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As PFAS Science Matures, Defendants' Opportunities for Dispositive Motions Increase

By Susan M. Razzano and John K. Adams

Introduction

The chemicals known as per- and polyfluoroalkyl substances (PFAS), which number in the thousands, continue to be the subject of substantial litigation and scientific research. Ever since the *Leach v. E.I. du Pont de Nemours & Company* C8 Science Panel issued its preliminary findings in 2012 on perfluorooctanoic acid (PFOA) and its "probable link" to certain diseases, plaintiffs in PFAS litigation have clung to this initial research to support allegations that exposure to any PFAS chemical caused their alleged injuries.[1] This story arc is not novel. From asbestos litigation to the silicone gel breast implant mass tort, the plaintiffs' bar has seized opportunities to file lawsuits alleging harm even while our understanding of the science at issue is uncertain. As a result, courts at first are reluctant to grant dispositive motions or exclude expert testimony, so long as the allegations or evidence are grounded in "scientific knowledge"—*i.e.*, reliable information from extant data or experiments.

While our understanding of PFAS compounds has advanced past the very first stages of basic scientific research, the evidence on whether and which

[1] *See Leach v. E.I. de Pont de Nemours & Co.*, No. 01-C-698 (Wood County W. Va. Cir. Ct.); *see also* C8 Science Panel, *available at* http://www.c8sciencepanel.org/prob_link.html.

Susan Razzano, a partner at Eimer Stahl, focuses her practice on product liability, toxic torts, consumer fraud litigation, antitrust, and commercial litigation, including settling and administering class action lawsuits.

John Adams, a graduate of Northwestern University's law and business schools and former CA7 clerk, is a stakeholder at Eimer Stahl, specializing in complex civil and commercial litigation along with mass torts.

PFAS chemicals can generally or specifically cause harm is still incomplete. As the science behind the causal link between myriad PFAS compounds and human disease evolves, however, courts must scrutinize whether plaintiffs' alleged injuries are plausibly related to the specific PFAS at issue. Although preliminary scientific research may have supported general allegations in earlier cases that any PFAS compound could cause injury, maturing science has heightened plaintiffs' burden to satisfy pleading standards and evidentiary requirements. This is because, while most studies to date have focused mostly on just a few PFAS such as the C8 chemicals in *Leach*, the "number of different PFAS [ranges from] 5,000-10,000, which is roughly the number of known species of mammals on Earth."[2] Accordingly, courts handling PFAS litigation are now beginning to require particularized pleadings of precise PFAS compounds and products to establish a plausible inference that defendant manufacturers or distributors bear responsibility for the PFAS products allegedly causing harm.[3]

Historical Example of Evolving Scientific Findings and Causation

In toxic tort cases, plaintiffs must establish both general and specific causation—*i.e.*, can the chemical even cause the alleged injury and did the chemical cause the alleged injury to this particular plaintiff?[4] This can be a relatively straightforward analysis in cases involving one plaintiff and one product. In large and complex mass tort cases like the PFAS litigation, however, courts have long recognized the need for special case management practices on causation to resolve alleged injuries.[5] One obvious practice is to identify a fair process to determine whether the claimed-of injury can be resolved on a groupwide basis.

Consider the silicone gel breast implant litigation. Throughout the 1990s, hundreds of thousands of women alleged that their silicone breast implants

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[2] *In re E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, 87 F.4th at 315, 321 (6th Cir. 2023).

[3] *See, e.g.*, *id.* at 320–21; *Hicks v. L'Oréal U.S.A.,* Nos. 22-cv-1989 (JPC) & 22-cv-3926 (JPC), 2023 WL 6386847, at *6–7 (S.D.N.Y. 2023).

[4] *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1103–04 (S.D. Fla. 2022) (citation omitted); *see also Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 471 (1st Cir. 2016) (explaining general and specific causation concepts in toxic tort case); *Nemeth v. Brenntag N. Am.*, 38 N.Y.3d 336, 342–43, 194 N.E.3d 266, 173 N.Y.S 3d 511 (N.Y. Ct. App. 2022) ("[I]t is well-established that an opinion on causation should set forth a plaintiff's exposure to a toxin, that the toxin is capable of causing the particular illness (general causation) and that plaintiff was exposed to sufficient levels of the toxin to cause the illness (specific causation) (citation omitted))."

[5] Federal Rule of Civil Procedure 16I(2)(L) provides the district court with broad discretion to "adopt[] special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems." *See also* Ann. Manual Complex Lit. § 22.1 (noting that, in mass tort cases, the "absence of precedent or of legislative or rule-making solutions should not foreclose innovation and creativity").

caused autoimmune disease, cancer, and other harmful side effects.[6] The science at the time of the first lawsuits neither supported nor rejected those allegations. As such, rather than dismissing the cases right away, courts presiding over early litigation appointed expert panels to advise them on general casual questions.[7] This included the multidistrict litigation (MDL) court which directed four experts in epidemiology, immunology, medicine, and toxicology to determine if any "existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone-gel breast implants cause or exacerbate" the plaintiffs' alleged injuries.[8] After a two year investigation, the science panel issued its expert opinion on general causation, concluding that there is little evidence linking implants to the alleged diseases.[9] This report gutted the erstwhile booming litigation.

The silicone gel breast implant litigation offers a few lessons on how courts approach exploding litigation involving inconclusive science. First, because of the yearslong scientific uncertainty around whether implants could cause the claimed injuries, trial courts in the early cases permitted factual and expert discovery on causation. Second, as the epidemiological evidence grew, courts became more confident resolving disputes over the scientific evidence. In *Hall v. Baxter Healthcare Corporation*, for example, prior to the release of the science panel's opinion, the court granted defendants' motion "to exclude expert testimony concerning causation of any systemic disease or syndrome" alleged to have been caused by silicone gel breast implants.[10] The court was willing to make this interim finding because the growing body of conflicting research could not "support expert testimony that silicone 'more likely than not' cause[d] disease or signs and symptoms of disease in women."[11] The court reserved final judgment on causation, however, pending final scientific results. Finally, cases filed or decided after science panel(s) release their findings based on epidemiological evidence rarely reach trial because defendants either prevail at summary judgment or settle.[12]

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[6] *See, e.g.*, *In re Breast Implant Cases*, 942 F. Supp. 958 (E.D.N.Y. 1996).

[7] 5 Modern Science Evidence Appendix B § 2 (2023).

[8] *In re Silicone Gel Breast Implant Products Liability Litigation, MDL 926*, 1996 WL 34401766 (N.D. Ala. 1996).

[9] Laura L. Hooper, *et al.*, *Assessing Causation in Breast Implant Litigation: The Role of Science Panel*, 64 Law & Contemp. Probs. 139, 144 (2001) ("[T]he panel members produced a report indicating a lack of reliable scientific evidence to establish an association between breast implants and any of the connective tissue diseases or the other autoimmune or rheumatic conditions.") (citing report).

[10] 947 F. Supp. 1387, 1394 (D. Ore. 1996); *see also* 5 Modern Scientific Evidence, Appendix B § 2 (discussing effects of *Hall* and other cases after further epidemiological evidence disproved plaintiffs' scientific allegations).

[11] *Hall*, 947 F. Supp. 1405.

[12] *See, e.g.*, *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882, 887 (10th Cir. 2005) (noting

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As past mass tort cases and the silicone gel breast implant litigation instruct, as the science matures, plaintiffs must allege (and ultimately prove) in more exacting detail that the compound to which they were exposed can and did cause their claimed-of injury. It is clearly not enough to maintain general allegations of harm resulting from a product years after scientists and researchers publish new analysis and data. PFAS litigation is not an exception as the recent case law described below demonstrates.

The Roots of PFAS Science

In 2001, a class action consisting of approximately 80,000 members was filed against DuPont alleging the class members' drinking water was contaminated with PFOA from DuPont's Parkersburg, West Virginia plant. After three years of litigation, the parties entered the "*Leach* Settlement Agreement" under which the litigation was stayed while DuPont funded a scientific panel to evaluate whether there was a "probable link"[13] between PFOA exposure and certain human diseases.[14] Seven years later, in 2012, the C8 Science Panel released its results, linking PFOA to six human diseases: high cholesterol, ulcerative colitis, thyroid disease, pregnancy-induced hypertension, and kidney and testicular cancer.[15] Thereafter, 3,500 class members who suffered from one of these diseases were allowed to bring individual personal injury claims against DuPont. DuPont could not challenge general causation for any linked disease(s), although it retained the right to challenge specific causation. As a result of the C8 Panel's findings, PFAS litigation against DuPont, other PFAS manufacturers, and the manufacturers of PFAS-containing products exploded.

The Implications of Evolving PFAS Science on Litigation

The common question in all PFAS personal injury cases relates to whether and which PFAS chemicals cause illness. Experts continue to study PFAS and their effects to answer this question. Like the early years of the silicone breast implant litigation, some scientific findings on the C8 chemistry of PFAS appear to raise serious concerns about adverse effects. But the C8 Science Panel's findings were admittedly preliminary. Indeed, one of the

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that the plaintiffs could not demonstrate general causation).

[13] "A 'probable link' in this setting is defined in the Settlement Agreement to mean that given the available scientific evidence, it is more likely than not that among class members a connection exists between PFOA exposure and a particular human disease." C8 Science Panel, *available at* http://www.c8sciencepanel.org/prob_link.html.

[14] Order Approving Final Settlement & Notice Plan, *Leach*, No. 01-C-608 (W. Va. Cir. Ct. Feb 28, 2005).

[15] *See* C8 Science Panel, *available at* http://www.c8sciencepanel.org/prob_link.html.

scientists on the C8 Science Panel admitted that it is "quite likely that some of the diseases for which [the C8 Science Panel] did declare a probable link will turn out, with improved research, to have been incorrectly judged."[16] And while more studies purporting to tie PFAS chemicals to injury have emerged, these studies have declined to offer conclusive results and are generally confined to just a few PFAS chemicals or compounds.[17] Most importantly, such studies cannot create *carte blanche* legal liability as to *all* PFAS. And the courts overseeing PFAS litigation are beginning to require better allegations or evidence linking the alleged injury to the specific chemical the plaintiffs were allegedly exposed to.

For example, nearly six years after the C8 Science Panel released its findings, the plaintiff in *Hardwick v. 3M* alleged on behalf of a class of "[a]ll individuals residing within the United States" that "human exposure to 0.05 parts per billion or more of one PFAS [or] PFOA[] in drinking water for one year or more had 'probable links' with certain human diseases," including cancer and high cholesterol.[18] And although the plaintiff supported his allegations with citations to the C8 Science Panel—arguing that "[d]ata exist[] to indicate that the presence, accumulation, toxic invasion, and/or persistence of PFAS in human blood . . . [are] injurious and physically harmful"[19]—the plaintiff declined to name the specific PFAS compound allegedly inflicting injury. Consequently, the Sixth Circuit ordered the district court to dismiss the case.[20] The Sixth Circuit reasoned that the failure to describe the allegedly harmful products in more detail was "patently insufficient to support a plausible inference that any of [the defendants] bear[s] responsibility for the particular PFAS in [the plaintiff's] blood."[21]

Similarly, the plaintiffs in *Hicks v. L'Oréal* alleged that PFOA is a "*likely* carcinogen" that harmed them when they used PFAS-containing cosmetic products.[22] The plaintiffs supported their allegations by citing preliminary research making "recommendations" on how to handle PFAS along with a 2021 study from the University of Notre Dame on PFAS in cosmetics.[23] Yet the plaintiffs refused to allege that this study from Notre Dame found actual

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[16] Sharon Lerner, *The Teflon Toxin: The Case Against DuPont*, The Intercept (Aug. 17, 2015), *available at* https://theintercept.com/2015/08/17/teflon-toxin-case-against-dupont/.

[17] *See id.* (mentioning unnamed studies from *Human Reproduction*, *Occupational and Environmental Medicine*, and *The Journal of Pediatric*); *see also Hicks,* 2023 WL 6386847, at *7–8 (noting inconclusive study).

[18] *Hardwick v. 3M Co., et al.*, No 2:18-cv-1185, Am. Compl., Dkt. 96, ¶¶ 53, 83 (S.D. Ohio 2019).

[19] *Id.* ¶¶ 53, 57.

[20] *In re E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, 87 F.4th 315, 318 (6th Cir. 2023).

[21] *Id*. at 321.

[22] *Hicks, v. L'Oréal U.S.A., Inc.*, No. 1:22-cv-01989, Am. Compl., Dkt. 25, ¶ 50 (S.D.N.Y.) (emphasis added).

[23] *Id.* ¶¶ 56–65.

evidence of harm.[24] The court therefore dismissed the complaint for failure to satisfy Article III standing, reasoning that the plaintiffs' "allegations boil[ed] down to describing general and unspecific results of [PFAS] testing, without meaningfully linking those results to [the plaintiffs'] actual" products.[25]

These recent cases and others show that absent particularized allegations (or evidence) that the defendant's product contained a PFAS compound found by science to be capable of inflicting the alleged injury, PFAS plaintiffs will have an increasingly difficult time surviving dispositive motions. While our knowledge of PFAS is still incomplete, given the recent scientific advancements, plaintiffs can no longer simply complain that an unspecified PFAS compound caused their injuries, by merely citing the preliminary findings of PFAS that are now more than a decade old. Defendants faced with new PFAS complaints should carefully review the allegations and challenge claims that do not align with the constantly evolving scientific evidence gaining acceptance in the medical community.

"[G]iven the recent scientific advancements, plaintiffs can no longer simply complain that an unspecified PFAS compound caused their injuries."

[24] *Id.* ¶ 90; *see also* Heather D. Whitehead, *et al.*, *Fluorinated Compounds in North America Cosmetics*, Environ. Sci. Tech. Letter (2021), *available at* https://pubs.acs.org/doi/10.1021/acs.estlett.1c00240.

[25] *Hicks,* 2023 WL 6386847, at *8–9; *see also Onaka v. Shisedio Americas Corp.*, No. 21-cv-10665-PAC, 2023 WL 2663877, at *5 (S.D.N.Y. 2023) (reaching similar conclusion when the plaintiffs did not plausibly allege that the presence of PFAS in their cosmetic products was so widespread as to render it plausible that any of the plaintiffs purchased a mislabeled product).