IN THE COURT OF APPEALS OF GEORGIA

Case No. A26A1118

BECTON, DICKINSON AND COMPANY and C. R. BARD, INC.,
Defendants/Appellants,

v.

GARY WALKER
Plaintiff/Appellee.

On Certificate of Immediate Review from the
State Court of Gwinnett County, No. 21-C-08201-S1

AMENDED *AMICUS CURIAE* BRIEF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED) IN SUPPORT OF DEFENDANTS/APPELLANTS

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STATEMENT OF INTEREST[1]

The Advanced Medical Technology Association ("AdvaMed") is the world's largest medical technology association, with approximately 650 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards. The innovations created by AdvaMed's members advance efficiency in health care through earlier disease detection and more effective treatments which, in turn, reduce the economic burden of disease and allow people to live longer, healthier, and more productive lives.

AdvaMed and its members have a strong interest in this appeal because ethylene oxide (EtO) is one of the most common methods used to sterilize medical technology and is crucial for preventing infections in patients undergoing surgical procedures and other medical treatments. Imposing liability over exposure to EtO without the proper legal, factual and scientific foundation would hinder the availability and use of this critical product. Without EtO, patients would face a

[1] *Amicus* states that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus*, its members, and its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

heightened risk of serious infection or lose access to lifesaving equipment as there is no alternative sterilization method for many devices.

STATEMENT OF THE CASE

Amicus adopts Defendants'/Appellants' Statement of the Case to the extent necessary for the arguments stated herein.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

This case involves alleged exposures to ethylene oxide (EtO), one of the most important and studied chemicals in the world. Among its many uses, it is critical to the ability of medical device manufacturers, hospitals and other health care providers to properly sterilize medical devices and other equipment to prevent life-altering and life-threatening infections. EtO is also ubiquitous. It exists in the atmosphere everywhere, is generated through numerous everyday activities, and is even created independently in the human body. Because high-level exposures over long periods of time have potential risks, EtO use is highly regulated by federal agencies and international bodies. Here, Mr. Walker tragically developed Diffuse Large B-Cell Lymphoma, the most common type of non-Hodgkin lymphoma. In this lawsuit, he alleges this disease was caused by exposure to EtO only at Defendant's facility in Georgia. To prevail, he must present expert testimony that shows, among other things, EtO can cause this cancer, how much exposure to EtO causes this cancer, and he was exposed to at least that amount from the BD facility.

It is uncontroverted that Mr. Walker's experts failed to make any of these required showings. Rather than exclude this testimony, though, the trial court allowed his experts to testify that Mr. Walker's exposure to EtO at the BD facility *caused* his cancer. This ruling is reversible error. The trial court rejected Eleventh Circuit precedent—which has since been adopted by this Court—requiring a plaintiff's experts to identify a threshold level of exposure necessary to cause injury in a toxic-tort case like this one. *See McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005); *Sterigenics US LLC v. Mutz*, 923 S.E.2d 176, 185 (Ga. Ct. App. 2025). In fact, this Court's ruling in *Sterigenics* involved EtO, just like the one here. This requirement makes sense: people are regularly exposed to EtO without incident, and EtO has a risk of harm only above certain levels. Compounding matters, the trial court excluded Defendant from introducing evidence of other sources of EtO. Thus, the jury was handcuffed. It was given allegations of causation not grounded in sound science and denied facts of potential alternative exposures.

The appeal has considerable importance for the ability of Georgians—and all Americans—to access quality health care. A liability finding based on Plaintiff's theory that *any exposure* to EtO at BD's facility caused his cancer will undermine the use of EtO, thereby preventing medical device manufacturers and hospitals from properly sterilizing their equipment. The result would be preventable infections and

significant harm—all without any reliable scientific determination that Mr. Walker's alleged EtO exposure from BD's facility could have caused or caused his cancer.

For these reasons, *amicus* respectfully requests that this court reverse the judgment below. The Court should ensure proper causation standards are applied, only truly at-fault parties are held responsible, and highly beneficial medical device sterilization is not improperly blamed—and then compromised—unnecessarily.

ARGUMENT

I. ETO IS A CRITICAL, REGULATED STERILIZER FOR MEDICAL DEVICES, AND LIABILTY BASED ON EXPOSURE TO ETO MUST NOT BE MADE WITHOUT PROPER SCIENTIFIC FOUNDATION.

EtO was discovered in the 1850s and has been a commercial sterilizer since the 1920s. *See* William Rutala & David Weber, *Sterilization of 20 Billion Medical Devices by Ethylene Oxide (ETO): Consequences of ETO Closures and Alternative Sterilization Technologies/Solutions*, 51 Am. J. of Infection Control 11, A82-A95 (2023).[2] Originally used to prevent premature spoilage in packaged meats, it has been employed since World War II in a wide variety of fields, "including the production of textiles, personal care items, and the sterilization of medical devices, cosmetics, and spices." AdvaMed, *Ethylene Oxide Sterilization's Invaluable Role in Protecting Public Health,* (accessed January 29, 2026) (hereinafter "Advamed").[3]

[2] https://www.ajicjournal.org/article/S0196-6553(23)00057-3/fulltext.

[3] https://www.advamed.org/our-work/key-issues/sterilization-ethylene-oxide/.

During this time, EtO has become an integral component of America's health care system, becoming the primary method for sterilizing plastic and other heat-sensitive devices for which there were, and still are, no other means of sterilization. *See id.*

EtO gas has strong microbicidal activity. As the Center for Disease Control has explained, it disrupts microbial metabolism and replication and inactivates bacteria, viruses, fungi, and even resistant spores. *See* CDC, *Ethylene Oxide "Gas" Sterilization*, Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008).[4] It is compatible with many medical device materials, which enables manufacturers to develop devices that would not be possible without EtO. It also has the unique ability to penetrate packaging and plastic without damaging them, infiltrating the cardboard box, through the outer wrap, and through layers and items inside. Rutala & Weber, *supra*, at A86.[5] Thus, it can effectively sterilize otherwise hard-to-sterilize product configurations, including the inside of plastic tubing such as catheters as well as entire device surgical kits. For example, the open-heart procedure pack contains over 75 items—from plastic tubing to metallic surgical blades—and EtO is the only sterilizer compatible with all of these products. *See id.*

[4] https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/ethylene-oxide-sterilization.html?utm_source=chatgpt.com.

[5] https://www.ajicjournal.org/article/S0196-6553(23)00057-3/fulltext.

Currently, about half of all medical devices in the United States are sterilized with EtO. *See* Scott Whitaker, AdvaMed President and CEO, *Testimony to the United States House of Representative's Committee on Energy and Commerce's Subcommittee on the Environment, Manufacturing and Critical Materials* (October 18, 2023) (hereinafter "*Whitaker Testimony*").[6] The Federal Food and Drug Administration (FDA) has cleared EtO for more single-use medical devices than any other sterilization modality (50,000 devices), and it is used on some twenty billion medical devices per year. *See* Rutala & Weber, *supra*, at A88.[7] Today, 95 percent of all surgical instruments are sterilized with EtO, including syringes, sutures, catheters, IV sets, plastic tubing, heart valves, pacemakers, gowns, pumps, respirators, surgical staplers, endoscopes, specula, and inhalation therapy supplies, among thousands of other devices. *Whitaker Testimony*, *supra*, at 6.

Further, for many of these medical devices, the FDA has concluded that EtO sterilization "may be the only effective sterilization method that does not negatively impact the device or function of the device." *See* Rutala & Weber, *supra*, at A87[8]; *see also* FDA, *Medical Device Sterilization Town Hall: FDA Activities and*

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[6] https://www.advamed.org/industry-updates/news/advamed-to-congress-epas-proposed-eto-regulations-put-patient-care-at-risk/.

[7] https://www.ajicjournal.org/article/S0196-6553(23)00057-3/fulltext.

[8] https://www.ajicjournal.org/article/S0196-6553(23)00057-3/fulltext.

Challenges in Reducing Reliance on Ethylene Oxide (EtO) (Jan. 26, 2024).[9] Many complex devices, including catheters, implantable electronics, and plastic surgical components, are heat- and moisture-sensitive and, therefore, cannot be treated with alternative sterilization methods. Other current sterilization technologies, namely radiation and steam sterilization, would damage these medical devices or would not clean them sufficiently, meaning they would no longer be available or safe. *Id.*

By allowing these medical devices and instruments to be sterile prior to patient use, EtO directly reduces the risk of device-associated infections and healthcare-associated infections ("HAIs"). HAIs are among the most common complications of care, occurring more than one million times a year—even with today's use of sterilization technology. Agency for Healthcare Research and Quality, *2013 Annual Hospital – Acquired Condition Rate and Estimates of Costs Savings and Deaths Averted From 2010 to 2013* (2013)[10]; *see also* SS Magill, et al., *Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals*, New Engl. J. Med. 379(18):1732-1744 (2018)[11] (estimating Americans are admitted to hospitals

[9] https://www.fda.gov/medical-devices/medical-devices-news-and-events/medical-device-sterilization-town-hall-fda-activities-and-challenges-reducing-reliance-ethylene?utm_source=chatgpt.com.

[10] https://psnet.ahrq.gov/issue/efforts-improve-patient-safety-result-13-million-fewer-patient-harms-interim-update-2013.

[11] https://psnet.ahrq.gov/issue/changes-prevalence-health-care-associated-infections-us-hospitals.

33.4 million times per year and 1 of every 31 of those patients has an HAI). The most common types of HAIs relate to the use of invasive devices or surgical procedures. If these devices were not properly sterilized and were contaminated with bacteria or other microbes, the number and severity of infections would increase dramatically. Patients would face greater risks from infectious diseases caused by bacteria, viruses, and fungi. And, because these patients already are suffering from an ailment or disease, their immune system's defenses may be weakened and the infection could be extremely serious—including leading to fatal outcomes.

A finding of liability in this and other such cases would invariably impede the ability of medical device manufacturers and hospitals to use EtO. Such a sterilization shortfall would lead to illnesses and deaths, as well as a shortage of medical devices, which is why it is critical that liability here is based on sound scientific principles.

II. THE TRIAL COURT DID NOT FULFILL ITS GATEKEEPING RESPONSIBILITY WHEN ALLOWING TESTIMONY ON PLAINTIFF'S UNFOUNDED "ANY EXPOSURE" THEORY.

This appeal presents the Court with the important opportunity to reinforce the need for trial courts to ensure that expert testimony results only from sound scientific principles. As with Federal Rule of Evidence 702, Georgia's rule governing the admissibility of expert testimony requires trial courts to act as gatekeepers to ensure the relevance and reliability of expert testimony. *See* O.C.G.A. § 24-7-702; *see also Kershaw v. Princeton Properties Mgmt*., *Inc*., 348 Ga. App. 779, 782 (2019) (citing

Scapa Dryer Fabrics, Inc. v. Knight, 299 Ga. 286, 289 (2016)). The purpose of this rule is to give trial courts the tools for admitting only expert evidence that is proven to be *reliable* and, therefore, can help the trier-of-fact make its factual determinations. This responsibility is needed because expert scientific testimony, as shown by this case, "can be both powerful and quite misleading." *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 595, 595 (1995).

Proper gatekeeping is particularly important in toxic tort cases, like this one, that seek to link a fairly common disease to exposure to a ubiquitous substance but only at one facility. As courts have explained, designating someone as an "expert" provides the witness with a cloak of authority. *See States v. Frazier*, 387 F.3d 1244, 1263 (11th Cir. 2004) (noting "expert testimony may be assigned talismanic significance in the eyes of lay jurors[.]"). Jurors can falsely assume the testimony is credible *because* it was admissible, including when the expert devises a plausible-enough-sounding theory for finding a source of money for people who are sick. Studies have shown that juries will fill the voids in the experts' testimony with sympathy and hindsight bias, regardless of the effectiveness of cross-examination or veracity of opposing expert evidence. *See* David P. Sklar, *Changing the Medical Malpractice System to Align with What We Know About Patient Safety and Quality Improvement*, 92 Acad. Med. 891, 891 (2017) (explaining juries may seek to "find someone to blame" to compensate a plaintiff). Plausibility, though, has never been

"a substitute for evidence, however great may be the emotional wish to believe." E. Bright Wilson, Jr., An Introduction to Scientific Research 26 (1952).

Because of this predicament, the Eleventh Circuit has established a two-tier causation system for toxic tort cases like this one. *See McClain*, 401 F.3d at 1241. The first classification is for the few chemicals the medical community routinely and widely recognizes cause the type of harm alleged, such as silica and silicosis. *See id.* at 1239-40. Most other chemical-disease relationships, as here, fall into the second classification, where plaintiffs must establish general causation through expert testimony that includes a dose-response methodology. *See id*. at 1243. In *In re Deepwater Horizon BELO Cases*, the Eleventh Circuit affirmed the dose-response methodology remains "the hallmark of basic toxicology because all substances potentially can be toxic," and "[m]ost low dose exposures—even for many years—will have no consequences at all." 119 F.4th 937, 941 (11th Cir. 2024) (cleaned up).

In October 2025, which is after the trial court issued its ruling here, this Court affirmed, in an EtO case, that Georgia law follows the Eleventh Circuit precedent and that a general causation expert's opinion that does not identify a specific level of exposure at which harm is caused is inadmissible under O.C.G.A. § 24-7-702. *See Sterigenics*, 923 S.E.2d at 184. The basis for this opinion is that "702 (b) is materially identical to Federal Rule 702 and Georgia courts have not addressed how to apply the reliability requirement of Rule 702 (b) to general causation opinions in toxic tort

cases, we look to federal decisions for guidance, particularly the decisions of the Eleventh Circuit." *Id.* (citations omitted). Thus, given *Sterigenics*, it is now clear that the trial court ruling that a plaintiff in a toxic tort case is not required to proffer a threshold level of a toxin to which he or she was exposed is reversible error.

To be clear, Plaintiff's general and specific causation experts did not provide any dose-response methodology. They testified that *any* exposure to EtO could cause cancer and *any* exposure at BD's facility could have caused Mr. Walker's cancer. Such "any exposure" theories, which have become common shortcuts in toxic tort cases, often are not based in sound science. Humans can defend against an array of toxins—up to a point. Disease results when exposures reach a level that overwhelms the body's defenses. Aspirin, alcohol, sunlight, even "poisons" like arsenic are poisonous only at sufficient doses. At lower doses, they are harmless, or even beneficial. For this reason, the bedrock principle of toxicology is "dose makes the poison." Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, in *Reference Manual on Scientific Evidence* 403 (Fed. Jud. Ctr. 3d ed. 2011); *see also* David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer In Toxicology For Judges And Lawyers*, 12 J.L. & Pol'y 5, 11 (2003) ("Dose is the

single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect.").[12]

To meet Georgia's reliability standard, Plaintiff's expert had to answer, in a scientifically reliable manner, the "how much" question. If background exposure is not enough, and if many exposed cohorts do not incur EtO-related disease, how much EtO is meaningful for a causation analysis? And did Plaintiff's exposures at a BD's site cross this threshold? Although the exact level of causation may not be known, the range of causative and non-causative exposures can be ascertained. Like other substances, scientists—including government regulators—make judgments about "safe" levels of exposure based on epidemiology and other studies. For this reason, numerous courts have rejected the *any exposure* theory or similar *cumulative exposure* approach in other toxic tort litigations. *See* William Anderson & Kieran Tuckley, *How Much is Enough? A Judicial Roadmap to Low Dose Causation Testimony in Asbestos and Tort Litigation*, 42 Am. J. Trial Advoc. 39 (2018).[13]

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[12] The "father of toxicology", physician and philosopher Paracelsus, first articulated this principle in the 16th century, stating: "All substances are poisonous—there is none which is not; the dose differentiates a poison from a remedy." David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer In Toxicology For Judges And Lawyers*, 12 J.L. & Pol'y 5, 11 (2003).

[13] *See, e.g., Betz v. Pneumo Abex LLC*, 44 A.3d 27 (Pa. 2012) (rejecting any exposure testimony, calling it a "fiction" and requiring experts to prove causative dose); *Ford Motor Co. v. Boomer*, 736 S.E.2d 724, 733 (Va. 2013) (holding experts "must opine as to what level of exposure is sufficient to cause mesothelioma, and whether the levels of exposure at issue . . . were sufficient."); *Bostic v. Georgia-Pacific Corp.*,

(Footnote continued on next page)

As one court assessing a different potentially hazardous substance explained, this methodology is like assuming a bucket of water thrown in the ocean contributes meaningfully to the size of the ocean. *See Moeller v. Garlock Sealing Tecsh.,* 660 F.3d 950, 955 (6th Cir. 2011). If it becomes this easy to convert a common disease into litigation, it will encourage similar lawsuits tying various diseases to routine exposures to any number of substances—all absent any scientific veracity.

III. THE TRIAL COURT ALSO ERRED IN NOT ALLOWING DEFENDANTS' EVIDENCE OF ENDOGENEOUS AND OTHER ALTERNATIVE SOURCES OF ETO EXPOSURE.

Further undermining the scientific analysis in this case, the trial court improperly excluded critical evidence of other potential sources of Mr. Walker's EtO exposure. To be clear, these other sources of EtO—endogenous sources that naturally make EtO in the human body and other background sources—are highly relevant and probative because they can "make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." O.C.G.A. § 24-4-401. Here, these other sources show that low-level exposures to EtO do not cause cancer, which directly counters Plaintiff's "any exposure" theory. Also, to the extent EtO caused Mr. Walker's cancer, Plaintiff's expert needed to account for these other exposures.

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439 S.W.3d 332 (Tex. 2014) (rejecting any exposure theory); *Moeller v. Garlock Sealing Techn., LLC*, 660 F.3d 950 (6th Cir. 2011) (same).

Endogenous EtO "is a major source of the total [EtO] exposure among the general population." Patrick Sheehan, et al., *Ethylene Oxide Exposure in U.S. Populations Residing Near Sterilization and Other Industrial Facilities: Context Based on Endogenous and Total Equivalent Concentration Exposures*, Int. J. Environ. Res. Public Health 18(2), 607 (2021).[14] It is "produced in the body from endogenous ethylene via multiple pathways," causing "all individuals [to] have some exposure to [EtO] regardless of their exogenous exposures to [EtO] in air." *See* CR Kirman, et al., *Ethylene Oxide Review: Characterization of Total Exposure Via Endogenous and Exogenous Pathways and Their Implications to Risk Assessment and Risk Management*, J. of Tox. and Envi. Health, Part B, 24:1, at 1 (2021). "For nonsmokers, endogenous exposures to [EtO] serve as the largest contributor to total exposure." *Id.* at 21. Here, BD designated Dr. Lewis Chodosh, a medical doctor and professor of cancer biology at the University of Pennsylvania, to proffer testimony that "our bodies produce a certain level of ethylene oxide to which our bodies have also developed mechanisms to repair." R. 69 at 41486:22-41488:02. This testimony follows with generally accepted scientific principles regarding endogenous EtO's impact on the human body and should have been admissible given its relevance here.

There are also "background sources" of EtO, which refers to any source of EtO other than the Defendant's sterilization plant. As this Court has noted, EtO "is

[14] https://pmc.ncbi.nlm.nih.gov/articles/PMC7828163/.

a major industrial chemical used in the production of several other industrial chemicals and as a pesticide, fumigant, and antimicrobial in many industries, including health care, medical device production, and food sterilization." *Sterigenics*, 923 S.E.2d at182. This Court has also recognized that "the atmosphere contains background levels of EtO." *Id*. Many consumer goods and products emit EtO, including above the EPA's emission benchmarks, such as charcoal grills, lawnmowers, vehicle exhaust, cigarettes, forest fires and decaying plants. *See* Montrose Air Quality Services, LLC, *Proton Transfer Reaction/Time of Flight Mass Spectrometry (PTR-TOF-MS) Measurements of "Everyday Sources" for Ethylene Oxide: Emerging Technologies Test Report* (Oct. 16, 2019) (prepared for AdvaMed).[15] "In fact, just one half of one percent of the ethylene oxide used in the U.S. is used for medical device sterilization." Gail Charnley, *Risk, Regulation, and Reality Checks: The Example of Ethylene Oxide*, RealClearPolicy (June 27, 2023).

For these reasons, courts across the country in other EtO exposure cases like this one have allowed evidence of endogenous and background levels of EtO on issues of causation. *See, e.g.*, Trial Tr., Nov. 1, 2024, *Glass v. B. Braun Med. Inc.*, Case No. 00315 (Pa. Ct. Com. Pl.), at 104:22–105:11; Order on Pls.' Combined Mot. in Lim., *Isaacks v. Terumo BCT Sterilization Servs., Inc.*, Case No. 2022-cv-031124

[15] https://www.advamed.org/wp-content/uploads/2019/10/everyday-sources-ethylene-oxide-test-report.pdf.

(Colo. Dist. Ct. Jan. 27, 2025); Trial Tr., Aug. 17, 2022, *Kamuda v. Sterigenics U.S., LLC*, Case No. 18-L-010475 (Ill. Cir. Ct. Cook Cnty.), at 205:3–13; Trial Tr., Nov. 14, 2022, *Fornek v. Sterigenics U.S.*, LLC, Case No. 18-L-010744 (Ill. Cir. Ct. Cook Cnty.), at 85:8–90:8; Trial Tr., Nov. 20, 2024, *Knobbe v. Isomedix Operations, Inc.*, Case No. 2022-L-008574 (Ill. Cir. Ct. Cook Cnty.), at 153:4–19.

In *Knobbe*, the court stated the position in that case that "manufactured EtO being sent into the atmosphere by the defendant was at such a small level that it is lower than what the body naturally emits on its own," which supported the position that the cancer was not caused by EtO. *Id.* at 132:21–133:13. This observation led the court to deny the plaintiff's motion to exclude evidence of endogenous EtO. The court also stated that it would not permit the inference "that EtO is unnatural" or "unacceptable" at any level. *Id.* at 134:9–14. This ruling is consistent with Dr. Chodosh's statements that "at doses and durations to which human beings are exposed, I do not believe there's any kind of human cancer that has been demonstrated to be caused by [EtO]." Dep. of Dr. Lewis Chodosh at 185:4–9.

Indeed, state and federal authorities have been monitoring EtO levels in Georgia's air. Beginning in 2020, the Georgia Environmental Protection Division released data showing the average levels of EtO in Covington, near BD's facility, were comparable or lower than two locations away from any industrial sources of EtO in rural General Coffee State Park and in South DeKalb. Georgia Environmental

Protection Division, *Ethylene Oxide Information* (accessed Feb. 9, 2026).[16] Expert testimony alleging BD's Convington facility caused Mr. Walker's cancer would have to account for these readings and these other potential alternative EtO sources.

IV. THE TRIAL COURT'S RULING MUST BE OVERTURNED SO UNRELIABLE EXPERT TESTIMONY DOES NOT UNDERMINE FEDERAL REGULATORY PROCESSES.

Finally, affirming the trial court's ruling would allow unreliable scientific theories to overtake the rigorous review EtO has undergone as part of the regulatory processes of several federal agencies, including the FDA, EPA, and OSHA. The Supreme Court has explained that science in the courtroom must employ "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). And federal regulations and international guidance on emissions, residuals and worker safety allow for the safe and responsible manufacture and use of EtO to sterilize medical products, which directly counters the Plaintiff's "any exposure" theory.

EtO has been subject to extensive scientific review as part of the federal government's efforts to manage its risks. Under the Clean Air Act, the EPA has established emission standards for EtO, concluding that it "does not expect EtO levels in the outdoor air around facilities that release it to be high enough to cause immediate health effects." USEPA, *Our Current Understanding of Ethylene Oxide*

[16] https://epd.georgia.gov/ethylene-oxide-information.

(EtO) (accessed Feb. 9, 2026).[17] The EPA has also emphasized the importance of dose with respect to the level of exposure that can cause harm: "This risk is not the same for everyone and depends on how long a person is exposed over the course of their lifetime or career, as well as how much EtO is actually in the air." *Id.*

With respect to medical device sterilization, FDA regulations help ensure that levels of EtO on medical devices are "within safe limits." FDA, *Sterilization for Medical Devices* (accessed Feb. 9, 2026).[18] Manufacturers must conduct extensive studies to demonstrate the required sterility assurance levels are achieved and to confirm that exposure to the sterilization process does not adversely affect a device's performance, safety, or effectiveness. *Id.*; *see also* FDA, *Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices* (Nov. 26, 2024).[19] The FDA works directly with the EPA on "safe limits [for] long-term and occupational exposure" to EtO. *Id*. These regulations are based on the scientific findings that "any exposure" to EtO does not cause cancer; dose matters.

To be sure, courts have sometimes allowed juries to assess and reach different conclusions about chemical products than federal or state regulators. But the

[17] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto.

[18] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#how.

[19] https://www.fda.gov/media/183833/download.

scientific standards in the courtroom should, at the very least, be comparable to those employed outside the courtroom, including by federal and state agencies.

CONCLUSION

For these reasons, this Court should reverse the judgment of the trial court and hold that the trial court erred when it allowed plaintiff's experts to testify on causation without establishing the proper scientific foundation for that testimony.

Respectfully submitted,

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Dated: February 13, 2026

CERTIFICATE OF WORD COUNT

This submission does not exceed the word-count limit imposed by Rule 20.

Respectfully submitted,

/s/ Caroline Gieser
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February 13, 2026

CERTIFICATE OF SERVICE

I certify that on February 13, 2026, I filed the foregoing Brief using the Court's e-filing (SCED) system. I also certify that there is a prior agreement among the parties to allow documents in a PDF format sent via e-mail to suffice for service under Supreme Court Rule 14. Pursuant to their agreement, I e-mailed the Brief to the following:

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