

IN THE STATE COURT OF COBB COUNTY
STATE OF GEORGIA

TOM MUTZ, *et al.*,

Plaintiffs,

vs.

STERIGENICS U.S., LLC,

Defendant.

CIVIL ACTION FILE
NO. 20-A-3448

EMMA J. BONNER,

Plaintiff,

vs.

STERIGENICS U.S., LLC,

Defendant.

CIVIL ACTION FILE
NO. 21-A-2420

MARY ANN HARRELL,

Plaintiff,

vs.

STERIGENICS U.S., LLC,

Defendant.

CIVIL ACTION FILE
NO. 21-A-4396

Order on Parties' 702 Motions to Exclude Experts and Sterigenics'
Motion for Summary Judgment

1. Statement of the Case

1.1. Introduction

“The dose makes the poison.” The 16th Century Swiss physician Paracelsus is still quoted when one must assess a substance’s harmfulness. In this case, the Court must decide if the challenged Phase II causation experts can give their opinions at trial as to whether the three Bellwether Plaintiffs’ ethylene oxide (EtO) doses are sufficiently linked to their cancers. The Court’s gatekeeping role is made even more difficult than the usual toxic tort case because EtO is naturally occurring, and it is produced by numerous manmade sources in our society. In other words, Sterigenics is not the only source of EtO exposure for these Plaintiffs.

That is why establishing background levels of EtO is so important to causation in this case. The most crucial issue this Court must decide is: Were Plaintiffs exposed to levels of Sterigenics-related EtO above background and was that dose sufficient to cause their specific harm?

There is no doubt that these Bellwether Plaintiffs¹ have suffered harm. They have each been diagnosed with cancer. Emma Bonner is a 76 year-old woman who was diagnosed with chronic lymphocytic leukemia (CLL) in 2011. Expert Report of Dr. Dean Felsher 6. Mary Ann Harrell is a 74 year-old woman who was diagnosed with breast cancer in 2006. *Id.* at 10. And Ava Mutz, now a college student, was just two years-old when she was diagnosed with acute lymphoblastic leukemia (ALL) in 2005. *Id.* at 12. All of them lived near the Smyrna Sterigenics plant.

¹ To manage such a complex case, the parties and the Court agreed to a “Bellwether Plaintiff” system where issues common to all plaintiffs may be litigated while the hundreds of cases not in the bellwether group are stayed. See First Consolidated Case Management Order June 11, 2021.

Sterigenics has operated a medical equipment sterilization plant, a global distribution center, and warehouses at 2971 Olympic Industrial Drive, Atlanta, Georgia 30339 for more than 60 years. To sterilize medical equipment, Sterigenics uses EtO, a chemical that the United States Environmental Protection Agency, among others, has determined to be carcinogenic in humans. *See* Court's Order on General Causation November 22, 2024.

1.2. Procedural History

This litigation has a long history with the Court. The first Sterigenics-related cases began populating the Court's docket in January 2020. To date, there are hundreds of plaintiffs seeking compensation from Sterigenics. There have been innumerable conferences, several scheduling orders, and numerous substantive orders. There have been at least four attempts for interlocutory review. Two of those applications have been successful. In 2022, Sterigenics appealed the Court's denial of severance of the close to 400 plaintiffs. In 2024, both parties appealed the Court's ruling on General Causation. At the time of this order, the parties and the Court are awaiting the opinion of the Court of Appeals as to General Causation.

Now, the parties have submitted their Rule 702 objections to their opponents' expert opinions. In addition, Sterigenics seeks Summary Judgment on Specific Causation as to each Bellwether Plaintiff and Partial Summary Judgment on the issue of Nuisance.

The parties have challenged various experts' testimony. Plaintiffs have moved the Court to exclude the specific causation testimony of the following defense experts:

Dr. Brian Mitchell

Daniele Wikoff, PhD

Dr. Phillip Beron

Mr. John Henshaw

Sterigenics likewise seeks to exclude the following Plaintiffs' experts:

H. Andrew Gray, PhD

Ranajit Sahu, PhD

Dean Felsher, MD, PhD.

Robert D. Harrison, MD.

After reviewing voluminous pleadings, briefs, exhibits and depositions, the Court held a weeklong hearing with seven experts testifying live before the court. The goal? To ascertain whether their opinions met the standards set out in O.C.G.A. § 24-7-702 (Rule 702) and will be admissible at trial.

2. Issues to be Decided

1. Whether Plaintiffs' Motions to Exclude Defense Experts should be granted.
2. Whether Sterigenics' Motions to Exclude Plaintiffs' Experts should be granted.
3. Whether summary judgment to Sterigenics is in order.

3. Principles of Law

3.1. In this Toxic Tort Case, Plaintiffs Must Establish a Genuine Issue of Material Fact as to Specific Causation to Survive Sterigenics' Motion for Summary Judgment and They Need Expert Testimony to do So.

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 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

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

material fact exists.³ Once the moving party discharges its burden, the burden then shifts to the non-moving party who must rebut the movant's showing by producing relevant and admissible evidence beyond the pleadings.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

Succinctly put, summary judgment is not a time for fact-finding; that task is reserved for trial. Rather, on summary judgment, the court must accept as fact all allegations the non-moving party makes, provided they are sufficiently supported by evidence of record. So, when competing narratives emerge on key events, courts are not at liberty to pick which side they think is more credible. Indeed, if "the only issue is one of credibility," the issue is factual, and a court cannot grant summary judgment. *City of Atlanta v. Block, Inc. of Delaware*, 375 Ga. App. 717, 726 (2025) (internal citations omitted). The judge's function is not to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial. *Mountain Bound, Inc. v. Alliant Food Service, Inc.*, 242 Ga. App. 557, 560 (2000). And if a reasonable jury could make more than one inference from the facts, and one of those permissible inferences creates a genuine issue of material fact, a court cannot grant summary judgment; it must hold a trial to get to the bottom of the matter. *Id.*

And to do so, Plaintiffs must provide experts who opine as to specific causation. *Wadley v. Mother Murphy's Laboratories, Inc.*, 357 Ga. App. 259, 263 (2020). "But when there is no obvious origin to an injury and it has multiple potential etiologies, expert testimony is

³ *Id.*

⁴ *Id.*

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

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

necessary to establish causation.” *Smith v. CSX Transp., Inc.*, 343 Ga. App. 508, 516 (2017). Without such expert testimony, summary judgment is appropriate. “Absent reliable expert testimony that exposure to a ...product contributed to the development of [a plaintiff’s harm}, there is insufficient evidence to create a jury issue as to causation.” *Butler v. Union Carbide Corp.*, 310 Ga. App. 21, 30 (2011).

3.2. Rule 702 Requires a Judge to Exercise its Gatekeeping Role to Allow Only Relevant and Reliable Evidence to Come Before the Jury.

Expert testimony is admissible in Georgia,

“[i]f 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: (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 will be admitted into evidence before the trier of fact.”

O.C.G.A. § 24-7-702.

The proponent must satisfy this burden by a preponderance of the evidence. *Humphrey v. Emory Clinic, Inc.*, 369 Ga. App. 131, 139 (2023).

Whether Plaintiffs have provided reliable expert testimony requires further analysis. Georgia is a “*Daubert* State” and requires that proffered expert testimony must “fit” the facts of the case. “[U]nder the Supreme Court of the United States’s opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, expert testimony is only admissible if it is both: (1) relevant and (2) reliable, and an expert opinion is ‘relevant’ if it will assist the trier of fact to understand the evidence or to determine a fact in issue.” *Cartledge v. Montano*, 325 Ga. App. 322, 325 (2013). (punctuation omitted.)

Sterigenics' Motion for Summary Judgment on Specific Causation (and Motion for Partial Summary Judgment as to Nuisance) hinge on the admissibility of some of those experts' opinions. The Court finds one Plaintiffs' expert, Dr. Sahu, key to this analysis. With its gatekeeping role in mind, the Court will start with Dr. Sahu's opinions.

4. Dr. Sahu

Dr. Sahu is undoubtedly a very accomplished scientist with a PhD in mechanical engineering from California Institute of Technology in 1988. He has worked in the environmental, mechanical and engineering fields for over 30 years. He's taught about air pollution and emission controls for several universities. He has consulted with the EPA and other entities in this regard as well. As such, he satisfies the first prong of this Rule 702 analysis.

With such an extensive background in air pollution, air dispersion modeling and risk assessments, it is no wonder that Plaintiffs hired him to establish the basis for specific causation in these cases.

In order to establish specific causation, Plaintiffs must have admissible expert opinions as to:

- 1) how much EtO Sterigenics emitted into the air over forty-four years (the "period of interest": 1967-2011),
- 2) what the background amount of EtO was over those years,
- 3) how much over that amount did Sterigenics emit into the neighborhoods surrounding the plant,
- 4) what amount of EtO emitted by Sterigenics reached Plaintiffs,
- 5) how much of Sterigenics-emitted EtO did Plaintiffs inhale, and

6) whether that amount contributed to Plaintiffs' diseases.⁷

Dr. Sahu's expertise is necessary to satisfy the first five of these requirements. Even in the best of circumstances, this would be a tall task. However, this task was made even more daunting by the lack of data for some calculations and by a lack of sound methodology for others.

4.1. Dr. Sahu's Conclusions as to the Amount of EtO that Sterigenics Emitted into the Air are Prohibited Because They are Based on Unreliable Facts.

Dr. Sahu used the mass balance methodology to determine how much EtO escaped the Sterigenics plant. "[S]ince EtO stylization is not a chemically reactive process, emissions can be estimated using a calculation methodology called mass balance. This approach is widely accepted by regulatory agencies, such as the EPA, and is commonly used by engineers." Expert Report of Dr. Ranajit Sahu 81. The methodology itself is relatively simple. To calculate how much EtO Sterigenics released into the atmosphere, one would need to know the amount of EtO Sterigenics used, subtract the amount of EtO that was captured by pollution controls, and the balance would necessarily be emitted by the plant. To be accurate, this relatively simple methodology needs reliable data as to the amount of EtO Sterigenics used. In this regard, Dr. Sahu is hampered a lack of such data.

4.1.1. Sahu's Mass Balance Analysis Fails Because Dr. Sahu's Calculations as to the Amount of EtO Used by Sterigenics over the Decades are Based on Insufficient Facts.

The "period of interest" in this matter is from 1967 to 2011. Sahu Report 90. Dr. Sahu admits he has no data of how much EtO Sterigenics used for the years prior to 1987 or for the years 1989-1994 and 2017-2021. *Id.* at 85. He estimated how much EtO was used

⁷ Dr. Sahu is not offered as a medical causation expert as to the Plaintiffs' cancers. (Sahu 5/25/ Dep. 32:18-21)

by dividing, “the annual EtO usage by the pallet capacity of the sterilization chambers at the facility for the years 1989, 1991, and from 1993 to 2018.”⁸ I then calculated the median of these values, which was used to estimate EtO usage for the years 1967 to 1988.” Sahu Report 89, *see also* Sahu 5/6/25 Dep. 96:4-99:15. Therefore, to calculate EtO usage for the forty-four year “period of interest” (1967-2011), Dr. Sahu only had yearly EtO data for twenty-two of these years (1989, 1991, and 1993 to 2011).

Finding the mean from decades of known EtO usage and applying it to decades of unknown EtO usage would be permissible if the plant had steady production. Here, that is not the case. Dr. Sahu’s Table 11 shows a wide variety of EtO usage for the years that are known. Sahu Report 90. Dr. Sahu admits his estimates are not based on empirical evidence as to the amount of EtO used by Sterigenics in the missing years because he did not know Sterigenics’ operating schedules. Sahu 5/6/25 Dep. 34:18-36:2.

Dr. Sahu’s reliance on irrelevant data also undercuts his calculation as to how much EtO Sterigenics used. He applies usage figures from 2012-2018 and partial monthly usage figures from 2019-2021 to the missing twenty-two years (1967-1988, and 1992). In other words, he uses irrelevant data (the years after the “period of interest”) to get the mean and apply it to the missing years. As such, his data is not reliable.

4.1.2. The Next Step of the Mass Balance Methodology, i.e., Estimating How Much EtO was Captured by Pollution Control Devices, is also Based on Unreliable Data.

To estimate how much EtO was captured and how much was released into the air, Dr. Sahu estimated the pollution controls’ “control efficiency.” “Control efficiency is a measurement of how effective air pollution devices are at attenuating the mass of toxic air

⁸ Dr. Sahu had “[m]onthly EtO usage data for the years 1999, 2001-20018, and portions of 2019, 2020, and 2021.” Sahu Report 89.

pollutants captured and routed through these devices.” Sahu Report 22. “Accurately estimating control efficiency (‘CE’) is central to accurately estimating emission to any reconstruction of emission estimates.” *Id.* This calculation is based on “splits” between the amount of EtO that went out through “chamber vacuum, backvent, aeration, fugitives, and residuals.” *Id.* at 81.

Dr. Sahu is critical of the splits upon which Sterigenics relies. The criticisms may be valid. Indeed, the “industry-standard” splits Sterigenics cites made be plucked out of thin air. “Sterigenics reliance on the generic ‘95/4/1’⁹ split for reporting and permit application purposes...is unsupported and was never the industry standard...” *Id.* at 82.

Dr. Sahu criticized Sterigenics for not conducting a site-specific analysis. “Instead of engaging in this site-specific inquiry...Sterigenics relied on a combination of generic assumptions, claiming that they were based on non-existent ‘industry standards’, along with optimistically high control efficiencies to estimate its TRI-reported EtO emissions.” *Id.* at 81. Dr. Sahu goes on to explain that taking data from other facilities is bad methodology. “Though the processes used at EtO sterilization facilities are generally similar, EtO emissions can vary substantially from one facility to the next. In particular, emission pathways like fugitives, aeration, and backventing can vary based on factors specific to, *inter alia*, a given facility’s size, design, payout, workflow, ventilation systems, and age. Control efficiencies of air pollution controls are also site-specific. Developing an accurate picture of emissions, therefore, is a site-specific inquiry.” *Id.* at 81. But it is Plaintiffs’ burden to establish how much EtO was released into the air to establish specific causation and Dr. Sahu uses unreliable data to establish how much EtO was captured by pollution control devices.

⁹ Splits, denoted by numerical figures such as 95/4/1, are shorthand for emission percentages between the chamber vacuum/aeration/backvent emissions respectively. Sahu Report 96.

Dr. Sahu says he conducted a site-specific inquiry of Sterigenics. But Dr. Sahu's choice of "splits" is not based on site-specific data. He relies on data from other companies—exactly the same type of data he criticizes Sterigenics for using. "Where I had site-specific information, I have used that, like for fugitives. But in the absence of that type of testing not being done in this time period through 2011, I have had to use conservative estimates." Sahu 5/6/25 Dep 110:6-15.

Dr. Sahu relies on other facilities' data to establish the efficacy of Sterigenics pollution control efforts. For residuals, he "used a value of 0.5% through 1999 and a value of 0.1% thereafter. The value of 0.1% is the low end of the range as reported to the EPA in September 2019 by another sterilization company, STERIS, which uses similar sterilization processes as Sterigenics and 0.5% is a conservative midpoint of the range reported by STERIS." Sahu Report 101. Similarly, he used other facilities to determine his estimates of aeration and backvents. *Id.* Even fugitive emission estimates come from other sterilization facilities. *Id.* at 114. As such, Dr. Sahu's determination of the amount of EtO captured by pollution control devices, i.e., the amount to be subtracted from the total amount of EtO Sterigenics used during the "period of interest", is based on unreliable data and fails a Rule 702 analysis.

4.1.3. Dr. Sahu's Determination of Fugitive Emissions Based on Sterigenics' Indoor Air Monitoring is Methodologically Flawed.

Another piece of the puzzle needed to estimate how much EtO was emitted into the air around Sterigenics is the amount of fugitive emissions. Fugitive emissions are those that went directly into the air around the plant without restraint. To be sure, it is not credible to conclude that no uncontrolled, fugitive emissions seeped into the area around the plant. But what amount? Dr. Sahu used readings from the plant's gas chromatograph ports and Sterigenics' employees' badge readers to estimate such amounts.

However, Dr. Sahu's badge data methodology is flawed. Dr. Sahu extrapolated badge readings from individual employees to estimate the concentration of EtO on a particular day in a particular room within the plant. Then he used that data to establish the amount of fugitive emissions. However, employees often moved around the plant and Dr. Sahu could not determine what room they were in. He would either count it as "facility wide," Sahu Report 108, Sahu Dep 5/6/25 136:16-19, or assign a location based on the employee's job description. Sahu Report 108, Sahu Dep 5/6/25 136:7-15. In fact, more than half of the badge reader data was not assigned to a particular room. Sahu Dep 5/6/25 137:1-18. Sometimes when he found an unknown location, he assigned it as "facility wide." And sometimes he did not count the unknown location reading at all. Sahu Dep 5/6/25 139:16-140:15.

Dr. Sahu opines that Sterigenics indoor pollution readings underestimate the amount of fugitive EtO emissions, i.e., that they are "conservative." One problem with the badge readings is, as Dr. Sahu opines, that the amount in any given room would be higher than the badge readings. Dr. Sahu states that because EtO is a gas, it rises when a room is warm and congregates towards the floor when a room is cold. Therefore, EtO is either concentrated above or below the employee's badge (estimated to be at a height of 5.5 feet). His opinion as to EtO rising in a warm room was curiously left out of his expert report. In fact, he specifically states in his report that EtO would settle towards the floor. "EtO is denser than air, with a relative vapor density of 1.5, allowing it to settle at lower levels in quiescent indoor environments." Sahu Report 12. And, Dr. Sahu opines, stationary sampling ports would also underestimate the amount of EtO in a room. He opines that lower levels of EtO would be found in corners where stationary sampling ports are likely to be. *Id.* at 44. *See also*

Sahu Dep 5/6/25 192:17-20. The Court finds the opinions as to warm EtO rising or not being found in corners *ipse dixit*.¹⁰

Because Dr. Sahu's mass balance estimates are based on plugged-in numbers to account for missing decades of EtO usage, and the calculations as to captured emissions are based on non-site-specific emission splits, and fugitive emission estimates are based on unreliable data and flawed methodology, Dr. Sahu's opinions as to the amount of EtO that Sterigenics emitted into the air around its Smyrna plant fail a Rule 702 analysis.

Of course, Plaintiffs would like for these challenges to Dr. Sahu's calculations to be addressed by vigorous cross-examination rather than by exclusion. However, the Court finds that—at every level in the mass balance methodology—there are significant gaps in reliable facts and improper uses of methodology. In a criminal case, a reviewing court is permitted to reverse a conviction on cumulative error. It may not be a perfect analogy, but this Court finds the cumulative effect of each reliance on scant data and flawed methodology as a basis for Dr. Sahu's mass balance calculation just too much to trust cross-examination to help the jury sort out reliable facts and methodology. Simply put, this evidence is not up to the Rule 702 standard.

4.2 Dr. Sahu's Calculation as to "Background" is Flawed Because It Relies on 2019 Emissions Sources.

Plaintiffs' burden is to isolate how much Sterigenics-attributable EtO *above background* did each Plaintiff inhale (or receive *in utero* as in the case of Mutz) and did that amount contribute to Plaintiffs' diseases. As such, calculating EtO background levels are essential to

¹⁰ In addition, such indoor air monitoring was only instituted at Sterigenics in 2002. Sahu Report page 45. Applying the data to thirty-five years of missing data in the "period of interest" (1967-2011) also makes Dr. Sahu's conclusion as to the amount of fugitive emissions suspect.

Plaintiffs' specific causation analysis. But calculating background is difficult. EtO is naturally occurring. Our bodies produce it. Dr. Samuel Cohen, hearing transcript.¹¹ Other animals bodies produce it. *Id.* Forest fires produce it. Dr. Ranajit Sahu hearing transcript. Lightning strikes produce it. *Id.* Cigarette smoke produces it. Dr. Samuel Cohen, hearing transcript. And industry polluters other than Sterigenics produce it. Sahu Dep 5/6/25 236:13-18.

Background EtO differs by location and varies over time even within the same location. "Background is not one value everywhere...Background might be different—different places, different times. So the idea—I know background seems to convey in some plain English meaning that it's some constant level value to—I mean, unchanging all places, all times, but that's not what background it..." Sahu Dep 5/6/25 234:13-21. Curiously, these Plaintiffs, who live within close proximity to the plant, would have different background levels. "Background can change, yes. Background for these Plaintiffs is different." Sahu Dep 5/6/25 235:2-3. *See also* Dr. Samuel Cohen, hearing testimony. Even the EPA—a federal agency with vast resources and a stated mission to protect the population from air pollution risks—is unable to quantify background EtO. "Recognizing the many issues associated with EtO monitoring data collected by various states, the US EPA has not determined even a regulatory background for EtO much less specific backgrounds for specific citizens in the United States." Sahu Report 133.

Again, Dr. Sahu was given a tall task. Because there was no monitoring data available to him, Dr. Sahu attempts to establish background by using the 2019 NATA results, i.e., modeling. Sahu Report 133, Sahu Dep 5/6/25 246:5-9. The NATA report took EtO

¹¹ At the time of entering this Order, the Court did not have the benefit of a certified transcript of the week-long *Daubert* hearing. A rough transcript was supplied to the parties and to the Court. When the Court refers to the August hearing, it will be cited as "hearing transcript."

emission from five EtO emitters and modeled how much EtO made it to census tracts relevant in this case.

The NATA results are essentially a snapshot in time, but Dr. Sahu uses them to calculate the background level of EtO in the Smyrna area for the forty-four year “period of interest.” He provides no validation for this use of the NATA report. Dr. Sahu counters this problem with the assertion that his estimates are “conservative”. Sahu Dep 5/6/25 242: 6-8, 244:1-3, 247:2-13.

When asked about using 2019 estimates to apply to the background levels for the “period of interest” in these cases, Dr. Sahu stated that these background levels would be “conservative”, i.e., more favorable to Sterigenics, because there was less industry in the past than today. Dr. Ranajit Sahu hearing testimony. This opinion is pure *ipse dixit*. Dr. Sahu has no information as to what industries may have been emitting EtO during the “period of interest” and what pollution controls they might have had. Indeed, by his own admission, Sterigenics would have released more EtO into the air earlier in its existence because of a lack of pollution controls.

(C)hamber vacuum emissions (i.e., from the initial evacuation after the EtO dwell phase of the cycle, and the subsequent washes—until the chamber door was opened) were not controlled at the Smyrna Facility until 1987. Aeration room emissions were not captured or controlled until 2000—and only then to meet regulatory requirements. Chamber exhaust vent, or backvent emissions, were left uncontrolled until 2016, well after the time period of interest in this matter. In addition, fugitive emissions were not captured (and therefore not controlled) at the Smyrna Facility for the entire time period of interest in this matter.

Sahu Report 22.

It only makes sense that other EtO emitters would have done the same thereby making EtO background levels higher than they are now.

Because his opinion as to the background level of EtO to which Plaintiffs were exposed is based on irrelevant data and flawed methodology, Dr. Sahu's opinion as to background EtO fails Rule 702 analysis.

4.3 Dr. Sahu's Assertions that His Estimates are "Conservative" does not Make Up for Limited Data and Flawed Methodologies.

When challenged as to his particular methodology on any given calculation, Dr. Sahu often claims his numbers are "conservative" and that the levels would be higher than his results would indicate. For example:

- Bonner's time away from Smyrna: Sahu Dep 5/6/25 29:22-23, 30:6-12, 53:17-21, 55:2-3.
- Harrel's time away from Smyrna: Sahu Dep 5/6/25 200:12-16.
- Emissions from backvents. Sahu Dep 5/6/25 61:23-62:3, 63:18-19, 447:10-15.
- Sterigenics' estimated use of EtO for the "period of interest": Sahu Dep 5/6/25 102:15-21, 103:1-7, 187:7-10.
- Control efficiencies and splits: Sahu Dep 5/6/25 110:6-15, 255:1-3, 269:16-20.
- Background estimates: Sahu Dep 5/6/25 235:15-19, 244:1-3.
- Fugitive emissions: Sahu Dep 5/6/25 365:10-11.
- Badge readers: Sahu Report 44, Sahu Dep 5/6/25 118:15-17, 119:13-120:17, 122:20-24, 123:8-13, 125:3-6, 130:4-9, 131:3-7, 149:9-11, 367:20-22, 369:10-11.
- Air modeling: Sahu Dep 5/6/25 136:16-19, 411:8-21.

At one time in Dr. Sahu's deposition, a clearly frustrated examiner asked, "Can you think of any—any calculation that you've done in this litigation that you won't say is an understatement?" Dr. Sahu answered, "I've tried to be conservative. I mean, that's the general philosophy is when you don't know something and you're estimating something,

because the facility has not collected data that is representative, you want to be conservative in favor of the defendants.” Sahu Dep 5/6/25 193:23-194:6. As such, Dr. Sahu defends his use of claiming “estimates are conservative” because he does not have the actual data. Sahu Dep 5/6/25 446:7-9. This is precisely the problem with Dr. Sahu’s testimony: through no fault of his own—or through no fault of Sterigenics for that matter—he simply does not have the relevant data.

4.4. Dr. Sahu’s Plaintiffs’ Risk Assessments are Prohibited Because They are Based on a Misuse of Methodology, They are not Helpful to the Jury and They Fail a Rule 403 Balancing Test.

Dr. Sahu uses a calculator, the EPA’s 2016 Integrated Risk Information System (IRIS) Inhalation Unit Risk (IUR), to calculate something for which it is explicitly not to be used. The EPA properly uses its IRIS IUR calculation to determine the risk of a person getting cancer from pollution sources. But Plaintiffs already have cancer. The EPA states its IUR “cannot be validly used to accurately predict the incidence of human disease or the type effects that chemical exposures have on humans. . . . *Such risk estimates also cannot be used to determine whether someone who already has cancer is ill because of past exposure.*” Defendants’ Motion to Exclude Ranajit Sahu, PhD, CEM under O.C.G.A. § 24-7-702, 27-28 (emphasis added). As such, the risk assessments are not helpful to the jury. Indeed, the only purpose for this evidence would appear to be to inflame the passions of the jurors. These risk assessments’ limited relevance is substantially outweighed by the risk of unfair prejudice. O.C.G.A. § 24-4-403. Therefore, it is excluded under Rule 702 and a Rule 403 analysis.

4.5. Dr. Sahu’s Plaintiff Mutz Exposure Levels Lack Reliable Methodology as He Calculates her Exposure *In Utero* as the Same as Early Childhood.

Ava Mutz was diagnosed with ALL at the tender age of two and a half. Unlike other Bellwether Plaintiffs, she did not have decades of exposure to EtO. In order to assess how

much EtO to which she was exposed, it makes sense that one would look to how much EtO her mother inhaled while she was pregnant with Ava. But calculating how much of the inhaled EtO made it to Ava *in utero* is not simple. It takes someone with specialized training in math and toxicology and toxicology is outside Dr. Sahu's expertise. Dr. Danielle Wikoff hearing testimony. Dr. Wikoff stated that the methodology for calculating *in utero* exposure is called "PKPU." Dr. Danielle Wikoff hearing testimony. Dr. Sahu did not use this calculation but used a calculation unrelated to *in utero*. "I have also used the same approach above to estimate the metrics for Ms. Mutz, *in utero*, using the same factor of 10 for the ADAF (age-dependent adjustment factor) as EPA has suggested for the early childhood period." Sahu Report 127. By using an inapplicable matrix, i.e., one applicable to children of tender years but not to fetuses, Dr. Sahu's opinion as to the amount of EtO Ava Mutz received in her short life before diagnosis unreliable and therefore excluded after a Rule 702 analysis.

4.6. Conclusion: Dr. Sahu's Expert Opinions Lack the Reliability Required by a Rule 702 Analysis and Summary Judgment as to Specific Causation is Appropriate.

Dr. Sahu's opinions as to dose and background are essential to Plaintiffs' cases. Because the Court finds that Dr. Sahu's opinions as to the amount of EtO Sterigenics emitted into the air over forty years (i.e., his opinion based on mass balance methodology), and the EtO background levels around Smyrna during those years fail Rule 702 analysis, Dr. Sahu's opinions as to specific causation must be excluded and Sterigenics' Motion for Summary Judgment to Specific Causation must be GRANTED.

However, if a reviewing court were to find this Court's analysis lacking, the Court will address all Rule 702 expert motions in the interest of judicial economy.

5. Plaintiffs' Motions to Exclude Sterigenics' Experts

The Court will now turn to Plaintiffs' Rule 702 motions as to Sterigenics' Experts.

5.1. Dr. Brian Mitchell

Dr. Brian Mitchell is a well-qualified oncologist. He opines that “non-occupational exposure to ethylene oxide has not been implicated as a cause of chronic lymphocytic leukemia (CLL).”¹² He opines similarly as to Ms. Mutz's acute lymphoblastic leukemia (ALL).¹³ His opinions satisfy the *Daubert* requirements as to general causation. Plaintiffs challenge him on specific causation. In a way, they are correct. Because Dr. Mitchell opines that EtO cannot cause the harms Plaintiffs generally allege (general causation), he may not opine that, as to these specific levels, their cancers were not caused by their exposure to EtO from the Sterigenics plant. But this is a distinction without a difference. Unlike the pretrial issues that are unique to this case, the jury will not have to decide on general or specific causation, only causation. As such, Dr. Mitchell may testify as to his causation opinions. Motion to Exclude Dr. Mitchell's causation opinions is DENIED.

5.2. Dr. Daniele Wikoff

Dr. Wikoff is the Chief Scientific Officer at ToxStrategies, Inc. She has a PhD in Toxicology. She's a member of numerous professional organizations and has authored more than 70 peer-reviewed articles. Her specific causation opinions appear to be straightforward math as to Plaintiffs' exposure levels as provided by Defendant's expert Dr. Bhat. It is noted that Dr. Bhat's calculations have not been challenged by Plaintiffs. Motion to Exclude Dr. Wikoff's expert opinions is DENIED.

¹² Expert Report of Dr. Brian Mitchell as to Emma Bonner 1.

¹³ Expert Report of Dr. Brian Mitchell as to Ava Mutz 1.

5.3. Dr. Phillip Beron

Sterigenics offers Dr. Phillip Beron, a radiation oncologist with a specialty in breast cancer, as a specific causation expert as to Mary Ann Harrell's breast cancer. There is no doubt that Dr. Beron is qualified to opine as to Ms. Harrell's risk factors for breast cancer, the latency period for breast cancer (i.e., the time between the development of the cancer cells and diagnosis), and her prognosis.

The level of dose is, of course, important to any causation analysis. Dr. Beron states there is no association between breast cancer and exposure to EtO at the low levels to which Ms. Harrell was exposed. As such, this opinion is a general causation opinion rather than a specific causation opinion. As with Dr. Mitchell, this is a distinction without a difference.

The Court finds his general causation opinion supported by a Rule 702 analysis. He reviewed the studies offered by both parties, the IARC conclusions and the American Cancer Society risk factors for breast cancer. However, he may not opine as to Ms. Harrell's level of exposure to secondhand smoke as a child as he has insufficient data from which to draw his conclusions.

Motion to Exclude Dr. Beron's expert opinion is DENIED IN PART and GRANTED IN PART.

5.4. Mr. John Henshaw

Plaintiffs challenge yet another expert, Mr. Henshaw, on whether he can explain the OSHA warnings to employees in the Sterigenics plant. The Court rules that Mr. Henshaw may testify there are warnings in the Sterigenics plant, they are required by OSHA and the threshold dose which is concerning to OSHA is one part per million per eight hour shift.

Motion to Exclude Mr. Henshaw is GRANTED IN PART and DENIED IN PART.

6. Sterigenics' Motions to Exclude Plaintiffs' Experts

6.1. Dr. Andrew Gray

Dr. Gray's calculations are the foundation for assessing Bellwether Plaintiffs' EtO exposure levels. He is an expert in assessing air quality impacts of industrial facilities. He has an PhD in Environmental Engineering Science and has authored over 50 scholarly publications.

Dr. Gray used the AERMOD dispersion model to calculate exposures of EtO to Plaintiffs. AERMOD takes meteorological data (like wind speed) from places such as local airports. It then models how a particular source's emissions from may have traveled. Dr. Gray used the AERMOD model to see if the emissions from Sterigenics may have reached Plaintiffs. Dr. Gray worked with Dr. Sahu on "receptors of interest" (i.e., places where a plaintiff may have lived, worked, or recreated) to determine precise exposures to these plaintiffs). Sahu Report 88.

Sterigenics argues that Dr. Gray's use of the AERMOD model lacks reliable methodology and seeks to have his testimony deemed inadmissible. It says he improperly substituted an hourly average of known meteorological conditions for hours that the model deemed calm or missing. Sterigenics rightfully cites to EPA rules that calm or missing hours should not be used in a calculation of emission concentrations. In other words, a calm or missing hour is removed and not considered when averaging other known data points.

Dr. Gray had another idea. With a wealth of readings (over 50 years), he would average hours on a particular day of the week and hour of that day (for example, Monday at 2 pm) and substitute those average hours for the calm or missing hours. As stated, this is in direct contradiction to EPA guidelines. Nevertheless, the Court finds it is a straightforward methodology that meets the Rule 702 standard. It is testable and reproducible. Its flaws may not survive vigorous cross examination, but that is an issue of weight not admissibility. Defendants' Motion to Exclude Dr. Gray is DENIED.

6.2. The Opinions of Drs. Felsher and Harrison Do Not Satisfy the Causation Requirements Under Georgia Law.

Both doctors testified in person at the week-long Rule 702 hearing. They are both highly credentialed physicians. Dr. Felsher is the Associate Chief of the Division of Oncology at Stanford University. He is a medical doctor with a PhD in molecular biology. Dr. Harrison is a medical doctor with a master's in public health. His areas of expertise are environmental medicine, health sciences, toxicology and epidemiology. He teaches toxicology to medical students and physicians.

Both experts rely on Dr. Sahu's inadmissible emissions and risk calculations and assert only that Plaintiffs' alleged EtO exposure was more than "de minimis" and contributed to their diseases.

6.2.1 Dr. Felsher

Dr. Felsher relied on Dr. Sahu's analysis as to Plaintiffs' exposure to Sterigenics-emitted EtO to opine that such exposure specifically caused Plaintiffs' cancers. Felsher Report 4, 7. He relied on Dr. Sahu's background calculations. Felsher Dep 5/12/25 242:14-17. He also relied on Dr. Sahu's risk assessments. *Id.* at 168:4-8. And because he relied on Dr. Sahu's calculations as to background and risk assessments are based on insufficient data and questionable methodology, Dr. Felsher's opinions must be excluded after a Rule 702 analysis.

If a reviewing court disagrees with the Court's analysis and permits Dr. Sahu's calculations relied upon, Dr. Felsher's differential diagnosis analyses (although allegedly flawed) are well-suited for cross-examination rather than exclusion.

6.2.2. Dr. Robert Harrison

Dr. Harrison conducted a qualitative and quantitative analysis of each Plaintiffs case and opines that the EtO emitted by Sterigenics is the specific cause of their cancers. He

considered Dr. Sahu's quantitative analysis as to background and risk assessment. Dr. Robert Harrison hearing testimony. Because Dr. Harrison considered unreliable data in his quantitative analysis, i.e., Dr. Sahu's conclusions as to background levels and risk assessments, his quantitative analysis opinion as to specific causation fails a Rule 702 analysis.

His qualitative analysis fails as well. He bases his specific causation opinion on the 2019 NATA study. The Court finds the 2019 NATA study irrelevant to these Plaintiffs who were diagnosed with cancer in 2011 or before. In addition, Dr. Harrison uses an "any exposure" methodology to find causation in these cases.

Because I know that they were exposed to ethylene oxide. In my opinion, I think there is adequate evidence to say that they were exposed to ethylene oxide. Both my qualitative review based on the Georgia data and the quantitative analysis by Dr. Sahu shows that their exposure to ethylene oxide put them at significant excess cancer risk, which makes, in my field and in my practice, when I see patients that more than a negligible, that makes it a more than a de minimis, that makes it a meaningful risk. So I didn't see any other conclusion aside from that. But I know that they're exposed, or I have reason to think, and I think the evidence is pretty solid here, that they're exposed to a carcinogen that is linked to their cancers.

Dr. Robert Harrison hearing testimony.

Because Dr. Harrison relied on Dr. Sahu's prohibited opinions and the irrelevant 2019 NATA study and his assumption that *any exposure* to EtO would be the cause of Plaintiffs' cancers, his differential diagnosis analysis is prohibited. His opinions are excluded in their entirety even if a reviewing court would find Dr. Sahu's calculations admissible.

The opinions of Drs. Felsher and Harrison do not meet Georgia's evidentiary standard for cause in fact or proximate causation. Without admissible evidence of specific causation, Sterigenics is entitled to summary judgment under Georgia law.

7. Standard of Care/State of the Art Opinions


In related Rule 702 motions, two Plaintiffs' experts (Dr. DeGrandchamps¹⁴ and Dr. Sahu) are challenged on their opinions not as to causation but as to "standard of care" or "state of the art" opinions. The Court finds their "standard of care" or "state of the art" opinions do not relate to causation and therefore are RESERVED for Motions in Limine closer to trial in the event of a trial.

8. Order

It is ORDERED that:

- 1) Plaintiffs' Motion to Exclude Sterigenics Experts Drs. Mitchell and Wikoff are DENIED;
- 2) Plaintiffs' Motion to Exclude Sterigenics Experts Dr. Berron and Mr. Henshaw are GRANTED IN PART and DENIED IN PART;
- 3) Sterigenics' Motions to Exclude Plaintiffs' Experts Drs. Sahu, Felsher, and Harrison are GRANTED;
- 4) Sterigenics' Motion to Exclude Dr. Gray is DENIED;
- 5) and Sterigenics' Motion for Summary Judgment as to each Bellwether Plaintiff is GRANTED.

This the 17TH day of October, 2025.



Judge Jane P. Manning
Cobb County State Court

¹⁴ Plaintiffs withdrew Dr. DeGrandchamp as an expert on "good corporate stewardship" shortly before the hearings. Instead, they offer him as a "state of the art" expert.