Legal Backgrounder

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The Rise and Potential Fall of the "One Molecule" Theory in Ethylene Oxide Litigation

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One of the central issues in toxic tort litigation is determining when exposure to a particular substance is sufficient to establish legal causation. In asbestos litigation, which began in the late 1960s, plaintiffs developed what became known as the "one fiber" or "every exposure" theory. Under that theory, plaintiffs argued that each inhaled asbestos fiber contributed to a person's cumulative dose and, therefore, to the development of diseases such as mesothelioma. The theory emerged in part from the practical difficulties of identifying which particular exposure—or even which particular fiber—caused a plaintiff's illness after years of exposure to multiple asbestos-containing products.

Over time, plaintiffs' counsel and expert witnesses expanded this causation framework to other chemical exposures. What began as the "one fiber" theory evolved into broader "every exposure," "any exposure," and "one molecule" theories that have appeared in litigation involving talc, ethylene oxide ("EtO"), per- and polyfluoroalkyl substances ("PFAS"), benzene, and other alleged toxic exposures. Although the terminology varies, the underlying premise remains largely the same: where a substance is alleged to have no safe threshold of exposure, each incremental exposure purportedly contributes to cumulative risk and may therefore be considered causally significant.

Defendants have consistently challenged the "one molecule" theory because it misapplies toxicological principles and ignores the fundamental concept that dose matters. Defendants explain that intensity and duration of exposure necessarily impact any potential risk associated with the alleged exposure at the levels plaintiff(s) purportedly experienced. They also argue that there is a lack of scientific evidence supporting a causal connection between trivial or *de minimis* exposures, or exposure nearing background levels, and the harm alleged in an individual case.

In the early years of EtO litigation, courts were reluctant to reject plaintiffs' theories, including the contention that any measurable exposure could be considered relevant to causation. Plaintiffs argued that EtO's purported genotoxic and mutagenic properties allow even a single molecule to trigger the cancer-causing process and that cumulative exposure renders even minimal exposures a substantial contributing factor to a plaintiff's cancer. "Any dose" theories made it past the expert admissibility and summary judgment phases in the early trial cases, and courts permitted plaintiffs' experts to present these theories at trial.

The first EtO exposure cases to go to trial were two of nearly 800 cases filed against Sterigenics in Cook County Circuit Court in Illinois, a notoriously plaintiff-friendly jurisdiction. The first, a

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breast cancer case, resulted in a verdict for plaintiff in 2022,[1] while the second, involving leukemia and a miscarriage, resulted in a full defense verdict later that year.[2]

Since the Illinois trials, parties have tried other EtO cases to verdict across the country. In 2024, a Philadelphia jury returned a full defense verdict for B. Braun Medical in a case involving a former employee's allegations that occupational exposure to EtO caused his leukemia.[3] In 2025, a Colorado jury returned a defense verdict in favor of Terumo BCT in a trial involving four plaintiffs who alleged that residential exposure to EtO emitted from Terumo's Lakewood facility caused their various cancers, including breast cancer, Hodgkin's lymphoma, and multiple myeloma.[4] Even though the court allowed plaintiffs' counsel and their experts to assert the "one-molecule" theory, the juries were seemingly not persuaded and rendered defense verdicts.

An increasing number of courts have embraced their gatekeeping role and rejected plaintiffs' causation theories in EtO litigation. Courts have grown more skeptical of plaintiffs' arguments, issuing firm rulings that reject arguments stemming from the "one molecule" theory, and signaling a clear demand for reliable, dose-specific causation analysis. The following cases exemplify these recent developments.

Pennsylvania State Court

In December 2025, a Pennsylvania state court denied plaintiff's motion for class certification in a medical monitoring EtO case alleging that a company's use of EtO at its Allentown manufacturing facility caused increased health risks for nearby residents.[5] A central aspect of the court's ruling was its determination that several of plaintiff's experts' opinions lacked a sufficient nexus to the class.

In denying class certification, the court found that plaintiff's proposed experts failed to apply scientifically reliable methodologies for establishing class-wide exposure and increased cancer risk.[6] The court noted that plaintiff's air dispersion expert did not quantify the dose experienced by individual residents even though he testified that individualized calculations would be necessary to determine each proposed class member's exposure level. The court also found that plaintiff's statistics expert, who relied on population-based epidemiological risk estimates, failed to identify a common exposure threshold to warrant medical monitoring.

Georgia State and Appellate Courts

On October 17, 2025, a Georgia state court excluded an air dispersion expert who offered the same opinions in the Pennsylvania case as well as in the 2022 Cook County trials. The Georgia court found methodological flaws in his assessment of the sterilization facility's EtO emissions and background EtO levels.[7] On appeal, the Georgia Court of Appeals vacated the trial court's order and remanded for further consideration under the Eleventh Circuit standard for admitting expert testimony in toxic tort cases.[8] The appellate court instructed the trial court to "pay careful attention

[1] *Kamuda v. Sterigenics, U.S. LLC*, No. 2018-L-010475 (Ill. Cir. Ct. Sep. 26, 2018).

[2] *Fornek v. Sterigenics U.S. LLC*, No. 2018-L-10744 (Ill. Cir. Ct. (Oct. 4, 2018).

[3] Verdict, *Glass v. B. Braun Med., Inc.*, No. 210500315 (Pa. Com. Pl. Dec. 5, 2024).

[4] Verdict, *Isaacks v. Terumo BCT Sterilization Servs., Inc.*, No. 2022CV031124 (Colo. Dist. Ct. Mar. 14, 2025).

[5] Memorandum Opinion, *Abdelaziz v. B. Braun US Device Mfg. LLC*, No. 2020-C-1984, at 4 (Pa. Com. Pl. Dec. 31, 2025).

[6] *Id.* at 24-30.

[7] *Mutz v. Sterigenics U.S., LLC*, No. 20-A-3448, 2025 WL 4075534 (Ga. State Ct. Oct. 17, 2025).

[8] *Sterigenics U.S., LLC v. Mutz*, 923 S.E.2d 176 (Ga. App. 2025).

to the experts' testimony about the dose-response relationship and whether the experts have identified a harmful level at which EtO could cause the harms alleged" and to "consider whether the experts can establish general causation through the alternative methodologies of epidemiology and background risk of disease."[9]

On March 30, 2026, the Georgia trial court reconsidered the testimony, still found plaintiffs' experts' opinions inadmissible, and again granted summary judgment for the sterilization facility. Using the standard set forth by the United States Court of Appeals for the Eleventh Circuit in *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005), the court rejected plaintiffs' contention that regulatory classifications of EtO as genotoxic and carcinogenic were sufficient to establish general causation. Rather, the court found that "the medical community does not routinely and widely recognize EtO as both toxic and causative of the alleged harm(s)," and that under *McClain*, the court must carefully analyze whether EtO is capable of causing cancer and whether it caused the specific plaintiffs' cancer.[10] The court noted that plaintiffs compounded their failure to present sufficient evidence of general causation by relying on "any exposure" theories, which warranted exclusion of their causation experts.[11]

As the *Mutz* court recognized, "[t]he dose or level of exposure at which EtO causes harm is important because, at low doses, an otherwise toxic substance may not cause the harm alleged by Plaintiffs."[12] Plaintiffs' experts admitted that there is no evidence of a threshold dose for EtO and presented "no evidence that the harm begins at a minimal level."[13] The experts instead relied on studies that were "dose-dependent at high levels of exposure," which failed to reliably support their opinions for lower doses more akin to the type alleged by plaintiffs.[14] Rejecting the "any exposure" theory, the court reasoned that the experts' "reliance on dose-response in studies puts the lie to their opinions that 'any exposure' or 'any exposure over background' can cause the harm alleged."[15]

After finding the experts' general causation opinions lacked sufficient evidence of a dose-response relationship, the *Mutz* court considered whether either of the "two other primary methodologies"— epidemiological studies or background risk of disease—could support their claims.[16] The court found that the epidemiological evidence did not support the experts' analyses because the studies only analyzed "the effect of high doses of EtO," lacked statistically significant findings, and "d[id] not take into consideration the background risk of disease."[17] Recognizing that humans produce EtO in their bodies (endogenous EtO), and that EtO exists in the ambient air from other exogenous sources, the court found that the experts lacked support for the background risk methodology. The court went a step further, determining that plaintiffs' experts improperly relied "primarily on regulatory findings and conclusory statements" of EtO's carcinogenicity.[18] Such regulatory and public health agency analyses cannot serve as evidence of causation, the court held,

[9] *Id.* at 185.

[10] Order, *Mutz v. Sterigenics U.S., LLC*, No. 20-A-3448, at 10, 12-15 (Ga. State Ct. Mar. 30, 2026).

[11] *Id.* at 15-17, 33.

[12] *Id.* at 17.

[13] *Id.* at 16-19.

[14] *Id.* at 17-19.

[15] *Id.* at 18.

[16] *Id.* at 19.

[17] *Id.* at 25-26.

[18] *Id.* at 9.

because "public policy protections and courtroom causation are not the same."[19]

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Multiple EtO litigations remain pending nationwide, and scientific causation continues to play a central role both at the expert admissibility stage and at trial. Courts serve a critical gatekeeping function in evaluating whether expert opinions on causation satisfy reliability standards under federal or state evidence rules and governing case law. As these cases progress, courts will likely grapple with tenuous expert opinions premised on "one molecule" theories and similar assumptions of causation.

[19] *Id.* at 8.