Ethylene Oxide: The Next Wave of Toxic Tort Litigation?

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December 4, 2025

Ethylene oxide (EtO) is a naturally occurring, colorless gas compound used primarily in the sterilization of medical and dental equipment, in construction, and in transportation. It can also be found in various consumer products, such as household cleaners and personal care items. The food industry employs EtO to prevent serious food-borne illnesses, such as those caused by *Salmonella and Escherichia coli (E. coli)*.

Due to EtO's ubiquity, the Environmental Protection Agency (EPA) estimates that a large class of people experience sufficient exposure to EtO that it puts them at risk of a variety of health issues. According to the EPA, short-term inhalation exposure to high amounts of EtO can cause headaches, dizziness, lung injury, fatigue, nausea, coughing, shortness of breath, wheezing, vomiting, and gastrointestinal disease. The EPA links longer-term exposure to EtO with various malignancies, including non-Hodgkin's lymphoma, myeloma, and lymphocytic leukemia, as well as breast cancer in women. The International Agency for Research on Cancer classifies EtO as a Group 1 carcinogen, meaning there is sufficient evidence that it can cause cancer in humans. However, this remains a hotly contested issue given that the epidemiological evidence based on such cancers was “limited” and relied primarily on animal studies.

Growing Litigation Over EtO Exposure

Cases arising out of EtO emissions from factories and product liability are becoming common. The Georgia Court of Appeals recently evaluated the standard that plaintiffs must meet to bring such claims. *See Sterigenics US LLC v. Mutz*, 2025 WL 3041770 (Ga. Ct. App. Oct. 31, 2025). In Mutz, eight bellwether plaintiffs lived, worked, and went to school near Sterigenics' EtO sterilization facility and were diagnosed with forms of hematopoietic, lymphatic, or breast cancer or birth defects. *Id*. at *4. The bellwether plaintiffs tendered three experts, Drs. Leslie Stayner, Dean Felsher and Aliasger Salem, who provided opinion testimony regarding general causation. *Id*. at *5. Stayner opined that there is strong evidence that exposure to EtO increases the risk of lymphatic, hematopoietic, and breast cancers. *Id*. He testified that his causation opinion was “independent of dose” and that “it's unlikely there's a safe level of exposure or threshold.” *Id*.

Felsher testified that exposure to EtO at “any level above background potentially can be a contributing cause” of cancer. *Id*. He further claimed that EtO exposure can cause “embryonic, reproductive, and developmental defects”; that there is a correlation with “intensity of exposure”; and that “it wouldn't take much” EtO to cause defects because an “embryo is only an embryo for a few days.” *Id*. Salem stated that EtO “exposure above background increases the risk of cancer” in a manner “proportional to dose and duration,” and “any exposure of [EtO] above background increases the risk of chromosomal aberrations and birth defects in a dose- and duration-dependent manner.” *Id*.

Because the trial court ruled that Stayner's general causation testimony regarding the link between EtO and lymphatic, hematopoietic, and breast cancers was admissible, the trial court denied Sterigenics' motion for summary judgment on plaintiffs' cancer claims. See *id*. at *6. However, the trial court granted summary judgment to Sterigenics on the birth defect claims after finding that Stayner did not opine on the link between EtO and birth defects and Felsher and Salem did not offer reliable opinions regarding birth defects. *Id*. Cross-appeals followed. *See id*. at *1.

Appellate Review: Applying Rule 702 and Daubert

The appellate court, in a lengthy opinion, concluded that the trial court abused its discretion by not applying the proper standard when evaluating plaintiffs' experts' opinions. See id. at *7. Because Georgia Rule of Evidence 702(b) is materially identical to Federal Rule of Evidence 702, and as Georgia courts have not addressed how to apply the reliability requirement of Rule 702(b) to general causation opinions in toxic tort cases, the court looked to the Eleventh Circuit's *McClain v. Metabolife International*, 401 F.3d 1233 (2005), and *Daubert v. Merrell Dow*, 509 U.S. 579 (1993) decisions for guidance. *Id*. at *2–4.

In so doing, the court noted the Eleventh Circuit's two-tier classification system to evaluate the admission of expert testimony on general causation in toxic tort cases. *Id*. at *3. Specifically, those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue, and those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury a plaintiff alleges. *Id*.

In vacating the trial court's order and remand for further consideration under the Eleventh Circuit, the court directed the trial court to determine whether EtO falls into the first category of toxic tort cases; i.e., whether the medical community routinely and widely recognizes that EtO is both toxic and causes the types of cancers and birth defects alleged by plaintiffs. *See Mutz* at *7.

Dose-Response and the Gatekeeper Role

If the court determines that EtO falls within the first category, the focus will shift to specific causation. *Id*. If the court determines that EtO instead falls within the second category, then the court must address the reliability of the methodology used by plaintiffs' general causation experts. *Id*. In so doing, the court must carefully evaluate the experts' testimony regarding the dose-response relationship and whether the experts identified a level of EtO that could cause the harms alleged. *Id*. The court further directed the trial court to consider whether the experts may establish general causation through the alternative methodologies of epidemiology and background risk of disease. *Id*.[1]

Defense counsel must be prepared to challenge opinions such as those expressed by plaintiffs' experts in *Mutz*; i.e., that all exposures substantially contribute to risk and/or are substantially causative to the development of claimed disease. As Paracelsus explained, “The dose makes the poison.” Given that EtO cases will likely increase as the EPA and Occupational Safety and Health Administration further regulate its use, there will be ample opportunity for the court to fulfill its scientific gatekeeper role.

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[1] While this appeal was pending, the trial court found that several of plaintiffs' experts' opinions were based on unreliable data and flawed methodology. For example, the court precluded the use of employees' badge readings to estimate the concentration of EtO in a particular room where there was no evidence as to which rooms the employees were in and calculations applied to same could not be compared to *in utero* exposure.