The Increasing Relevance of Biomonitoring Research to Toxic Tort Litigation

By Anthony G. Hopp

These days, you can’t open a newspaper or watch a news program without hearing about chemicals in your body. Apparently, dioxins, flame retardants, pesticides, and metals are all floating in your bloodstream. Plastic bottles and food containers are said to leach chemicals into your food. Researchers have tested umbilical cord blood and proven that even unborn children are exposed to synthetic chemicals.

The science of biomonitoring has exploded in the past 10 years. Public-interest groups, advocacy groups, the Centers for Disease Control and Prevention (CDC), and state departments of health have collected mountains of data about the types of chemicals we carry around with us. The question for toxic tort lawyers is what, if any, relevance there is to the data. Until recently, the answer was “not much.” Increasingly, however, sophisticated analysis of the large amounts of available biomonitoring data has provided some clues to disease causation. As more data are collected over the next decade, biomonitoring is likely to become increasingly relevant in the courtroom. However, it will not be biomonitoring data alone that prove to be significant; rather, it will be biomonitoring data combined with epidemiological analysis.

How Might Biomonitoring Data Be Useful in Toxic Tort Litigation?

Proof of causation in toxic tort cases is two-pronged. The first prong is generic or general causation; the second is specific or individual causation. Jaros v. DuPont (In re Hanford Nuclear Reservation Litig.), 292 F.3d 1124, 1129 (9th Cir. 2002); see also Jack v. Glaxo Wellcome, Inc., 239 F. Supp. 2d 1308, 1320–21 (N.D. Ga. 2002).

Proving General Causation

General causation is established by demonstrating that exposure to a substance can cause a particular disease. Before the question of what caused the plaintiff’s specific injury can be answered, one must first independently “rule in” the toxin in question as a matter of general causation. See, e.g., Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 989 (8th Cir. 2001) (affirming district court’s exclusion of plaintiff’s experts because they lacked a proper basis for “ruling in” the drug in question as a potential cause of alleged injury). Cases from around the federal system recognize that plaintiffs must establish general causation first, or specific causation does not become an issue: “[W]ithout general causation, there can be no specific causation.” Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (10th Cir. 2005); Meister v. Med’g Eng’g Corp., 267 F.3d 1123 (D.C. Cir. 2001); Dowors v. Perstorp Components, Inc., 126 F. Supp. 2d 1090 (E.D. Tenn. 1999).


Proving Specific Causation

Once the alleged toxin has been “ruled in” as a potential cause of a plaintiff’s illness, the plaintiff must then prove specific causation: that the actual exposure to the alleged toxin was of sufficient levels to cause the disease. Raynor v. Merrell Pharms., Inc., 104 F.3d 1371, 1376 (D.C. Cir. 1997); see also Savage v. Union Pac. R.R. Co., 67 F. Supp. 2d 1021, 1031 (E.D. Ark. 1999) (“In order to carry the burden of proving a plaintiff’s injury was caused by exposure to a specified substance, the plaintiff must demonstrate ‘the levels of exposure that are hazardous to human beings generally as well as the plaintiff’s actual level of exposure.’”) (quoting Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1106 (8th Cir. 1996)). Specific causation requires proof of how much of a particular substance is necessary to cause the disease at issue and the level of plaintiff’s exposure. Wright, 91 F.3d at 1106 (reversing
What Is Biomonitoring and Where Do the Data Come From?

“Biomonitoring” is a general term for a variety of tests used to measure the presence, or burden, of various substances in a person’s body. Dennis Paustenbach & David Galbraith, “Biomonitoring: Is Body Burden Relevant to Public Health?,” 44 Regulatory Toxicology and Pharmacology 249 (2006).

Biomonitoring can take the form of blood, urine, tissue, or even breath tests. While biomonitoring tests come in various forms, they all have a common purpose: to measure the amount of a particular substance that has been ingested, inhaled, or absorbed into the human body. Id.

Private groups, such as the Environmental Working Group in the United States and Environmental Defense in Canada, have published small-scale studies demonstrating the range of contaminants found in the blood of adults and children. In 2006, California passed a law that created a biomonitoring program, S.B. 1379, 2005-06 Cal. Leg., Reg. Sess., Statutes of 2006, Chapter 599 (codified at Cal. Health & Safety Code §§ 105440–105459), available at www.cdph.ca.gov/programs/Biomonitoring/Documents/SB1379.pdf. The program has not yet begun to collect data, however. The Minnesota Department of Public Health has also established a biomonitoring pilot program. Yet, the largest source of available biomonitoring data is the federal government and its agencies.

The CDC has been collecting data on human exposure to environmental chemicals for at least the past 10 years. In December 2009, the CDC released its Fourth National Report on Human Exposure to Environmental Chemicals, (available at www.cdc.gov/exposurerereport/pdf/FourthReport.pdf). The data in the report were collected from a random sample of participants in the National Health and Nutrition Examination Survey (NHANES). NHANES, which has been conducted for 50 years, is a series of surveys on the health status, health-related behaviors, and nutrition of the U.S. population. It combines interviews with physical examinations. The interviews include demographic, socioeconomic, dietary, and health-related questions, while the examination consists of medical, dental, and physiological measurements and laboratory tests. Since the early 1960s, the NHANES program has examined a representative sample of approximately 5,000 people annually. Ctrs. for Disease Control, Dep’t of Health & Human Servs., National Health and Nutrition Examination Survey, 2007–2008, Overview (2008), available at www.cdc.gov/nchs/data/nhanes_07_08/overviewbrochure_0708.pdf. As a result, the NHANES program has collected a massive amount of public health data that are available to qualified researchers.


A series of national and regional databases of biomonitoring information has thus been established and will continue to grow. By itself, however, this information is only of limited use for proving causation in toxic tort litigation.

First, biomonitoring is often not specific. That is, it may be possible to measure the level of a particular substance in a person’s blood or urine, but unless that substance is unique to the defendant, proof of the amount of the substance in someone’s blood or urine will not help to prove causation or fault. Dioxins, for example, are widespread contaminants in the food supply. Food consumption is the primary pathway for human dioxin exposure. Comm. on the Implications of Dioxin in the Food Supply, Inst. of Medicine of the Nat’l Academies, Dioxins
and Dioxin-Like Compounds in the Food Supply: Strategies to Decrease Exposure (2003), available at www.nap.edu/open-book.php?record_id=10763&page=R1. These substances accumulate in fat cells and build up over time. If the plaintiff sues a local industrial plant for an alleged dioxin-related illness, it can be difficult to separate the food-related dioxins from the dioxins that allegedly emanated from the defendant's plant.

Second, biomonitoring tests often take place years after the relevant exposure. Many of the illnesses that result in toxic tort litigation are latent diseases; that is, they do not occur immediately after exposure to a chemical but many years later. At the same time, assuming that the plaintiff is no longer in contact with the chemical, the body will slowly rid itself of the offending substance. If, for example, a plaintiff had extensive contact with a chemical in the 1970s and became sick 30 years later, biomonitoring would be of little use in tying the chemical to the disease. Frozen blood samples, if they are available for some reason, might be helpful in this regard. Arnold Schecter et al., “Polybrominated Diphenyl Ether Flame Retardants in the U.S. Population: Current Levels, Temporal Trends, and Comparison with Dioxins, Dibenzofurans, and Polychlorinated Biphenyls,” 47 J. of Occupational & Envtl. Med. 199, 208 (2005).

With very few exceptions, the plaintiff's blood or urine level of a synthetic substance at the time a lawsuit is commenced is not helpful to prove causation. Lead is a major exception. High blood lead levels are known to cause cognitive and developmental problems. Bruce P. Lanphear et al., “Cognitive Deficits Associated with Blood Lead Concentrations <10 µg/dL in U.S. Children and Adolescents,” 115(6) Pub. Health Reps. 521 (2000).

In fact, biomonitoring results of an individual plaintiff are almost never helpful in proving the plaintiff's claim. Several litigation experts have attempted to use cross-sectional biomonitoring studies of groups of plaintiffs to prove that the plaintiffs were “overexposed” to chemicals released from defendants' manufacturing operations or otherwise deposited by defendants. James Dahlgren et al., “Exposure Assessment of Residents Living Near a Wood Treatment Plant,” 92 Envtl. Res. 99 (2003); James Dahlgren et al., “Biomonitoring for Creosote and Pentachlorophenol in Nearby Residents of a Wood Treatment Plant,” 66 Organohalogen Compounds 2476 (2004). Because the biomonitoring measurements in such studies are often taken only once, and only after the plaintiffs have allegedly become ill, they are not useful in proving causation.

The mere presence of a synthetic substance in a person's body is not, in itself, actionable in most jurisdictions. See In re Rezulin Prods. Liab. Litig., 361 F. Supp. 2d 268, 275–76 (S.D.N.Y. 2005) (Under Texas law, sub-cellular damage absent any clinically manifest detriment is not a compensable injury); Parker v. Wellman, 230 F. App'x 878, 882 (11th Cir. 2007) (holding that sub-cellular damage resulting in sub-clinical injury does not constitute current, physical harm); Schweitzer v. Consol. Rail Corp. (Conrail), 758 F.2d 936, 942 (3d Cir. 1985) (holding that sub-clinical injury resulting from exposure to asbestos is insufficient to constitute actual loss or damage); Laswell v. Brown, 683 F.2d 261, 269 (8th Cir. 1982) (allegations of exposure to an “unusually high risk of disease in genetically passed cellular damage” was insufficient to state a claim); Eagle-Picher Indus., Inc. v. Liberty Mut. Ins. Co., 682 F.2d 12, 19 (1st Cir. 1982) (insurance policies do not cover sub-clinical claims); but see Donovan v. Philip Morris USA, Inc., 914 N.E.2d 891, 901 (Mass. 2009) (sub-cellular damage can support a claim for medical monitoring).

While it may sound counterintuitive, biomonitoring's usefulness in toxic tort litigation comes not from its role in proving or disproving individual claims; rather, it comes from its ability to add precision to epidemiological studies used to prove general causation.

Biomonitoring and Epidemiology: The Future of Toxic Tort Litigation?

Epidemiologists seek to discover the factors that increase the risk of a particular disease in a group of people. Leon Gordis, Epidemiology 3 (4th ed. 2009). The first step in the process is to determine whether an association exists between exposure to a factor, such as an environmental agent, and the development of a disease. Id. at 8. The second step is to determine whether the association, if it exists, is causal or, rather, results from chance. Id. Epidemiologists statistically compare groups of people with a disease (cases) with groups of people without the disease (controls); they then compare the exposures of the cases with the exposures of the controls. Generally, the larger the study population, the greater the statistical power of the study.

Collecting exposure data for epidemiological studies, however, has often been difficult. In a drinking water exposure case, for example, the epidemiologist may know the level of the alleged contaminant in the water but has to make assumptions about how much water the cases and controls each drank. In occupational exposure studies, cases and controls often answer questionnaires in which they are asked to recall their exposures over many years or even decades. Due to potentially faulty recall, exposure measurements may be lacking in precision.

The growing availability of biomonitoring data may help to bring newfound precision to the science of epidemiology. While biomonitoring results will not be universally available, where they are available, they can be quite powerful.

Some recent studies help to illustrate this point:

- Perfluorooctanoic Acid (PFOA) and Thyroid Disease. Using data from the National Health and Nutrition Examination Survey, a group of British researchers recently reported an association between blood levels of PFOA (a chemical used in non-stick coatings) and thyroid disease.

Phthalates and Behavior. Data from the Mount Sinai Children’s Environmental Health Study was used to show an association between phthalates (compounds found in plastics) in maternal urine and behavioral disorders in children. Stephanie M. Engel et al., “Prenatal Phthalate Exposure Is Associated with Childhood Behavior and Executive Functioning,” Envtl. Health Perspectives, Jan. 28, 2010, available at http://ehp03.niehs.nih.gov/article/info%3Adoi%2F10.1289%2Fehp.0901543.


The authors of these studies and others like them have used increasing amounts of biomonitoring data to bring a new level of precision to exposure assessments in epidemiological studies. Given that the CDC and others are continuing to collect these data and to make them available to researchers, we can expect to see many more such studies in the near future.

It is important, however, not to overstate the usefulness of these studies in proving causation in a toxic tort case. One study, however well researched, does not establish causation. Factors other than the precision of exposure measurements are still important. Confounders, both identified and unidentified, can influence the outcome of epidemiological studies. Courts will still have to sift through the available science and decide each case based on the weight of the evidence. Still, the combination of biomonitoring data and epidemiological analysis is a helpful development for toxic tort practitioners and the courts.

Conclusion
An individual biomonitoring result, by itself, is still not worth much in the courtroom. However, the increasing availability of large amounts of biomonitoring data, in the context of health studies such as NHANES, presents useful opportunities for both epidemiologists and lawyers. As additional work is done to analyze the growing database of information, scientists—and, by extension, lawyers—will have additional tools with which to prove or disprove causation.

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