results obtained. This issue is implicit in the discussion of data "fit" so important to the W.R. Grace bankruptcy court and has been discussed in numerous judicial decisions. One recent case, *Gallaway v. Empire Fire & Marine Insurance*, No. 03-113, 2007 WL 1199502 (W.D. La. Apr. 20, 2007), *aff'd*, *Medlin v. Newman*, No. 07-30460, 2007 WL 4180542 (5th Cir. Nov. 27, 2007), illustrates the power that competent defense modeling can have over plaintiff claims of exposure.

In *Gallaway*, the plaintiffs alleged that they had been "engulfed" by a "cloud" of hydrochloric acid ("HCL") fumes after a truck carrying liquid HCL was involved in a road accident that caused acid to leak from the truck. Although no one disputed that some level of fumes was present at the accident, absent defensive modeling efforts, the plaintiffs' testimony of their exposure might have gone unchallenged. However, an air dispersion model used by emergency responders to predict chemical dispersion after an accidental release showed that the plaintiffs "could not have been exposed to harmful levels of HCL such that would have caused their alleged chronic symptoms." *Id.* at *2–3.

The court was persuaded that the defense expert who presented the model had reviewed available factual information about the event, including meteorological records and emergency response reports, and had made appropriate inputs to the model regarding—among other things—the amount of chemical spilled, the location of the chemical source, the duration of the spill, and the position of the plaintiffs relative to that source. *Id.* at *3. Because the plaintiffs did not present any evidence to counter the defendants' model, the court granted summary judgment to the defendants and dismissed all of the plaintiffs' claims. *Id.*

These cases demonstrate the importance of critically analyzing the factual basis for alleged exposure claims and carefully delineating the areas in which "supporting" data may be challenged as inconsistent with the facts. Any exposure methodology is likely to have flaws; proper exploration and presentation of these defects can provide an early litigation victory to the prepared defendant. ■

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