IN THE STATE COURT OF COBB COUNTY
STATE OF GEORGIA

TOM MUTZ, *et al.*,

Plaintiffs,

v.

STERIGENICS U.S., LLC, *et al.*,

Defendants.

CIVIL ACTION
NO. 20-A-3448

Related Civil Action Nos.:

1. 20-A-2703
2. 20-A-2978
3. 20-A-3012
4. 20-A-151
5. 21-A-2425
6. 21-A-2420
7. 21-A-2414
8. 21-A-2406
9. 21-A-2462

# ORDER (1) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO EXCLUDE EXPERT TESTIMONY AND (2) GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Supplying sterilized medical equipment is important to a community's health. Breathing toxin-free air is too. So when a corporation undertakes sterilizing medical equipment with a toxic substance like Ethylene Oxide (EtO), it must comply with applicable standards of care to avoid poisoning the surrounding areas. In 2019, the EPA

found an excess of EtO in the air around the Smyrna, Georgia Sterigenics plant. As a result, hundreds filed suit claiming they were harmed by exposure to EtO. These harms include lymphoma, leukemia, breast cancer, and birth defects – all diseases Plaintiffs claim EtO exposure can and did cause. The issues to be decided in this multi-plaintiff litigation are therefore:

i. Whether Sterigenics emitted excess EtO into the air;
ii. Whether Plaintiffs were exposed to EtO and in what amount they were exposed; and
iii. Whether Plaintiffs suffered harm as a result of their exposure.

Early in the litigation, the Court issued a scheduling order breaking the case into several "phases." Phase One would address whether there was enough evidence to prove general causation. That is the question before the Court now: "[I]s [EtO] capable of causing a particular injury or condition[?]"[1]

To prove causation in this toxic tort case, Plaintiffs offered three experts: Dr. Felsher, Dr. Stayner, and Dr. Salem. These experts, Defendants say, do not satisfy O.C.G.A. § 24-7-702. And in the absence of reliable expert testimony, Defendants argue summary judgment is appropriate. The Court held argument on Defendants' 702 motions and their Motion for Summary Judgment on November 14, 2024. The Court likewise received supplemental briefing on causation.

## A. Legal Standards.

*1. Summary Judgment.*

Summary judgment shall be awarded to the moving party when, viewing all facts and inferences in a light most favorable to the non-moving party, it is

[1] Bowers v. CSX Transp., Inc., 369 Ga. App. 875, 877 (2023).

demonstrated that the evidence does not create a triable issue of fact.[2] The moving party can satisfy this burden by pointing to affidavits, depositions, or documents, which demonstrate that no genuine issue of material fact exists.[3] Once the moving party discharges its burden, the burden then shifts to the non-moving party to produce evidence that a material issue of fact remains.[4] A "shadowy semblance of an issue" is not enough to defeat a motion for summary judgment.[5] Instead, a party opposing a motion for summary judgment must submit probative evidence creating a genuine question about an actual fact in issue.[6] Without admissible expert testimony as to general causation in a toxic tort case, summary judgment must be granted.[7]

2. *Rule 702.*

O.C.G.A. § 24-7-702 establishes when expert testimony is admissible in Georgia. It reads in relevant part:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if:
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> (1) The testimony is based upon sufficient facts or data;
> (2) The testimony is the product of reliable principles and methods; and
> (3) The witness has applied the principles and methods reliably to the facts of the case which have been or

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[2] Lau's Corp. Inc. v. Haskins, 261 Ga. 491, 491 (1991).

[3] Id.

[4] Id.

[5] Holland v. Sanfax Corp., 106 Ga. App. 1, 5 (1962).

[6] See Upshaw v. Roberts Timber Co., 266 Ga. App. 135, 137 (2004).

[7] See Fulmore v. Csx Transp., 252 Ga. App. 884, 887 (2001).

> will be admitted into evidence before the trier of fact.

The proponent must satisfy this burden by a preponderance of the evidence.[8]

### B. EtO is Neither a Category One nor Category Two Toxin.

First, an important frolic and detour. Fundamental to this case is a threshold question: is EtO a category one or two toxic substance? Or does it belong in a category in between?

> In analyzing the experts' testimony, we note that toxic tort cases usually come in two broad categories: 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. **Examples of the first type include toxins like asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; and cigarette smoke, which causes cancer.**[9]

When a substance falls into category one, general causation is established without expert testimony. Basically, "[t]he court need not undertake an extensive *Daubert* analysis on the general toxicity question...."[10] General causation is almost an afterthought. But when a substance falls into the second category, expert testimony must establish causation.[11] Here, both the litigants and this Court have operated on the premise that EtO falls into the second category.[12] With the benefit of oral argument and briefing, the Court now concludes EtO falls into a category between one and two.

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[8] Humphrey v. Emory Clinic, Inc., 369 Ga. App. 131, 139 (2023) (emphasis added).

[9] McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1239 (2005).

[10] Id.

[11] Id.

[12] First Consolidated Case Management Order (June 11, 2021).

An explanation is due. Plaintiffs' experts all agree that EtO is generally considered a carcinogen.[13] And the Court finds that opinion supported by sufficient facts and data, and the opinion is the product of reliable methodology. Particularly persuasive to the Court is the 2016 EPA study which analyzed hundreds of studies and is supported by hundreds of scientists.[14] At any rate, because their experts speak in unison, Plaintiffs argue a general consensus among the scientific community that EtO is a carcinogen.

Plaintiffs buttress this finding with the fact that Defendants placed numerous warnings around the sterilization plant as to the hazards of EtO.[15] Defendants, for their part, claimed at oral argument that warnings are required by regulatory agencies and should not be consider an admission of any sort.[16] Although Defendants went onto argue that their expert witnesses dispute the toxic properties of EtO, the Court finds that Plaintiffs have shown that EtO is generally recognized as a carcinogen. This is proven by a preponderance of the evidence.

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[13] See Report of Dr. Leslie Stayner, p. 2. ("EtO is a well-recognized case of cancer in humans. This is both my opinion and the conclusion reached by the IARC (2007, 2009), EPA (2016), NIOSH (1981) and NTP (1999). The determination that EtO causes cancer by these agencies has been based on several lines of evidence including findings from experimental studies in animals, epidemiologic studies, and mechanistic studies on the mutagenicity of Eto. The epidemiologic studies provide particularly strong evidence that EtO causes lymphatic and hematopoietic cancers, and breast cancer."); see, *also*, Salem Report p. * 6. ("EtO is a known genotoxic cancer-causing agent."); see Felsher dep. 35:11-25.

[14] See Felsher Dep. 160:16-161:2 ("IRIS did a study. The EPA didn't just review and spit back out what Stayner and Steenland did. They looked at the entire literature. They looked at the primary data. They reviewed the date. They then did an integrative analysis. They used mathematical modeling. That's a study. It's ---it's science. I give the EPA much more credit than simply saying—they didn't simply regurgitate what Stayner and Steenland did. They analyzed the date and –in detail. They integrate—they did an integrative analysis.").

[15] Plaintiffs' Consolidated Opposition to Defendants' Motion for Summary Judgment p. *13.

[16] The Court was unable to find support for this contention in the record.

Presumably, in a Frye jurisdiction, this would be enough to establish general causation. The Frye standard, "generally accepted in the scientific community," is not independent of nor doomed to fail in a Daubert analysis.

> Finally, "general acceptance" can yet have a bearing on the inquiry. A "reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." Widespread acceptance can be an important factor in ruling particular evidence admissible, and "a known technique which has been able to attract only minimal support within the community," may properly viewed with skepticism.[17]

In fact, the Frye standard is a harder standard to meet than Daubert. "[T]he Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*...."[18]

Despite finding that EtO is generally accepted in the scientific community as a known carcinogen, the Court is hesitant to uniformly declare EtO a category one toxin. Georgia courts have only classified two substances as category one toxins: asbestos[19] and silica.[20] These substances have a one-to-one relationship with the disease. In contrast, there is no one-to-one relationship with EtO and Plaintiffs' injuries. So – although there is a general acceptance that EtO is a carcinogen – there is

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[17] Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993).

[18] GE v. Joiner, 522 U.S. 136, 142 (1997).

[19] Fullmore v. CSX, 252 Ga App 889, 891(2001) (""Where, as here, the cases undisputedly involve plaintiffs who have contracted asbestosis, which by definition, results only from an overexposure to asbestos, the proof of asbestosis conclusively establishes such overexposure.").

[20] Fouch v. Bicknell, 326 Ga App 863, 869 (2014) ("In this case, it is undisputed that as a result of his sandblasting employment, Fouch contracted silicosis, which by definition, results only from an overexposure to silica...As a result, Fouch did not have to establish that he was exposed to a specific threshold level of silica necessary to induce silicosis.").

a mismatch between EtO and the other category two substances. Indeed, unlike asbestos (which causes asbestosis) and silica (which causes silicosis), EtO does not alone cause the injuries Plaintiffs allege. What does that mean to the 702 analysis? Do Plaintiffs still need to prove a dose-response relationship as required by McClain and subsequent 11th Circuit opinions?

The 11th Circuit has ruled repeatedly (and as recently as October 2024) that general causation in a category two case must address the dose-response relationship.[21] Plaintiffs dispute whether Deepwater Horizon is controlling but acknowledge that McClain *is* controlling to our discussion.

> In the second category of toxic tort cases, the *Daubert* analysis covers not only the expert's methodology for the plaintiff-specific questions about individual causation but also the general question of whether the drug or chemical can cause the harm plaintiff alleges. This is called general causation. "General causation is concerned with whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease." Michael D. Green et al., *Reference Guide on Epidemiology, in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 392 (Federal Judicial Center, 2d ed. 2000). Thus, in this case, **Plaintiffs' experts must offer reliable opinions about Metabolife's general toxicity for the harm Plaintiffs allege** and that it in fact harmed them.[22]

Thus, a dose-response analysis is mandatory in any category two case.

McClain's discussion of the dose-response relationship mirrors the conflating of general and specific causation that vexes Georgia courts.[23] Georgia has not ruled

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[21] See In re Deepwater Horizon Belo Cases, U.S. Dist. LEXIS 48865 (11th Cir. 2024).

[22] McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1239 (2005) (emphasis added).

[23] In toxic tort cases, "scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden . . .." Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996). Or, as the Tenth Circuit explained in Mitchell v. Gencorp, 165 F.3d 778, 781 (10th Cir. 1999), to carry the burden in a toxic tort case, "a plaintiff must demonstrate the levels of exposure

specifically on general causation in a category two case (*i.e.*, where the toxin is neither asbestos nor silica). Rather, opinions and orders lump general and specific causation together.[24]

If Georgia adopts the 11th Circuit analysis outlined in McClain, requiring a specific dose-response relationship would make it nearly impossible for a plaintiff to prove general causation in anything other than a category one case. At the same time, if Georgia adopts the Plaintiffs' analysis, general (proximate) causation would be assumed in all cases. Consequently, this Court paves a third way: if a plaintiff establishes by a preponderance of the evidence that the medical or scientific community generally accepts the substance as a harmful toxin, and a Daubert-qualified expert opines that *any* exposure creates a risk of a plaintiff's harm, then a specific dose-response relationship is not required to prove general causation.

This approach is entirely consistent with Federal court rulings referenced in Defendants' Exhibit 3, which was admitted at the November 14, 2024 hearing. In Daubert v. Merrell Dow, the substance was an anti-nausea drug that the plaintiffs claimed caused birth defects. Presumably, the drug was not a toxin that *any exposure* would cause harm. In the remaining cases contained in Defendants' Exhibit 3, the

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that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover...." (citation omitted); see, *also*, Moore v. Ashland Chem. Inc., 151 F.3d 269, 278 (5th Cir. 1998) (excluding expert testimony which "offered no scientific support for his general theory that exposure to toluene solution at any level would cause RADS."); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (2005); see, *also*, In re Deepwater Horizon Belo Cases v. BP Expl. & Prod., Inc., 2024 U.S. App. LEXIS 26402, *17-18 (2024) ("Jenkins and Siples contend that proof of some threshold level of exposure is 'only relevant to *specific* causation.' In support, they argue that *McClain* concerned only 'toxicological principles or specific causation.' But this reading turns *McClain* on its head. The passages that Jenkins and Siples quote address *both* general and specific causation.").

[24] See, *e.g.*, Wadley v. Mother Murphy's Laboratories, Inc., 357 Ga. App. 259, 263 (2020), Buczek v. Sterigenics,(2024).

substances were not found to be carcinogenic,[25] were clearly a category two substance,[26] or dose was not an issue.[27]

The most recent 11th Circuit case on this issue, Deepwater Horizon, the court specifically found that when a substance fell into the second category of toxic torts a harmful level of exposure must be established by expert testimony.[28] "[T]o be reliable

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[25] See In re Acetaminophen, 707 F. Supp. 3d 309 (2023) (substance was not a carcinogen); Daniels-Feasel v. Forest Pharms., Inc., 2021 U.S. Dist. LEXIS 168292, *22-23 (substance not a carcinogen); In re Zantac (Ranitidine) Prods. Liab. Litig., 644 F. Supp. 3d 1075, 1094 (2022) ("[T]here is no scientist outside this litigation who concluded ranitidine causes cancer...."); In re Viagra 527 F. Supp 2d 1071 (2008) (the substance was not a carcinogen).

[26] In Chapman v. P&G Distrib., LLC, zinc, clearly a category 2 substance, was allegedly the culprit.

> Millions of consumers have regularly used Fixodent for decades without complaint. Nevertheless, [the Chapmans] claim that Fixodent is toxic because it contains zinc in a calcium-zinc compound – even though zinc is undeniably an essential nutrient the body must have to function properly." see Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1257 (11th Cir. 2010) (per curiam) (recognizing in a products liability case that two-thirds of patients who took an antipsychotic prescription drug, Seroquel, did not experience weight gain, which plaintiff alleged was the cause of her diabetes). Therefore, the district judge properly determined that Fixodent, containing zinc, was in *McClain* category two and conducted the requisite *Daubert* review of proffered expert testimony, which included a thorough hearing and consideration of "thousands of pages of filings by the parties, including the experts' reports and depositions, and scientific literature.

766 F.3d 1296, 1304 (2014)(internal citations omitted).

[27] In Taylor v. Bristol-Myers Squibb, 93 F. 4th 339 (2024), the expert was excluded for reasons other than his failure to identify dose. Dose was established in In re: Zoloft, 858 F.3d 787 (2017). In In re Lipitor v. Pfizer, 892 F.3d 624 (2018), dose was established. On the other hand, Norris v. Baxter Healthcase Corp, 397 F3d 878, (2005), and In re Viagra, 527 F. Supp 2d 1071 (2008) were not a dose-relationship cases.

[28] Why look to the 11th Circuit for help in this case? Because, as Plaintiffs admit, there is a dearth of caselaw on general causation in Georgia and what is required from an evidentiary standpoint to survive summary judgment. And to establish general causation in a category two substance, a court must have a qualified expert's opinion that satisfies O.C.G.A. § 24-7-702. That is an evidentiary issue. If Georgia law is silent on any rule of evidence, the Court must look to the Federal Rules, especially the 11th Circuit. "In 2011, our General Assembly enacted a new Evidence Code... Many provisions of the new Evidence Code were borrowed from the Federal Rules of Evidence, and when

and helpful, a general causation expert in these [backend-litigation] cases must identify a harmful level at which a chemical in the oil or dispersant can cause the chronic conditions at issue here.... Because they bring a toxic-tort action – *one where the medical community has not recognized the toxicity* of the oil and dispersants used to clean up the...spill – they must prove general causation through admissible, reliable expert testimony."[29] Here, we have evidence that the medical community *does* recognize the carcinogenic nature of EtO. Therefore, accepting the reasoning in Deepwater Horizon, the requirement that a threshold level be disclosed by the expert does not apply.

This analysis echoes one conducted by the 11th Circuit in Taylor v. Mentor Worldwide LLC, 940 F.3d 582 (2019). In that case, the defendant claimed a dose-response relationship was required in a case involving a mesh sling that allegedly degraded and shed polypropylene particles. There, the court ruled that a dose-response relationship was not needed when any exposure to the harmful substance causes a plaintiff's injury. Distinguishing the case from McClain, the 11th Circuit found:

> The case before us is markedly different. The dose-response relationship is not implicated here. The logic of *McClain* therefore is not transferrable to this case. In *McClain*, the missing piece — among others — was how much ephedrine and caffeine were required to start a chain reaction leading to a stroke or heart attack. That piece was important because there evidently was a level of ephedrine and caffeine that a person could

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our courts consider the meaning of these provisions, they look to decisions of the federal appeals courts construing and applying the Federal Rules, especially the decisions of the Eleventh Circuit." State v. Frost, 297 Ga. 296, 299 (2015). Accordingly, the Court will look to federal appeals courts, especially the 11th Circuit, when Georgia courts have not weighed in on an evidentiary issue in this case.

[29] In re Deepwater Horizon Belo Cases, 2024 U.S. App. LEXIS 26402, *11-14 (2024) (emphasis added)(internal quotes omitted).

> consume safely. But in this case, Dr. El-Ghannam testified that *all* ObTape degrades and that *any* polypropylene particles it sheds spark a response by the body's immune system, which leads to inflammation and erosion. There was no suggestion that there was a level of degradation that would not cause those harmful effects.[30]

Accordingly, the Court finds that EtO is in a category between category one and category two toxins: a widely accepted harmful toxin that can cause at least some of the harms alleged by Plaintiffs.[31] And in this category, to move from phase one (general causation) to phase two (specific causation), Plaintiffs must offer expert opinion saying any exposure to EtO causes Plaintiffs' injury.

**C. Analysis.**

Plaintiffs' experts offered opinions that exposure to EtO can cause the Plaintiffs' injuries. But they failed to say how much exposure to EtO can cause the injuries. For his part, Dr. Stayner opines that *any* exposure can cause certain cancers. Dr. Felsher and Dr. Salem, for their part, claim that *any exposure above background* can cause cancers and birth defects. However, the jurisprudence of the 11th Circuit states such *any exposure above background* testimony is not helpful to a jury in a toxic tort case. Without it, the expert testimony lacks the "fit" requirement of a Rule 702 analysis.

*a. Dr. Stayner's Testimony Meets the 702 Requirements as to Hematopoietic, Lymphatic and Breast Cancers.*

Dr Stayner's opinion survives a 702 analysis. Dr. Stayner is the author of one of the studies which found that EtO can cause hematopoietic and lymphatic cancers.[32]

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[30] Id. at 595. (Emphasis in original.)

[31] Almost thirty years ago, the 5th Circuit acknowledged as much. "Evidence has been found that suggests a connection between EtO exposure and human lymphatic and hematopoietic cancers...." Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194, 197 (5th Cir. 1996).

[32] Stayner Report p. 1.

He opines that there is no safe level of exposure to EtO.[33] He did a systematic review of the literature.[34] He relied on the conclusions of IARC, and other studies, citing the extensive literature that comes to the same conclusion: that EtO is a "mutagen and a cytogeny and causes DNA damage."[35] Because Dr. Stayner reliably opines that *any* exposure to EtO – a widely accepted carcinogen – can cause breast, hematopoietic, and lymphatic cancers, his opinions survive Defendants' Rule 702 challenge. And thus, given that Plaintiffs have qualified expert testimony regarding general causation, Defendants' motion for summary judgment as to breast, hematopoietic, and lymphatic cancers is DENIED.

*b. Causation Testimony as to Birth Defects Fails to Meet 702 Requirements.*

Plaintiff Roslyn Gil's[36] case is not as fortunate as the other bellwether Plaintiffs. Dr. Stayner specifically did not opine on the relationship between EtO exposure and birth defects.[37] Similarly, Dr. Felsher states that his scope of testimony is limited to the "causal relationship between ethylene oxide (EtO) exposure and cancer generally."[38] His report is silent on the issue of birth defects. Yet he opined about birth defects at the end of his deposition citing his decades of experience. And while Defendants' counsel asked for updated materials, none were provided.[39]

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[33] Stayner Dep. 33:20-34:2.

[34] Stayner Dep. 65:8-66:8.

[35] Stayner Dep. 68:6-10.

[36] The Court is unsure how to spell Miss Gil's first name. In the caption of the case, it is spelled "Roslyn." In the "Factual Allegations" section of the complaint, it is spelled "Rosalyn."

[37] Stayner Dep. 13:6-9.

[38] Felsher Report p. 4.

[39] Felsher Dep. 393:6-18.

Likewise, Dr. Salem's testimony fails a 702 analysis. Dr. Salem's report cites to studies that link EtO to fetal deaths but not birth defects. In addition, Dr. Salem's deposition testimony on birth defects is slim. He cites one study that saw certain birth defects in mice (absent lower jaw, an exposed brain, vestigial eye and an edematous).[40] But he cannot cite to a study to support a correlation to cleft palate, single-gene disorders, heart defects, neurodevelopmental disorders, or adrenal abnormalities.[41] Curiously, the comprehensive EPA 2016 report does not list birth defects as one of the risks linked to EtO exposure even though it states that children are more susceptible to harm from EtO exposure.

> Scientific evidence in humans indicates that regular exposure to EtO over many years increases the risk of cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. Studies also show that long-term exposure to EtO increases the risk of breast cancer in women. Children are more sensitive to EtO than adults. This is because ethylene oxide can damage DNA, and growing children are more susceptible to DNA damage because their cells divide more rapidly than adults. The contribution to lifetime cancer risk from a single year of exposure to ethylene oxide is greater if that year occurred during childhood.[42]

As such, there is an absence of reliable expert opinion testimony on whether exposure to EtO generally can cause birth defects in humans. Absent a qualified expert to testify regarding general causation on these conditions, Defendants motion for summary judgment is GRANTED as to Rosyln Gils' claims.

*c. Dr. Felsher and Dr. Salem's Expert Testimony do not meet 702 Requirements.*

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[40] Salem Dep. 321:11-13.

[41] Salem Dep 325:21-326:7; 324:15-25.

[42] Salem Report p. 8.

Unlike Dr. Stayner, who has been studying the relationship between EtO and cancer for decades, Dr. Salem and Dr. Felsher are relatively new to the discipline. Their first in-depth dive into the EtO science has come about only when related to recent litigation.[43] Although this testimony may make for "hired gun" fodder on cross-examination, it does not automatically disqualify their testimony under a Daubert analysis. Rather, it is their dubious claims about EtO and dose that disqualify them from opining on general causation. While they both agree, like Dr. Stayner, that EtO is a carcinogen and that any exposure of EtO is harmful, they repeatedly tie the risk of disease to a dose and duration analysis. The recurring phrase is "any exposure above background."

They both readily admit that EtO is a naturally occurring substance. But they claim while naturally occurring EtO is not harmful to humans, manmade EtO is. "[A]nything above background, that background, that value that is not related to human, anything above that background I'm saying could be an increased risk."[44] Dr. Salem agrees. "[T]he conclusion that I feel comfortable supporting as a scientist is that any exposure above background increases the risk of cancer."[45] Dr. Felsher explains that naturally occurring EtO cannot cause cancer, but manmade EtO can.

> Well, whatever the background that's truly background related to natural circumstances is something we've coevolved with for eons. I mean, it would be some amount of some chemicals as a consequence of the nature of chemistry. The ethylene oxide that's spilled into the atmosphere from Sterigenics is manmade, not expected. You can't – you don't know that you're getting this extra amount of ethylene oxide. Your body – Sterigenics hasn't existed long enough that your body's

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[43] Salem Dep. 48:13-49:12.

[44] Felsher Dep. 100:17-20.

[45] Salem Dep. 88:9-12.

> coped with this as something. It's not like there's been an evolutionary adaptation to living next to Sterigenics.[46]

Dr. Felsher also states that the properties of a naturally occurring EtO molecule and a manmade molecule are different. "[I]n terms of its physical properties of what it does to an individual could be very different."[47] He goes on:

> "Because a molecule in background that's existed for eons because of some natural process is not going to have the physical consequences when you breathe it is as the same as when you're bombarded without any warning continually by molecules from a sterilization facility. I can guarantee you the bacteria that you're sterilizing do not worry about the background levels of ethylene oxide. But when you give them extra ethylene oxide, it starts damaging their DNA."[48]

He provides no support for this argument. "[Dr. Felsher] has simply substituted his own *ipse dixit* for scientific proof on this essential issue."[49]

Dr. Felsher also opines that endogenous EtO, that created by the body, cannot cause cancer.[50] Later he states that inhaling endogenous EtO can cause cancer.[51] This endogenous EtO is presumably the same substance that creates some of the non-manmade background levels that Felsher says are safe. Unfortunately, he cannot cite to any studies. Again, internal inconsistencies and a lack scientific literature on the subject makes Dr. Felsher's opinions suspect. Dr. Salem's and Dr. Felsher's testimony

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[46] Felsher Dep. 90:14-91:1.

[47] Felsher Dep. 91:3-5.

[48] Felsher Dep. 94:6-16.

[49] McClain, 401 F.3d at 1242.

[50] Felsher Dep. 114:17-120:15.

[51] Felsher Dep.132:8-23.

that naturally occurring EtO does not cause cancer lacks support in the scientific community.

And "background" is a moving target, according to Dr. Felsher.

> [I]t depends on what we're calling background. If we're calling background ethylene oxide that incudes ethylene oxide released by Sterigenics into the atmosphere that people didn't know about until previously they called it background., but it actually turns out—well actually, it isn't background. It turned out that there were measurable levels of ethylene oxide as, for example, has been discovered in Willowbrook.[52] When Willowbrook closed and ethylene oxide levels were measured in the atmosphere around your facility there in Willowbrook, the levels went down. So actually, the background was much lower because it was misinterpreted previously that the background was background and not related to human release of ethylene oxide from Sterigenics.[53]

As such, Dr. Felsher's opinion on background is not based on sufficient facts or data, and his opinions generally are not grounded in an adequate methodology to support them.

Regarding Dr. Salem, his reliance on "any exposure above background" crumbles when he is asked about naturally occurring EtO as "background." Despite repeatedly saying that he could not establish a level of EtO "above background" that increases the risk for cancer, Dr. Salem would require a specific level if he were to evaluate naturally occurring background levels and their risk of cancer. When asked, "Do you believe that exposure to background levels of ethylene oxide in the ambient air can cause cancer?" He replied, "My statements here today are all drawn on data; and if I'm presented with data that shows a *specific measurement and shows what that link*

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[52] Willowbrook, IL, had a Sterigenics facility that was the subject of litigation. The facility has since closed.

[53] Felsher Dep. 99:4-20.

*is to a particular incidence rate*, I'm willing to consider it and make a statement on it, but everything else is drawn on specific data that I've reviewed."[54] This internal inconsistency between what he can testify to (*i.e.*, any exposure above background for manmade EtO increases the risk of harm) and what he would require to give an opinion on naturally occurring EtO (specific levels linked to a specific harm) belies a lack of scientific rigor.[55]

Further, Dr. Salem agrees that endogenous EtO does not cause cancer. "...I did do searches on...whether endogenous EtO was linked to cancer, and I could not find any study anywhere that showed endogenous EtO was a cause of cancer."[56] But "the absence of epidemiological evidence showing a specific association between EtO and a specific cancer does not mean that it does not exist; it simply means that scientists have not been able to study it."[57] Later in the deposition, he admitted that there was a study, the *Kirman* paper which studied endogenous EtO. He decided it was a flawed study by relying on others' opinions of it and he discounted the study because it was industry sponsored.[58]

Dr. Salem was not familiar with studies that endogenous (*i.e.*, not manmade) processes can cause damage to DNA.[59] The reason for not reading those studies? "They don't specifically refer to ethylene oxide."[60] This oversight may be attributable to Dr. Salem's recent interest in EtO. "[M]y experience in evaluating such studies and

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[54] Salem Dep. 192:11-22. (Emphasis added.).

[55] See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

[56] Salem Dep. 106:10-13

[57] Salem Report p. 16.

[58] Salem Dep. 107:16-108:8.

[59] Salem Dep. 102:23-104:23.

[60] Salem Dep. 104:20-21.

carrying out similar studies places me in an exceptionally strong position for interpreting and understanding peer-reviewed studies by others on EtO."[61] Such testimony lacks specific data to support it. Evidence that Dr. Salem cherry-picked studies works against finding Dr. Salem a qualified expert.

The "any exposure above background" standard, when the background level is not quantified, is the scientific equivalent of the-straw-that-broke-the-camel's-back. Such analysis does not meet the Daubert requirements as to "fit." The experts also failed to establish a reliable methodology as to the difference between naturally occurring EtO and manmade EtO. Indeed, their testimony is internally inconsistent. As such, the Court GRANTS Defendants' motion to exclude Dr. Felsher and Dr. Salem.

**D. Plaintiffs' Due Process Claims.**

As a last ditch-effort, Plaintiffs claim a violation of due process. Particularly, they say they would be surprised "if the Court ... require[d] some version of exposure level calculation in Phase One (General Causation)...."[62] This argument lacks merit.

From the very beginning, Plaintiffs have been on notice of the Court's requirements. As early as 2021, for example, the Court wrote in the initial scheduling order:

> In a toxic tort case, the plaintiff must prove both general causation ... and specific causation.... **[B]oth types of causation involves a question of concentration levels** of the toxin to which plaintiff was exposed....[63]

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[61] Salem Report p. 4.

[62] Plaintiffs' Supplemental Brief at p. 14.

[63] First Consolidated Case Management Order at p *15. n5 (June 11, 2021) (emphasis added)).

This was Plaintiffs' first clue. Then came another: the first and second consolidated case management orders contain the same language on concentration levels. And the Court provided the final clue when it wrote:

> In Phase 1..., Plaintiffs must prove that exposure to EtO emission is capable of causing the harm that Plaintiffs allege. To carry their burden, they must demonstrate "the levels of exposure that are hazardous to human beings **generally**.[64]

Over and over, the Court told Plaintiffs that it would look to "levels of exposure" in Phase 1. So, any claim of surprise at this juncture is belied by the record. Plaintiffs request that the Court defer rulings on the pending motions is DENIED.

**E. Conclusion.**

To conclude, the Court (1) DENIES Defendants' motion to exclude Dr. Stayner's expert testimony; (2) GRANTS Defendants' motion to exclude Drs. Felsher and Salem's expert testimony; (3) DENIES summary judgment on Plaintiffs' claims for breast, hematopoietic, and lymphatic cancer injuries; (4) GRANTS summary judgment on Rosayln Gils' claims; and (5) DENIES Plaintiffs' request to defer rulings on pending motions based on due process grounds.

SO ORDERED this 22nd day of November 2024.

Judge Jane P. Manning
State Court of Cobb County

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[64] Order p. * 2 (March 29, 2023) (emphasis in original).