

**IN THE COURT OF APPEALS
FOR THE STATE OF GEORGIA**

	Trial Court Case Nos.	Court of Appeals Case Nos.
A.M. Mutz	20-A-3448	A25A1378
Lyndsey Hayes	21-A-2462	A25A1380
Chad & Karen Stephens	21-A-2425	A25A1382
Ralph Stephen Franks	21-A-2414	A25A1384
Emma Bonner	21-A-2420	A25A1386
Olivia & Roslyn Gil	20-A-3012	A25A1388
Matthew Cassacia (Goppman)	21-A-0151	A25A1390
Mary Ann Harrell	21-A-4396	A25A1392
<i>Plaintiffs-Appellants & Cross-Appellants,</i>		
v.		Appeals from the State Court of Cobb County
Sterigenics U.S., LLC, <i>et al.</i>		
<i>Defendants-Appellees.</i>		

BRIEF OF PLAINTIFFS-APPELLANTS/CROSS-APPELLANTS

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TABLE OF CONTENTS

I. Introduction 4

II. Enumeration of Errors 8

III. Jurisdictional Statement..... 9

IV. Statement of the Case..... 10

A. Sterigenics Has Been Continuously Emitting EtO—A Dangerous and Stealthy Carcinogenic and Mutagenic Gas—into the Smyrna Community for Over Five Decades 10

B. Appellants Suffered Life-Altering Injuries Consistent with Exposure to EtO from Sterigenics’ Facility.15

C. Appellants Presented Reliable General Causation Evidence from Three Eminently Qualified Experts that Opined that EtO Can Cause the Type of Injuries Suffered..... 16

D. The Trial Court Erroneously Excludes Drs. Felsher and Salem for Expressing the Conservative Opinions that Exposure to EtO Above Background Levels Increases the Risk of Developing Cancer..... 22

E. After Erroneously Excluding Drs. Felsher and Salem, the Trial Court Commits Further Error by Granting Partial Summary Judgment to Sterigenics on the Birth Defect Claims. 26

V. Argument and Authority 27

A. Standard of Review 28

B. The Trial Court Erred as a Matter of Law by Applying a More Stringent General Causation Standard Than That Required Under Georgia Law..... 29

1. Georgia toxic tort law does not require proof of dose or quantitative concentration levels to a particular toxin to prove general causation .. 29

2. The relevance and “fit” of an expert’s general causation opinions are issues determined under Georgia’s substantive tort law..... 33

C. The Trial Court Abused Its Discretion by Applying an Incorrect Legal Standard in Excluding Drs. Felsher and Salem as Experts. 36

1. The trial court erred by applying the McClain classification framework 37

2. The trial court erred by effectively finding that EtO is a category one toxin but refusing to classify it as such40

3. The trial court erred by effectively treating EtO as a category two toxin and requiring Appellants to quantify the levels of exposure while disregarding qualitative evidence of the levels of EtO exposure.....40

4. Even if EtO is a category 2 toxin, the trial court erred by failing to credit that Drs. Felsher’s and Salem’s general causation opinions were the product of recognized, accepted, and reliable methodologies 41

VI. Conclusion43

I. Introduction¹

In this toxic tort case, the question is straightforward: can ethylene oxide—a sterilizing agent that destroys microorganisms and DNA—cause cancer and birth defects in humans? Virtually every reputable scientific and medical organization says yes. As do numerous federal and international government agencies. Scientists, medical practitioners, researchers, and academics agree based on the overwhelming weight of the evidence.

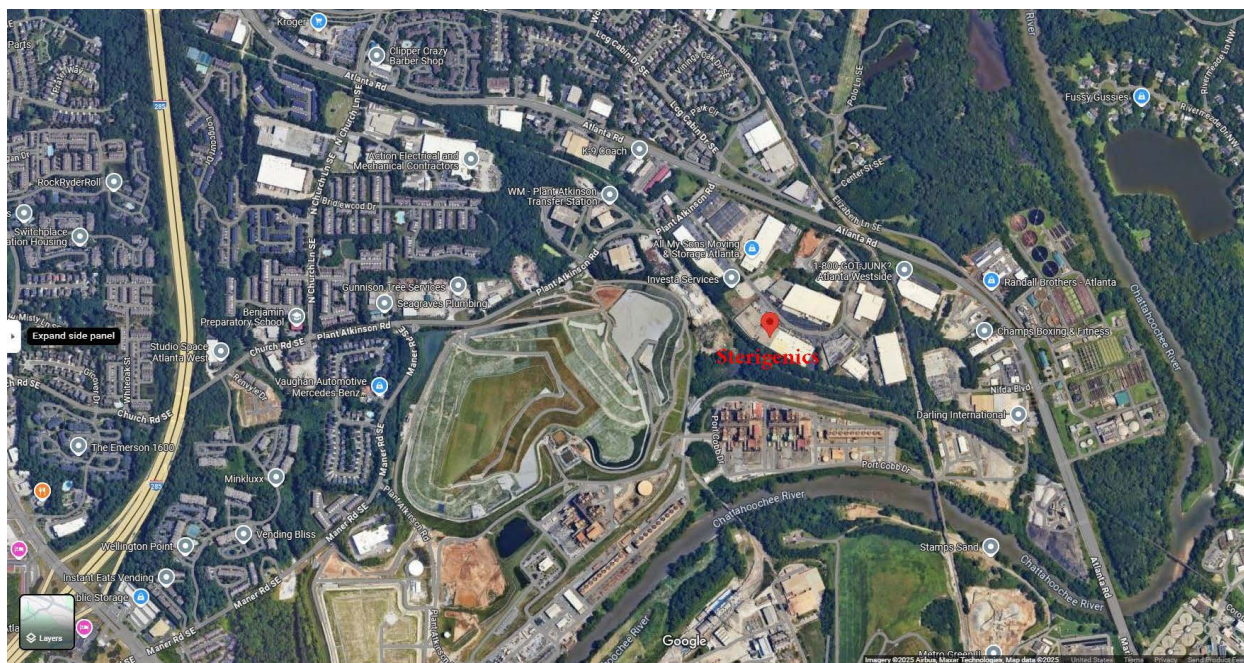
The debate is settled and the answer is clear. Ethylene oxide, commonly referred to as “EtO” is a potent human carcinogen that poses a serious reproductive hazard. This consensus is unsurprising. The scientific, medical, and industrial communities have known for decades that EtO poses such risks. In its gaseous form, EtO is colorless, odorless, and highly invasive. The EtO sterilization process was patented almost a century ago.² EtO is highly effective at destroying living microorganisms and was chosen based

¹ Although there are multiple defendants in the litigation and on appeal, the differences do not matter for purposes of these appeals and, for convenience, all are referred to as Sterigenics. Likewise, there are eight bellwether Plaintiffs. Several are Appellants and many others are Cross-Appellants herein. All references to Appellants herein encompasses and refers to Cross-Appellants across all cases. (Case Nos. A25A1377—A25A1392.)

² See U.S. Patent No. 2,189,947 (filed May 27, 1937), *available for viewing at*:<https://patentimages.storage.googleapis.com/4a/ea/48/9ccea0c3df86cfc/US2189947.pdf>

on its ability to “annihilate” and “kill” cells by irreparably damaging DNA and cell membranes. The same characteristics that make EtO an ideal sterilant make it deadly to humans—it destroys cellular organisms, human cells, and DNA indiscriminately.

Defendants-Appellees Sterigenics US, LLC and Sotera Health, LLC (and their predecessors) have been using EtO to sterilize medical supplies from a non-descript building in Smyrna. **Defendant-Appellee Prologis** is the property owner. For over half-a-century, they have annually used and emitted tens to hundreds of thousands of pounds of EtO into the nearby community. One comprised of residential neighborhoods, houses, schools, and other places of business and recreation:



(V8-347.)³

The bellwether Plaintiffs-Appellants lived, worked, and went to school near the Sterigenics' EtO sterilization facility. They were all diagnosed with forms of hematopoietic, lymphatic, or breast cancer or birth defects. Hundreds of plaintiffs, who also lived and worked in the community and developed cancer, have also filed cases in the State Court of Cobb County. These claims require proof of causation (both general and specific). The trial court bifurcated discovery on causation, first focusing on general causation—whether the toxin can cause the injury in the general population. Thus, only general causation was before the trial court in the rulings now on appeal.

To answer the general causation question, the Appellants offered the testimony of Dr. Dean Felsher and Dr. Aliasger Salem.⁴ Both have impeccable credentials and many decades of experience studying and treating cancer and birth defects. Drs. Felsher and Salem both testified that EtO can cause hematopoietic, lymphatic, and breast cancer and birth defects.

³ The image referenced in the record is from Google Earth but was uploaded in black and white and low resolution, making it grainy and hard to discern details. The color image directly from Google Earth was substituted.

⁴ Appellants also disclosed Dr. Leslie Stayner as a general causation expert on their cancer claims. The trial court denied the motion to exclude Dr. Stayner, and Sterigenics has separately appealed that ruling in their seven appeals in the other companion cases and cross-appeal in this case.

Both experts also testified that the risk of developing these conditions significantly increases at exposure levels of EtO above background levels. The trial court agreed with the proposition that EtO can cause cancer, but rejected Drs. Felsher and Salem's testimony regarding background levels of EtO and birth defects, and excluded both experts' opinions in full. The trial court then granted partial summary judgment on the birth defect claims.

In excluding these well qualified experts' opinions on cancer and birth defects, the trial court improperly applied a general causation requirement that was contrary to Georgia law. **General causation** simply requires proof that a substance **can cause** a particular illness or condition. Because EtO is widely recognized as within the highest tier of cancer-causing and mutagenic agents, the excluded testimony was sufficiently reliable to reach the jury. The trial court's inexplicable exclusion of these two experts' testimony turned on at least four reversible errors.

First, the trial court required quantitative evidence of background EtO levels, the amount by which each Appellant's exposure exceeded those levels, or both even though Georgia substantive law does not require quantitative evidence of dose or precise exposure levels to prove general causation. Qualitative evidence suffices. **Second**, the trial court applied a foreign toxin classification framework that has no basis in Georgia law.

Third, even if that framework were applicable, the court contradicted its own factual findings, applied the framework incorrectly, and fabricated an entirely new intermediate toxin category. The trial court then compounded the error by requiring quantitative proof of exposure levels for its new intermediate category. **Finally**, even if EtO required category two toxin level proof, the trial court failed to recognize that Drs. Felsher's and Salem's opinions were the product of reliable methodologies; each applied the Bradford Hill factors and considered the weight of the evidence, which included epidemiological, animal, in vitro, mechanistic, dose response assessment, and population-based studies.

Accordingly, this Court should reverse.

II. Enumeration of Errors

The trial court committed legal errors, misapplied the law, and abused its discretion by excluding the general causation opinions of Drs. Felsher and Salem and its corresponding grant of partial summary judgment on Appellants' birth defect claims. The enumeration of errors are:

1. Failing to analyze the relevance and fit of the experts' general causation opinions under the contours of the applicable substantive Georgia toxic tort law, which simply requires proof that EtO can cause cancer and birth defects.

2. Misapplying the twofold toxin classification framework utilized by the Eleventh Circuit Court of Appeals as if it were a controlling aspect of Georgia substantive toxic tort law for causation rather than an evidence rule that Georgia courts have disavowed.
3. Creating a wholly new intermediate category within the Eleventh Circuit's two-tiered framework, despite the trial court's conclusion that EtO fits within the first category of toxins for which general causation should be presumed.
4. Failing to recognize or consider that Drs. Felsher's and Salem's general causation opinions were the product of reliable and recognized methodologies.
5. Granting partial summary judgment on the birth defect claims.

III. Jurisdictional Statement

This Court has jurisdiction over this appeal and cross-appeals that arise from appeals in related cases. (A25A1377—A25A1392.) The appeal and cross-appeals are proper because they involve a granted interlocutory appeal, O.C.G.A. § 5-6-34(b), and appeal of a grant of partial summary judgment. *See* O.C.G.A. § 9-11-56(h) (“An order granting summary judgment on any issue or as to any party shall be subject to review by appeal.”). *See also Sapp v. ABC Credit*, 243 Ga. 151, 153 (1979) (Rule 56(h) “gives a ... right

to a direct appeal from an order granting summary judgment on any issue even though the judgment is not final.... This is also true where the appeal is from a grant of partial summary judgment.”). This Court has jurisdiction because this case does not fall within the categories reserved to the exclusive jurisdiction of the Supreme Court. *See* Ga. Const., Art., VI, § VI ¶¶ II-III.

IV. Statement of the Case

A. Sterigenics Has Been Continuously Emitting EtO—A Dangerous and Stealthy Carcinogenic and Mutagenic Gas—into the Smyrna Community for Over Five Decades

Since 1967, Sterigenics (and their predecessors) have actively emitted EtO gas into the residential communities surrounding their Smyrna facility. (R2-V2-8-9, 19).⁵ In ordinary environmental conditions (*i.e.*, room temperature and common atmospheric levels), EtO gas is colorless, odorless, and can persist in the environment for up to 150 days. (R2-V2-8, 15.)

Sterigenics uses hundreds of thousands of pounds of EtO gas to sterilize medical equipment, devices, and supplies in its facility at 2971 Olympic Industrial Dr. SE, Smyrna, Georgia. (R2-V2-9, 19.) Sterigenics’ building is a stone’s throw away from neighborhoods, schools, and

⁵ On April 28, the trial court supplemented the appellate record for Case No. A25A1377 with materials that were inadvertently omitted from the original record. Unless otherwise noted, materials from this supplemental record are cited using the following convention: “R2-V2-p. no.”

businesses where people live, work, and gather daily. (R2-V2-9, 19.) Sterigenics' selection of EtO as its sterilant of choice is no accident: the toxin causes "an irreversible reaction with DNA and proteins so that 'cell is now unable to repair the damage.'" (R2-V2-15.) The objective is "to destroy and kill organisms at the cellular level." (R2-V2-19.) The cells of all life forms—from amoebae, to molds, to humans—cannot withstand its cell and DNA destroying properties. (R2-V2-15.) Because it is a highly invasive gas, even the structural protections of homes, schools, or office buildings provide no safe harbor; EtO can easily penetrate solid objects such as walls, cardboard, packaging, paper, and cloth. (R2-V2-15, 20.)

Highly summarized, Sterigenics' EtO sterilization process involves injecting "overwhelming quantities" of EtO into a vacuum-sealed chamber. (V2-R2-20.) Once completed, the toxic gas in the chamber is evacuated and emitted from stacks on the facility's roof. (V2-R2-19-20.) The sterilized products are taken to an aeration room for "off-gassing" thereby creating another source of emissions. Any off-gassed EtO emissions that are not captured, routed through emission control systems, and emitted via the stacks instead escape from any cracks or crevices in the building. These emissions are known as "fugitive emissions." (V2-R2-20-21.)

For two decades, Sterigenics' Smyrna facility had *no* emission control system installed to capture EtO before it was vented from the facility's stacks. (R2-V2-9, 24-25.) As a result, virtually every pound of EtO gas used was dispersed into the surrounding communities. An emission control device was installed in 1987, which converted some EtO gas into liquid ethylene glycol. Even with this system, however, any remaining unconverted EtO gas was still emitted into the community; the facility's aeration room and exhaust chamber backvent emissions remained uncontrolled. Sterigenics installed aeration room emission controls in 2000 and backvent emission controls in 2016. (R2-V2-24-25, 27-32.) Given those operational realities, EtO emitted from Sterigenics' Smyrna facility undoubtedly invaded the surrounding community. (R2-V2-8-15.)

EtO also has other pernicious health effects and hazards. Sterigenics has known that EtO is carcinogenic since at least the early 1980s. (R2-V2-15.) Sterigenics also recognized that EtO is mutagenic, oncogenic, and hazardous to the human reproductive system. (R2-V2-15.) Indeed, for many years, Sterigenics' own safety materials unambiguously warned its employees that EtO is carcinogenic, mutagenic, a reproductive hazard, and can cause birth defects. (R2-V2-15.) Here are a few examples:

Ethylene Oxide Is Highly Toxic

- **Cancer hazard**
- **Reproductive hazard**
- **Mutagenic hazard**
- **Neurotoxic hazard**

ONE Sterigenics 4

Ethylene Oxide - Health/Safety Issues

- Ethylene Oxide is now classified as “Known to be a Human Carcinogen” (2000 National Toxicology Program Report)
- Ethylene Oxide is also a reproductive risk
- Ethylene Oxide is flammable and explosive

Because of health risks, OSHA developed an EtO standard

(DATE)



Ethylene Oxide - Health/Safety Issues

- Ethylene Oxide is classified as “Known to be a Human Carcinogen” (2000 National Toxicology Program Report)
- Ethylene Oxide is also a Reproductive Risk
- Ethylene Oxide is Flammable and can be Explosive




Ethylene Oxide - Health/Safety Issues

Because of EO's Hazards,
OSHA has unique
regulations for facilities
that handle EO.

29 CFR 1910.1047

DANGER
ETHYLENE OXIDE

**CANCER HAZARD AND
REPRODUCTIVE HAZARD;
AUTHORIZED PERSONNEL
ONLY; RESPIRATORS AND
PROTECTIVE CLOTHING
MAY BE REQUIRED TO BE
WORN IN THIS AREA.**

Sterigenics.

(V11-375; R2-V6-2985; R2-V7-3171-3172.)

Sterigenics' internal recognition that EtO is carcinogenic, mutagenic, oncogenic, and a reproductive hazard that can cause birth defects makes sense in light of the scientific consensus on EtO's dangers. Numerous reputable medical, scientific, and regulatory entities and agencies have found as such. For instance, the U.S. Environmental Protection Agency (EPA), in its 2016 IRIS assessment, determined to a "high" probability that EtO is "carcinogenic to humans." (R2-V2-228-229.) It later confirmed these findings and classified EtO as a human carcinogen and mutagen that can cause cancer in humans. (R2-V2-438-439.) Likewise, the U.S. Department of Health & Human Services Agency for Toxic Substances and Disease Registry, the Centers for Disease Control, the International Agency for Research on Cancer, the World Health Organization, the National Toxicology

Program, and the National Institute for Occupational Safety and Health all agree that EtO is carcinogenic to humans. (*See generally* R2-V3-828-834; R2-V4-1306-1830; R2-V5-1863-1864, 2007-2008; A25A1388, V2-126-128.)

There is also regulatory, scientific, and medical agreement that EtO exposure can cause reproductive harm and birth defects. The EPA and the Occupational Safety and Health Administration (OSHA) have observed that there is credible scientific and medical evidence to support an association between EtO exposure and adverse reproductive harm in both males and females. (R2-V2-2073, 2087-2088.) The EPA has specifically noted that young children are especially susceptible to the carcinogenic and mutagenic effects of EtO due to their accelerated growth rate. (R2-V2-438-439.)

In sum, Sterigenics used and emitted tremendous amounts of EtO into the community surrounding its Smyrna facility at levels far above background levels. (R2-V2-14.) Consequently, unsuspecting members of the community were unknowingly exposed to this highly invasive, extremely carcinogenic, mutagenic, and lethal cellular assassin. Tragically, Appellants were among those exposed, and their exposures caused grave, permanent, and life-altering injuries.

B. Appellants Suffered Life-Altering Injuries Consistent with Exposure to EtO from Sterigenics' Facility.

Appellants are all individuals that lived, worked, attended school, and otherwise went about their daily lives in close proximity to Sterigenics' Smyrna facility. Some lived nearby several decades; others for a shorter amount time; some lived there during the important developmental phases of childhood and adolescence. (V2-2114-2123.) Appellants share two tragic and unfortunate commonalities: (1) they all reside or resided close enough to Sterigenics' Smyrna facility to be exposed to emissions from that facility; and (2) they were all diagnosed with forms of hematopoietic, lymphatic, or breast cancer or serious birth defects. (V2-2114-2123.)

Appellants filed lawsuits asserting various tort claims against Sterigenics, contending that their cancers and birth defects were caused by EtO from Sterigenics' Smyrna facility. (A25A1378, V2-13-35; A25A1380, V2-6-29; A25A1382, V2-5-29; A25A1384, V2-5-28; A25A1386, V2-6-27; A25A1388, V2-17-39; A25A1390, V2-5-29; A25A1392, V2-8-24.)

C. Appellants Presented Reliable General Causation Evidence from Three Eminently Qualified Experts that Opined that EtO Can Cause the Type of Injuries Suffered.

Early in the proceedings, the trial court bifurcated discovery on causation into two separate phases—general causation first then specific causation second. (V2-250-276.) During the general causation phase, the trial court ordered that fact and expert discovery be directed towards the

“Threshold Causation Issue.” That is, whether “the Facility’s EtO emission can cause a particular injury or condition as alleged in Plaintiffs complaints.” (V2-263.) During the general causation discovery phase, the parties sought clarification from the trial court as to the parameters and meaning of the Threshold Causation Issue. (V2-522-546.)

On March 29, 2023, the trial court entered its order on general causation and the Threshold Causation Issue. (V2-547-549.) In that order, the trial court began by noting the two-tiered classification system employed by the Eleventh Circuit Court of Appeals in toxic tort cases; “first, those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue, and second, those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges.” (V2-547.) (citing *McClain v. Metabolife, Inc.*, 401 F.3d 1233 (11th Cir. 2005)). For toxins in the first category, no additional general causation inquiry is required. However, toxins in the second category require a more comprehensive general causation analysis. At that stage, the trial court concluded that this case “falls into the second category.” Accordingly, the trial court instructed that for general causation, “Plaintiffs must prove that exposure to EtO emission is capable of causing the harm that Plaintiffs allege,” and that to do so, they “must demonstrate the levels of

exposure that are hazardous to human beings generally.” (V2-547) (internal quotations omitted).

Based on the trial court’s general causation order, Appellants disclosed three general causation experts—Drs. Leslie Stayner, Dean Felsher, and Aliasger Salem. (V10-367-394.) Each expert had impeccable academic and work credentials and experience in their respective fields of epidemiology, oncology, and cancer biology. (V10-328-364; R2-V2-100-101, 130-202; R2-V5-2096-2154, 2312-2418.)

Dr. Felsher is board-certified in internal medicine and medical oncology, is the current Associate Chief of the Division of Oncology at Stanford University, and also runs the Dean Felsher Laboratory, devoted to investigating the oncogenic process. (V2-2060-2061; R2-V5-2346-2408.) Dr. Felsher was also the protégé of the Nobel Laureate physician and scientist credited with the discovery of oncogenes (*e.g.*, genes that initiate cancer growth). (V2-2060-2061; R2-V5-2346-2408.)

First, Dr. Felsher explained that exposure to EtO “can be considered to be a carcinogen” and that when exposures are treated as a continuous variable “there’s no level that’s not associated with some increased risk.”⁶

⁶ A continuous variable is a descriptive quality that can take any value within a specified range. Height, weight, distance, and time are common examples of continuous variables.

(R2-V6-2435, 2446.) Second, he testified that the effects of EtO exposure are exacerbated for sustained periods of exposure and exposures while a person is young and undergoing rapid physiological development. (R2-V5-2341-2342; R2-V6-2426.) Third, he testified that the increased cancer risk associated with EtO exposure is supralinear; that is, the cancer risk increases more rapidly at lower exposure levels and the marginal risk plateaus as exposure levels reach a certain high threshold, like the levels to which EtO sterilization workers are exposed. (R2-V5-2342; R2-V6-2425.)

Based on application of the Bradford Hill factors, and a weight of the evidence evaluation of epidemiological, toxicological, mechanistic, and animal studies, and the EPA's 2016 Integrated Risk Information Assessment (IRIS) (R2-V2-210-437), Dr. Felsher concluded that EtO "can be a cause of lymphohematopoietic cancers and breast cancer." (R2-V5-2320-2333; R2-V6-2499-2500.)⁷ Specifically addressing the levels of exposure that are hazardous to human beings generally, Dr. Felsher explained that "any level above background" can cause or "be a contributing cause" of lymphohematopoietic and breast cancers. (R2-V6-2425.)

⁷ The Bradford Hill factors were formulated by and are attributed to noted English epidemiologist, Sir Austin Bradford Hill. The Bradford Hill factors consist of nine factors that practitioners should weigh and consider to evaluate the strength of the evidence for a causal relationship between an exposure and an outcome. (R2-V5-2332.)

Dr. Aliasger Salem is a pharmaceutical science professor specializing in cancer biology and toxicology. (V2-2056-2057; V5-347-366.) Dr. Salem has led or contributed to numerous studies, papers, and research projects on the origin and development of cancer, including hematopoietic cancers and breast cancer. (V2-2056-2058; V5-347-366.) Dr. Salem also considered the Bradford Hill factors and weight of the available epidemiological, animal, in vitro, and mechanistic evidence and other scientific and medical literature to form his opinions on whether EtO exposure can cause hematopoietic cancers, breast cancer, and birth defects. (V2-2056-2059; V5-66, 508-509.)

Dr. Salem opined that EtO “is a genotoxic carcinogen and exposure to it increases the risk of cancer.” (V5-74.) He elaborated “that ethylene oxide exposure above background increases the risk of cancer,” that this risk “is proportional to dose and duration,” and that “exposure to ethylene oxide as a cancer-causing agent above background increases the risk proportional to the dose and duration.” (V5-67-68.)

Drs. Felsher and Salem also testified that EtO exposure can cause birth defects. Dr. Felsher explained that EtO exposure can cause “embryonic, reproductive, and developmental defects” and that “it wouldn’t take so much” EtO to do so because an “embryo is only an embryo for a few days.” (R2-V6-2515.) Similarly, Dr. Salem opined “that any exposure of ethylene

oxide above background increases the risk of chromosomal aberrations and birth defects in a dose-and-duration-dependent manner.” (V5-73-74.)⁸

In short, Appellants presented expert testimony that fully answered the two questions for general causation; that (1) “exposure to EtO emission is capable of causing the harm that Plaintiffs allege” and (2) “the levels of exposure that are hazardous to human beings generally.” (V2-547.) Appellants’ experts collectively opined that EtO exposure can cause hematopoietic, lymphatic, breast cancer, and birth defects, all of which are consistent with scientific consensus. Their opinions regarding hazardous exposure levels were a bit more nuanced. All agreed that there was no safe level of exposure that did not entail some risk. Drs. Felsher and Salem expressed the more conservative opinion that the hazardous levels of EtO exposure were at levels above background; whereas, based upon the mutagenic properties of EtO and the diminishment of risk in smaller increments at already low levels of exposure, Dr. Stayner expressed a more

⁸ As to Appellants’ final general causation expert, Dr. Stayner, the trial court found that he passed *Daubert* muster. And rightfully so. Dr. Stayner was Chief of the National Institute for Occupational Safety and Health Evaluation Branch for twenty years and co-led and co-authored four (in 1991, 1993, 2003, and 2004) of the “most reliable” and “best conducted” studies on EtO’s carcinogenicity and risks of exposure. (V6-28; V9-88-89; V10-328-363, 401.) Because Sterigenics has appealed the trial court’s ruling as to Dr. Stayner, Appellants will elaborate on the reliability and soundness of his methodology and general causation opinions in their response briefs.

measured opinion that there is likely no safe level of exposure or threshold. (V10-34-36, 256-257.)

The trial court's rulings related to Drs. Felsher and Salem misapplied Georgia law in a way that did not account for these scientifically sound and consistent, albeit nuanced, opinions, resulting in its erroneous rulings.

D. The Trial Court Erroneously Excludes Drs. Felsher and Salem for Expressing the Conservative Opinions that Exposure to EtO Above Background Levels Increases the Risk of Developing Cancer.

Sterigenics moved to exclude the testimony of Drs. Felsher, Stayner, and Salem. (V2-590-645.) Sterigenics' contended that the opinions of these three experts were unreliable, and thus, were inadmissible under O.C.G.A. § 24-7-702. Sterigenics primarily relied on decisions from the Eleventh Circuit Court of Appeals and federal district courts. (V2-567-645.) The gravamen of Sterigenics' argument was that general causation expert testimony in toxic tort causes could only survive the inquiry under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) by providing a quantitative dose-response assessment methodology showing the levels of EtO exposure that are hazardous to humans generally. Sterigenics argued that Appellants' experts failed to show a dose-response assessment, and thus, their opinions were unreliable and must be excluded. (V2-567-589, 2124-2141.)

Appellants explained that the trial court should deny Sterigenics' motions for three reasons. First, they offered reliable expert opinions complying with Georgia toxic tort causation law and the trial court's March 29, 2023, order. That is, they opined that EtO can cause both cancer and birth defects, and that any level of exposure, or more conservatively, exposure above background levels, was unsafe and increased the risk of developing such conditions. (V2-2087-2090, 2154-2159.) Second, they argued that if the two-tiered toxic tort classification system from pre-January 1, 2013 federal caselaw were applicable, EtO is a category one toxin for which Appellants had met their general causation burden. (V2-2050-2054, 2151-2153.) Finally, they argued that even if the two-tiered classification applies and the trial court deemed EtO in category two, their experts still reliably established general causation via the considerable weight of epidemiological, mechanistic, in vitro, and animal study evidence. (V2-2161-2162.)

The trial court held a hearing on Sterigenics' motions on November 14, 2024. (V14-1-111.) As it related to Drs. Felsner and Salem's opinions that exposure to EtO at levels above background was unsafe and increased the risk of developing cancer or birth defects, the trial court had "a problem with this background stuff" because the experts "never established what the levels are" or "what background is." (V14-41-42.) The trial court also struggled with

the difference between “endogenous” EtO (*i.e.*, EtO biologically generated within the human body) and “exogenous” EtO (*i.e.*, EtO generated outside the human body). (V14-42-49.)

The trial court also inquired whether it had discretion to “assess credibility” in evaluating the admissibility of an expert’s opinion under O.C.G.A. § 24-7-702. (V14-59, “Let’s talk about Felsher for a second. Am I required or am I permitted to assess credibility of witnesses in coming up with the 702 decision?”) The trial court expressed doubts about Dr. Felsher’s opinions and stated that he was “clearly biased” based on his deposition demeanor and the fact that much of Dr. Felsher’s study, work, and formulation of opinions regarding the hazards associated with EtO was conducted in conjunction with this case and other recent EtO litigation. (V14-59-60.) The trial court went so far as to declare that Dr. Felsher—a Stanford University oncologist with a cancer laboratory named after him—“has some junk science in him.” (V14-81.)

Eight days after the hearing, the trial court issued its order partially granting and partially denying Sterigenics’ motions to exclude expert testimony. (A25A1388, V2-123-141.) The trial court denied the motion as to Dr. Stayner because he “reliably opines that *any* exposure to EtO – a widely

accepted carcinogen – can cause breast, hematopoietic, and lymphatic cancers.” (A25A1388, V2-133-134.) (emphasis in original)⁹

Conversely, the trial court granted Sterigenics’ motions as to Drs. Felsher and Salem on their general causation opinions. Specifically, the trial court ruled that their opinions “that *any exposure above background* can cause cancers and birth defects ... [are] not helpful to the jury in a toxic tort case.” (A25A1388, V2-133) (emphasis in original.) The trial court characterized these opinions as “dubious” and “the scientific equivalent of the straw-that-broke-the-camel’s-back.” (A25A1388, V2-136, 140.) It concluded that these opinions were “not grounded in an adequate methodology,” relied on “cherry-picked” data, and lacked “scientific rigor.” (A25A1388, V2-138-140.) Most telling, the trial court appeared to discredit their opinions because Drs. Felsher and Salem were, according to the trial court, “new to the discipline” and had a “recent interest in EtO” in connection with “recent litigation.” (A25A1388, V2-136, 139.)¹⁰

⁹ The trial court’s one paragraph summary misconstrues and misunderstands Dr. Stayner’s general causation opinions for EtO exposure. Given that Sterigenics has appealed the trial court’s denial of its motion as to Dr. Stayner, Appellants will further address and elaborate on this point as needed in their response to Sterigenics’ principal appeal brief.

¹⁰ The trial court’s exclusion of Drs. Felsher and Salem was especially puzzling in light of the fact that both have survived *Daubert* challenges in two materially identical EtO cases in the State Court of Gwinnett County,

E. After Erroneously Excluding Drs. Felsher and Salem, the Trial Court Commits Further Error by Granting Partial Summary Judgment to Sterigenics on the Birth Defect Claims.

The trial court's order partially granted and partially denied Sterigenics' motions to exclude expert testimony, and also concomitantly partially granted and partially denied Sterigenics' summary judgment motion. (A25A1388, V2-123-141.) Based upon its ruling that Dr. Stayner's cancer-related general causation opinion was reliable and admissible, the trial court denied Sterigenics' motion on Appellants' breast, hematopoietic, and lymphatic cancer claims. (A25A1388, V2-141.) But based on the exclusion of Drs. Felsher and Salem, the trial court granted summary judgment on Appellants' birth defect claims. (A25A1388, V2-134-135, 141.)

The trial court failed to follow binding Georgia law and, instead, dogmatically adhered to the Eleventh Circuit's two-tiered classification system (except for not following it properly despite the trial court's factual findings) for toxins in toxic tort cases. The trial court did so even though the Eleventh Circuit's two-tiered system has never been adopted or applied as a matter of Georgia's toxic tort substantive law; it conflicts with recent binding

Georgia, *see Buczek v. Sterigenics U.S., LLC*, Case No. 20-C-05918-S1; *Walker v. Becton Dickinson*, 21-C-08201-S1, as well as several other EtO cases in Illinois and Colorado.

appellate case law. Finally, despite expressly finding “that EtO is generally accepted in the scientific community as a known carcinogen,” the trial court declined to classify EtO as a category one toxin. (A25A1388, V2-128.) Instead, the trial court arbitrarily fabricated an intermediate, blended classification “between category one and category two toxins” (*e.g.*, a category 1.5). Then it analyzed the admissibility of Appellants’ experts under this new and previously non-existent standard. (A25A1388, V2-133.) The trial court erred at every step in this process.

Appellants timely filed this notice of appeal on December 11, 2024. (A25A1388, V2-1-3.)¹¹ Sterigenics timely appealed, and Cross-Appellants timely filed their notices of cross-appeal. (A25A1377, 1379, 1381, 1383, 1385, 1389, 1391-V2-1-8; A25A1378, 1380, 1382, 1384, 1386, 1390, 1392-V2-1-4.)

V. Argument and Authority

The trial court committed four critical legal errors in excluding Drs. Felsher’s and Salem’s general causation opinions. First, it failed to apply Georgia’s substantive toxic tort law for causation in analyzing the reliability and “fit” of their opinions on general causation. Instead, it applied an

¹¹ Unless otherwise noted, most citations to the record herein are to the record for the direct appeal in Case No. A25A1377, *Sterigenics, et al. v. Mutz*. Plaintiffs will indicate citation to the record from any of the other appeals using the convention “Case No., Vol. No.—Page No.”

incorrect legal standard by adopting and applying the two-tiered toxin classification framework used by federal courts. Second, even if this two-tiered classification system applies, the trial court erred by effectively finding that EtO is a category one toxin but refusing to classify it as such. Third, the trial court erred by effectively treating EtO as a category two toxin and requiring quantitative evidence of exposure levels. Finally, even if the two-tiered classification system and the more stringent methodologies required by federal courts for general causation did apply in Georgia, the trial court erred by disregarding that Drs. Felsher and Salem employed reliable methodologies in formulating and reaching their general causation opinions.

A. Standard of Review

An appellate court reviews de novo “a question of law regarding whether a trial court correctly interpreted and applied” the correct legal standard. *Great West Cas. Co. v. Bloomfield*, 303 Ga. App. 26, 27 (2010). *See also Temples v. Hitson*, 369 Ga. App. 767, 768 n.1 (2023) (“This appeal presents a question of law, which we review de novo.”); *State v. McKnight*, 367 Ga. App. 633, 634 (2023) (“When an issue turns on the proper interpretation of a statute, it is a question of law, which is reviewed de novo on appeal.”).

“Whether expert testimony ought to be admitted under OCGA § 24-7-

702 is a question committed to the sound discretion of the trial court.” *Natl’l Emergency Med. Servs. v. Smith*, 368 Ga. App. 18, 22 (2023) (cleaned up). But the application of the incorrect legal standard is always an abuse of discretion. *State v. Berman*, 367 Ga. App. 447, 450 (2023).

B. The Trial Court Erred as a Matter of Law by Applying a More Stringent General Causation Standard Than That Required Under Georgia Law.

1. Georgia toxic tort law does not require proof of dose or quantitative concentration levels to prove general causation.

As with any tort case brought under Georgia law, questions regarding causation (*i.e.*, general and specific causation in a toxic tort case or cause-in-fact and proximate cause in a garden-variety tort case) are controlled by and decided under Georgia substantive law. *See Norfolk S. Ry. v. Zeagler*, 293 Ga. 582, 587 (2013) (comparing Georgia’s substantive law for causation in tort cases with that applicable in tort claims brought under FELA). By contrast, the court’s inquiry into the admissibility of expert testimony is an evidentiary matter decided under O.C.G.A. § 24-7-702.

In the absence of any Georgia appellate caselaw interpreting and applying Georgia’s evidence rules, Eleventh Circuit caselaw existing as of January 1, 2013 that interprets and applies a materially identical federal rule “also reflects” the meaning of Georgia’s rule; federal cases decided after that date are only “persuasive authority.” *State v. Alamanza*, 304 Ga. 553, 558-

59 n.5 (2018). But precedential value—dispositive, persuasive, or otherwise—of federal caselaw interpreting rules of evidence “ends” when “a Georgia appellate court decides the issue under the new Code.” *Id.* at 558.

In assessing the “relevance” of an expert’s testimony under O.C.G.A. § 24-7-702, a “court must consider the ‘fit’ between the expert testimony and the issues in dispute.” *Scapa Dryer Fabrics, Inc. v. Knight*, 299 Ga. 286, 290 (2016). In making this determination, a court must assess whether an expert’s opinions “‘fit’ the pertinent causation inquiry under Georgia law.” *Id.* Consequently, in a toxic tort case brought under Georgia law, the “fit” determination is made following Georgia substantive tort law.

In a toxic tort case under Georgia law, a plaintiff must offer proof of “exposure to a toxic chemical” and causation. *Ga. Power Co. v. Campbell*, 360 Ga. App. 422, 427 (2021). The causation requirement has two sub-components—general causation and specific causation. General causation requires a plaintiff to prove “that exposure to a substance is capable of causing a particular injury or disease” whereas specific causation requires proof “that exposure to a substance under the circumstances of the case contributed to his illness or disease.” *Id.* (quoting *Fouch v. Bicknell Supply Co.*, 326 Ga. App. 863, 868 (2014)).

Here, Appellants' exposure to **some** EtO from Sterigenics' Smyrna facility is undisputed. (R2-V2-8-19; (V8-75-78, 360-362.) The trial court bifurcated causation discovery into separate phases for general and specific causation, and this appeal involves issues and trial court rulings that arose exclusively during the general causation phase. Consequently, these appeals only implicate questions concerning general causation—whether EtO can cause hematopoietic, lymphatic, and breast cancer and birth defects in the general population.

As its name implies, general causation under Georgia law is a more general inquiry than that involved in specific causation. *See Fulmore v. Csx Transp.*, 252 Ga. App. 884, 891-92 (2001), *overruled in part on other grounds by, Norfolk & W. Ry. v. Ayers*, 538 U.S. 135 (2003) (stating general causation involves “whether exposure to a substance **is capable of causing a particular injury or disease**” while specific causation involves “whether exposure to a substance **under the circumstances of the case** caused a particular plaintiff's illness or disease”) (emphasis added); *Butler v. Union Carbide Corp.*, 310 Ga. App. 21, 25 (2011) (“General causation is whether a substance is capable of causing a particular injury or condition **in the general population**, while specific causation is whether a substance caused a particular individual's injury.”) (emphasis added); *Smith v. CSX*

Transp., Inc., 343 Ga. App. 508, 514 (2017) (noting that general causation involves proof of whether certain activities “**can cause**” a condition or injury) (emphasis added; italics in original).

In *Fouch*, a panel of this Court provided further guidance as to the type of evidence that is sufficient to prove causation in a toxic tort case:

“While proving both types of causation involves a question of the concentration levels of the toxin to which the plaintiff was exposed, there is no specific requirement that the plaintiff show specific air measurement readings or **dosage amounts** in order to establish causation. Rather, in toxic tort cases, proof of causation generally requires reliable expert testimony[.]”

Fouch, 326 Ga. App. at 868-69 (cleaned up; emphasis added). In *Scapa*, our Supreme Court approvingly cited *Fouch*. It noted that Georgia toxic tort law does not require “the plaintiff’s expert to estimate the extent of the exposure in **precise quantitative terms**” because “[s]uch an estimate may not be possible in many cases, and our Court of Appeals has held that it is not absolutely required.” *Scapa*, 299 Ga. at 292 n.9 (emphasis added). Instead, Georgia law allows one to prove exposure levels to a particular toxin by providing a “qualitative” expert opinion or assessment. *Id.* at 293. See *McKenney’s, Inc. v. Sinyard*, 350 Ga. App. 260, 272 (2019) (holding that plaintiff’s qualitative evidence of “exposure to ‘great amounts’ of asbestos” sufficed to prove causation despite lack of quantitative evidence).

These cases make plain four important legal principles. First, a plaintiff

must generally prove some exposure to a toxin and causation. Second, as to the first sub-component of causation—general causation—a plaintiff must prove that the toxin **can cause a particular injury or condition in the general population**. Third, proof of a quantitative dose or concentration level is not required for general causation. Finally, the proof required for general causation is not exacting, can be qualitative, and does not need to meet a particular quantifiable standard. Indeed, courts routinely find minimal evidence of a general nature adequate. *See Bowers v. CSX Transp., Inc.*, 369 Ga. App. 875, 877 (2023) (noting that CSX did not challenge “general causation” expert testimony that diesel fumes can cause particular injuries); *Wadley v. Mother Murphy’s Lab, Inc.*, 357 Ga. App. 259, 264 (2020) (noting general causation was not in issue in case involving injuries caused by exposure to diacetyl); *CSX Transp., Inc. v. McDowell*, 294 Ga. App. 871, 874 (2008) (challenge to specific causation expert testimony for injuries caused by exposure to hydrogen sulfide); *Shiver v. Ga. & Fla. Railnet, Inc.*, 287 Ga. App. 828, 830 (2007) (suggesting expert’s testimony that “it is common knowledge that diesel fumes are dangerous to breathe” sufficient to prove general causation).

2. The relevance and “fit” of an expert’s general causation opinions are issues determined under Georgia’s substantive tort law

The trial court determined that Drs. Felsher's and Salem's general causation opinions that EtO exposure above background levels can cause hematopoietic, lymphatic, and breast cancer and birth defects lacked proper "fit" under O.C.G.A. § 24-7-702. This "fit" determination, however, was erroneous as a matter of law because the trial court expressly made it under "the jurisprudence of the 11th Circuit." (A25A1388, V2-133.) In so doing, the trial court abdicated its gatekeeping function and applied a foreign legal standard that is entirely inappropriate and inconsistent with Georgia law. The Georgia Supreme Court has made it abundantly clear that in evaluating an expert's opinions for "fit" under O.C.G.A. §24-7-702 "the pertinent causation inquiry [arises] under Georgia law." *Scapa*, 299 Ga. at 290.

Here, the trial court was required to analyze the relevance and "fit" of Drs. Felsher's and Salem's general causation opinions that EtO exposure can cause hematopoietic, lymphatic, and breast cancer and birth defects under Georgia substantive toxic tort law. And Georgia substantive law that has plainly disavowed any requirement that a plaintiff provide quantitative evidence, such as "dose" or precise exposure levels to prove whether a toxin **can cause** a particular injury or condition. *Id.* at 292 n.9; *Fouch*, 326 Ga. App. at 868-69. Yet, the trial court improperly required Plaintiffs to provide such quantitative evidence for Drs. Felsher's and Salem's opinions to have

proper “fit.” (A25A1388, V2-140.) The trial court rejected the “‘any exposure above background’ standard when the background level is not **quantified.**” (emphasis added); (V14-41-42, trial court stating that it had “a problem with this background stuff” because Plaintiffs’ experts “never established what the levels are” or “what background is.”)

Furthermore, the trial court overlooked or ignored the considerable qualitative evidence upon which Drs. Felsher’s and Salem’s general causation opinions were based. Namely, each applied the Bradford Hill considerations and analyzed the weight of the evidence, including hundreds of epidemiological, in vitro, animal, and mechanistic studies, Sterigenics’ own documents that identify EtO as a cancer and reproductive hazard, and each experts’ decades of experience treating and researching oncology, toxicology, and mutagenicity of various toxins.

Recent decisions from this Court strongly indicate that Bradford Hill and weight of the evidence are reliable general causation methodologies. *See Bowers*, 369 Ga. App. at 876-77 n.3 (noting that CSX did not challenge “general causation” expert testimony that diesel fumes can cause lung cancer that was based on “International Agency for Research on Cancer literature, which synthesized various studies and confirmed a causal link between lung cancer and exposure to diesel exhaust, asbestos, and silica”); *Wadley*, 357

Ga. App. at 262 (noting that expert’s general causation opinion that exposure to low levels of diacetyl can cause lung disease, which was based on “numerous” articles and “the overall weight of the evidence,” was unchallenged). *See also Humphrey v. Emory Clinic, Inc.*, 369 Ga. App. 131, 139 (2023) (concluding expert’s causation opinion was “deficient” because it was not based on “any peer-reviewed literature,” “adequate study,” or “any published scientific studies”); *Bowers*, 369 Ga. App. at 885 (McFadden, P.J., dissenting) (describing “the Bradford Hill criteria” as “a widely accepted set of criteria for determining causation in cases of chronic disease”).

These were critical errors of law by the trial court. But as discussed below, the trial court also abused its discretion by committing additional legal errors that independently, or cumulatively, resulted in reversible error.

C. The Trial Court Abused Its Discretion by Applying an Incorrect Legal Standard in Excluding Drs. Felsher and Salem as Expert Witnesses.

Georgia’s evidence rules govern the reliability of Drs. Felsher’s and Salem’s general causation opinions. *See* O.C.G.A. § 24-7-702–703. Yet, the trial court failed to apply the proper legal and evidentiary framework and committed several errors in determining that those opinions were unreliable and lacked proper “fit” under Georgia’s evidence rules.

1. The trial court erred by applying the McClain toxin classification framework.

The trial court applied the two-tiered classification system announced by the Eleventh Circuit Court of Appeals in *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005). In evaluating the admissibility of expert testimony for general causation, *McClain* delineated between two categories of types of toxins and set out different standards for each. The first category involves “those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue,” while the second category involves “those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges.” *McClain*, 401 F.3d at 1239. Although there is no exhaustive list describing which toxins fall into which category, *McClain* listed asbestos, silica, and cigarette smoke, as examples of category-one toxins. For category one toxins, *McClain* held that “an extensive *Daubert* analysis” on general causation is unnecessary “when the medical community recognizes that the agent causes the type of harm plaintiff alleges.” *Id.*

Although *McClain* was decided prior to January 1, 2013, and was thus incorporated into O.C.G.A. 24-7-702, this applies only to interpretation and application of rules and provisions in that statute that are “materially identical” to federal rule 702. *Almanza*, 304 Ga. at 556. Even then, that

precedential value “ends” when “a Georgia appellate court decides the issue under” Georgia’s evidence rules. *Id.* at 558. Regardless, questions of relevance and “fit” of an expert’s testimony are decided under Georgia substantive law; not matters decided solely under Georgia’s evidence rules.

Here, the *McClain* two-tiered toxin classification framework is a component of federal toxic tort substantive law; not an interpretation of federal rule of evidence 702 expressly or impliedly grafted into that rule. Consequently, the trial court lacked any discernible legal basis for concluding that the *McClain* toxin classification framework was grafted into Georgia’s substantive toxic tort law. Even if the *McClain* toxin classification framework were an evidence rule component that could have provided an understanding of what O.C.G.A. § 24-7-702 means, any such understanding ended when Georgia appellate courts decided cases involving the admissibility of toxic tort expert testimony under O.C.G.A. § 24-7-702.

Notably, *Scapa* (2016) and *Fouch* (2014) were both decided after January 1, 2013. Neither case mentions, adopts, or applies the *McClain* toxin classification framework. *See generally, Scapa*, 299 Ga. at 290-94; *Fouch*, 326 Ga. App. at 869-871. Sterigenics argued below that *Scapa* and *Fouch* involved asbestos and silica exposure respectively, and thus, application of the *McClain* toxin classifications was unnecessary because only specific

causation was at issue. True enough. *See Scapa Dryer Fabrics, Inc. v. Knight*, 332 Ga. App. 82, 95 (2015) (noting “general causation ... is undisputed” because exposure to asbestos “is capable of causing mesothelioma in the general population”); *Fouch*, 326 Ga. App. at 871 (noting silicosis “results only from an exposure to silica”). *Scapa* and *Fouch*—and their description of reliable causation evidence—remain relevant even if they had expressly cited *McClain* and acknowledged that asbestos and silica were category one toxins. But *McClain*’s list of category one toxins was not exhaustive, and it did not limit its holding to toxins with “signature diseases,” as cigarette smoke was a category one toxin.¹²

Regardless, this Court has decided several cases after January 1, 2013 that involve toxins that would qualify as category two toxins under *McClain*, yet none of those cases mention or apply this framework. *See Cleveland v. Sentinel Ins. Co.*, 354 Ga. App. 795 (2020) (mold); *Wadley*, 357 Ga. App. at 259 (diacetyl); *Bowers*, 369 Ga. App. at 877 (diesel smoke).

Accordingly, the *McClain* two-tiered toxin classification framework is not part of Georgia’s substantive toxic tort law, and the trial court erred by forcing Appellants to prove their case within that framework.

¹² Cigarette smoke is commonly associated with lung cancer, but it causes and has been associated with other diseases (*e.g.*, throat cancer, emphysema, chronic obstructive pulmonary disease, etc.).

2. The trial court erred by effectively finding that EtO is a category one toxin but not classifying it as such.

Even if the *McClain* classification framework were a part of Georgia's substantive toxic tort law or evidence rules, the trial court erred by concluding that EtO was not a category one toxin. A category one toxin is one "in which the medical community generally recognizes the toxicity of the drug or chemical at issue[.]" *McClain*, 401 F.3d at 1239. The trial court found that EtO was such a toxin when it found "EtO is generally accepted in the scientific community as a known carcinogen." (A25A1388, V2-128.)¹³ This sufficed for general causation and should have ended the analysis.

Yet, the trial court inexplicably created a new, intermediate category one-and-a-half toxin out of thin air. It then imposed evidentiary requirements for this new category that were wholly consistent with a category two toxin by requiring quantitative evidence of a dose or hazardous threshold levels. This was further error.

3. The trial court erred by effectively treating EtO as a category two toxin and then requiring Appellants to quantify the levels of exposure while disregarding qualitative evidence of the levels of EtO exposure.

¹³ At least one court outside Georgia has recognized EtO as a "category one" toxin under the *McClain* framework. *See, e.g.,* Combined Order on Defendants' Motions for Determination of Law, *Issacks et al. v. Terumo et al.*, 2022CV031124 (Dist. Ct. Colo., Jan. 8, 2025) at 4-5.

The trial court's evidentiary requirement for its newly created category one-and-a-half toxin is hopelessly flawed and problematic. For starters, it required Appellants to "offer expert opinion saying **any** exposure to EtO causes [their] injury." (A25A1388, V2-133.) (emphasis added). Yet, it required Drs. Felsher and Salem to quantify background EtO levels, levels above background, or both for their opinions to be reliable and fit under O.C.G.A. § 24-7-702. This was contrary to Georgia law, not to mention the trial court's own requirements for a category one-and-a-half toxin.

Moreover, the trial court failed to consider the substantial qualitative evidence that supported Drs. Felsher's and Salem's opinions that exposures to EtO increases the risk of developing cancer or birth defects. *See infra* § V.B.2. (R2-V6-2435, 2446, Dr. Felsher testifying that "there's no level [of EtO] that's not associated with some increased risk.")

4. Even if EtO is a category two toxin, the trial court erred by failing to credit that Drs. Felsher's and Salem's general causation opinions were the product of recognized, accepted, and reliable methodologies.

Assuming, *arguendo*, that EtO is a *McClain* category one-and-a-half or two toxin, Drs. Felsher's and Salem's opinions that exposure to EtO above background levels can cause cancer and birth defects are based on reliable and recognized methodologies.

Post-*McClain*, the Eleventh Circuit has recognized three “indispensable” methodologies to prove general causation in a toxic tort case: “dose-response, epidemiological evidence, and background risk of disease.” *Chapman v. P&G Distrib., LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014). An “expert must rely on at least one of three 'primary' types of evidence for his or her [general causation] opinion to be considered reliable.” *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1181 (S.D. Fla. 2022) (internal citations omitted; brackets added).

Here, Drs. Felsher’s and Salem’s general causation opinions were grounded in all three methodologies. First, they relied on numerous peer-reviewed and respected epidemiological cohort and other studies that show an association between EtO exposure and developing cancer. Even Sterigenics’ experts cite and rely on many of these studies, further validating their reliability. Second, they consider background risk in the form of population-based studies. Finally, they did consider dose: that EtO exposure above background levels increases the risk of cancer and birth defects. But even if this methodology were problematic (it is not), the use of the other two primary methodologies—epidemiology and background risk—render their general causation opinions reliable. *Henderson v. Lockheed Martin Corp.*, 2023 U.S. Dist. LEXIS 237286, *30-31 (M.D. Fla. Sept. 15, 2023) (noting

dose-response “is not the *only* way, nor is it even the best way” to prove general causation).

Simply put, the trial court determined these issues under federal substantive law that did not apply, ignored subsequent opinions of this Court and the Supreme Court of Georgia on the 702 framework, and overlooked other acceptable methodologies under the federal 702 decisional law in reaching its unusual conclusion—that opinions that EtO causes cancer and birth defects are inadmissible. And doing so despite its express finding that EtO is generally known by the scientific community to cause cancer because it is a direct acting mutagen.

VI. Conclusion

The prevailing consensus among scientific, medical, and governmental authorities is that EtO can cause cancer and birth defects. Appellants’ experts, Drs. Felsher and Salem, agreed that EtO can cause cancer and birth defects. They developed their opinions by applying the widely accepted Bradford Hill factors, and considering the weight of the evidence, including hundreds of reliable epidemiological, in vitro, animal, mechanistic, and population-based studies. Their opinions are reliable and admissible and fit the pertinent causation inquiry under Georgia substantive toxic tort law.

Instead of analyzing these opinions under Georgia substantive law, the

trial court applied foreign federal law that starkly departs from Georgia law. This misapplication of the proper legal standard was legal error and warrants reversal. But the trial court committed further errors by misapplying Eleventh Circuit evidence rules and—despite effectively finding EtO was a category one toxin—fabricating a new intermediate category that required quantitative proof akin to a category two toxin. Finally, the trial court disregarded the fact that Drs. Felsher’s and Salem’s general causation opinions were the product of reliable and acceptable methodologies for proving the toxicity of a category two toxin.

Accordingly, the trial court’s exclusion of Drs. Felsher and Salem, and the subsequent grant of partial summary judgment on the birth defect claims, were the product of legal error. This Court should reverse.

This submission does not exceed the word count limit imposed by Rule 24.

Respectfully submitted this 1st day of May, 2025.

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CERTIFICATE OF SERVICE

I certify that there is a prior agreement with opposing counsel to allow documents in a PDF format sent via email to suffice for service and that I have served a copy of this **Principal Brief of Plaintiffs-Appellants and Plaintiffs-Cross-Appellants** by such means to the following counsel of record:

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