

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
No. 7:23-CV-897

IN RE:)	PLAINTIFFS' LEADERSHIP
CAMP LEJEUNE WATER LITIGATION)	GROUP'S RESPONSE TO
)	DEFENDANT'S STATEMENT OF
This Pleading Relates to:)	APPEAL REGARDING DOCKET
)	ENTRY 821
ALL CASES)	

INTRODUCTION

Defendant appeals an order applying a rule it requested, which its own expert violated when she offered untimely general causation opinions in specific causation reports. Judge Jones properly assessed the testimony of Defendant's Phase III expert Dr. Lisa Bailey, and correctly determined that portions of Dr. Bailey's reports offered general causation methodologies and metrics that Defendant admits were not disclosed by the Phase II deadline. Specifically, drawing on regulatory agency reports and not any Phase II opinions, Dr. Bailey reached her own conclusions about the levels of toxic exposure that would not cause disease in humans generally (i.e., general causation determinations), called toxicity criteria and points of departure ("PODs"). Dr. Bailey used these reference values as benchmarks for comparison to Plaintiffs' exposures in two of her three methodologies (risk analysis and margins of exposure analysis). Judge Jones struck only those portions of Dr. Bailey's reports that offered or relied on these newly disclosed toxicity criteria and PODs. Because Judge Jones's order [D.E. 821] (the "Order") did not clearly err and was not contrary to law, it should be affirmed.

BACKGROUND

This Court established a phased expert discovery schedule, with expert testimony related to general causation (whether an exposure level can cause harm in humans generally) due in Phase II, and expert testimony related to specific causation (whether a specific plaintiff's exposure caused his or her harm) due in Phase III. [D.E. 821] at 1-2. At Phase II, Defendant's expert Dr. Julie Goodman disclosed general causation assessments for each Track 1 disease based on epidemiological literature. *See, e.g.,* Goodman Rep. (Bladder) at 5 (JA Ex. 75, D.E. 463-14). Dr. Goodman did not discuss risk assessment or the type of reference values agencies use to conduct regulatory risk assessments, such as toxicity criteria or PODs. *See* [D.E. 821] at 5-

6. The only Phase II expert that testified about risk assessment was Defendant's expert Dr. John Lipscomb, who opined that risk assessment and regulatory reference values are *inappropriate* for assessing causation. *See* [D.E. 816-1] at 1-2 & nn.1-2. No Phase II experts disclosed toxicity criteria or PODs, meaning PLG's Phase II experts had no opportunity to assess or rebut them.

At Phase III, Defendant's expert Dr. Bailey conducted three analyses to conclude that Camp Lejeune water did not cause any Track 1 Plaintiff's disease. First, in Sections 5.1 and 8 of each of her reports, she conducted an epidemiological analysis relying on Dr. Goodman's Phase II reports; these analyses are not at issue in this appeal. Next, in Sections 5.2 and 6-7 of her reports, and Appendix E to some reports, Dr. Bailey conducted risk assessments and margins of exposure analyses comparing each Plaintiff's individual exposures to toxicity criteria and PODs, respectively. *See, e.g.*, Bailey Rep. (Cagiano) §§ 5.2, 6, 7, App. E (JA Ex. 371, D.E. 490-6). Dr. Bailey selected, adjusted, and/or calculated each of the toxicity criteria and PODs she relied on, which were the same for every report for the same disease. *See* [D.E. 800] at 2-4 & n.7.

On June 23, 2025, Defendant moved to exclude what it called untimely general causation opinions in Plaintiffs' Phase III experts' reports. [D.E. 410.] The PLG opposed, including by arguing that Defendant's expert Dr. Bailey had introduced new general causation opinions. [D.E. 437] at 5-6. On July 22, 2025, the Court partially granted Defendant's motion, ruling that Phase III experts cannot offer "novel threshold calculations" or "any general causation methodologies that were not timely disclosed in Phase II." [D.E. 444] at 5, 8. That is because the Phases were meant to act as "building blocks," with Phase II disclosures informing what both parties would present in Phase III. *Id.* at 5.

Based on the July 22, 2025 order, the PLG moved to strike Dr. Bailey's new general causation testimony and testimony relying on it. [D.E. 787.] Defendant opposed [D.E. 790] and

the PLG replied [D.E. 800]. On February 13, 2026, the Court heard oral argument, at which Defendant conceded that “none of the United States Phase II experts disclosed these toxicity criteria” used by Dr. Bailey. Feb. 13, 2026, Hr’g Tr. [D.E. 812] at 74:3-4. After the hearing, Defendant filed a “Notice” regarding Phase II experts who had cited different sections of the same reports Dr. Bailey relied on for her toxicity criteria and PODs. [D.E. 815.] The PLG moved for leave to respond. [D.E. 816, 816-1.] On March 5, 2026, the Court granted PLG’s motion to strike Dr. Bailey’s testimony in the Order on appeal. [D.E. 821.]

STANDARD OF REVIEW

“Under Local Rule 72.4(a), Judge Jones’s order should not be disturbed unless it is ‘clearly erroneous or contrary to law.’” *Myers v. AT&T Inc.*, No. 5:12-CV-714, 2016 WL 225671, at *9 (E.D.N.C. Jan. 19, 2016) (quoting Local Rule 72.4(a)).

ARGUMENT

I. Toxicity Criteria and Points of Departure Are General Causation Metrics.

General causation testimony address “‘the levels of exposure that are hazardous to human beings generally,’ whereas specific causation considers the ‘plaintiff’s actual level of exposure.’” [D.E. 821] at 2 (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999)). Dr. Bailey’s toxicity criteria and PODs are calculations of the levels of toxins that may be hazardous to human beings *generally*. Dr. Bailey defined “toxicity criteria” as “quantitative estimates of risk of the adverse health effects associated with a given chemical exposure level,” “derived from . . . epidemiology or animal studies.” *E.g.*, Bailey Rep. (Cagiano) at 3 (JA Ex. 371, D.E. 490-6). PODs are related metrics “from which cancer and noncancer toxicity criteria are typically derived.” *Id.* at 10. These metrics are “established by US EPA and ATSDR” for protecting “populations.” *Id.* In other words, toxicity criteria and PODs are generalized,

population-level metrics, that are not unique to individuals. In Dr. Bailey’s words, they are “chemical-specific,” not plaintiff-specific. *Id.* Because these metrics are about the levels of a toxin that may be hazardous to human populations generally, and do not reflect any plaintiff’s actual level of exposure, they are general causation metrics. *See Westberry*, 178 F.3d at 264.

Defendant does not contest that toxicity criteria and PODs are population-level metrics that are not unique to each Plaintiff. Defendant admits “[t]oxicity criteria are regulatory values used to estimate potential human health risk” (i.e., risk of hazard to human beings generally) and to “develop exposure levels that agencies consider health-protective benchmarks.” [D.E. 829] at 4. Regulatory benchmarks are obviously not plaintiff-specific. Defendant was required to disclose at Phase II such general “benchmarks” against which its Phase III experts would compare each plaintiff’s individual exposure. By not disclosing the benchmarks Dr. Bailey used until Phase III, the PLG “was deprived of any opportunity to evaluate, probe, or rebut the opinions at issue through its own Phase II experts.” [D.E. 410] at 9 (Defendant arguing why untimely general causation opinions should be excluded).

The clearest sign that Dr. Bailey’s toxicity criteria and PODs are general, not specific, causation metrics is that they are exactly the same in every report related to the same disease, regardless of each Plaintiff’s specific exposure. For example, compare Section 5.2 and Appendix E in each of Dr. Bailey’s five bladder cancer reports—each is the same. *See* [D.E. 800] at 4 & n.7. They have the same calculations, the same tables, and the same numbers. This applies to Dr. Bailey’s reports for the other Track 1 diseases too. *See id.* Defendant ignores the uniformity of Dr. Bailey’s toxicity criteria and PODs, despite the PLG raising it in briefing and at argument. *See* [D.E. 787] at 4; [D.E. 800] 4 & n.7; Feb. 13, 2026, Hr’g Tr. [D.E. 812] 68:19–69:9.

Consider also how Dr. Bailey used these metrics. For her risk assessment and margin of

exposure analyses, Dr. Bailey compared each “individual exposure assessment” (which *are* specific causation metrics) to “the potential health effects that the chemical of interest may have on humans” based on “regulatory toxicity criteria” and PODs (which are not). *E.g.*, Bailey Rep. (Cagiano) at 20 (JA Ex. 371, D.E. 490-6). That second piece of the comparison is a general causation metric of how much of each toxin might be hazardous to human beings generally, and thus was due by the general causation deadline in Phase II. *See* [D.E. 821] at 6-7.

Defendant’s appeal mischaracterizes how Dr. Bailey used toxicity criteria, asserting that “Dr. Bailey did not use toxicity criteria to opine on levels of chemicals that could or could not cause disease in humans.” [D.E. 829] at 6. But that is exactly what she did. Dr. Bailey described her toxicity criteria as “concentrations at or below which adverse health effects are not expected”—in other words, levels of chemicals that could not cause disease in humans. *E.g.*, Bailey Rep. (Welch) at 3 (JA Ex. 547, D.E. 503). Put differently, Dr. Bailey opined that the level of each toxin that *is* hazardous to humans is *above* each of the numbers in her tables in Section 5.2 of each report. She then compared Plaintiffs’ exposures to those benchmark levels to conclude that Plaintiffs’ exposure levels were not “levels that are of concern for human health”—i.e., levels that could cause disease in humans. *E.g., id.* at 39.

II. Defendant’s Appeal Is Based on the Faulty Premise that Evidence *Against* General Causation Was Not Subject to the Court’s Phase II Deadline.

Rather than contesting that toxicity criteria and PODs are population-level metrics, Defendant instead argues that they were not subject to the Court’s general causation deadline because they “do not establish causation.” [D.E. 829] at 5. Defendant argues that “regulatory thresholds” like toxicity criteria and PODs are conservative and lower than the levels required to prove Plaintiffs’ burden on causation. *Id.* at 5-6. Therefore, Defendant argues they are somehow not related to causation at all, and not subject to the Court’s phased schedule. That is not right.

Arguments for *and against* causation are two sides of the same coin; “both parties are bound” by the Court’s scheduling orders. [D.E. 685] at 4. Whether these metrics *prove* Plaintiffs’ burden on causation is different from whether they are *generalized, population-level metrics* that the Court required to be disclosed at Phase II. Defendant’s appeal argues the wrong question.

As explained, Dr. Bailey used toxicity criteria and PODs to opine against causation. *See supra* at 4-5. She said so herself, explaining that her “risk calculation, using regulatory criteria” is “a screening-level conservative first step in a causation analysis.” *E.g.*, Bailey Rep. (Cagiano) at 20 (JA Ex. 371, D.E. 490-6). Although Dr. Bailey argued that “application of regulatory risk calculations for an individual causation analysis is overly conservative” if used to *prove* causation, she argued that it can be used to *disprove* causation “if the conservative regulatory risk estimates fall at or below US EPA’s acceptable risk range,” which she argues indicates “the exposures of concern are not likely to be causally associated with the health effect of concern.” *Id.* The PLG disagrees with Dr. Bailey that this is a reliable methodology to disprove causation. *See* [D.E. 625] (pending *Daubert* motion) at 1-2, 17-18. But that is beside the point for Defendant’s appeal. Reliably or not, Dr. Bailey used regulatory metrics (toxicity criteria and PODs) to argue against causation. Defendant’s suggestion that risk assessment as used by Dr. Bailey is not related to causation, and thus not subject to the Court’s phased schedule, is contradicted by Dr. Bailey’s own reports. Indeed, if Dr. Bailey’s opinions were not aimed at disproving causation, it is unclear what relevant purpose they serve. *See* [D.E. 776] at 1.

Defendant cites cases for the proposition that regulatory thresholds or assessments are insufficient for *Plaintiffs* to *prove* causation. *See Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 847, 853 (E.D.N.C. 2015) (considering plaintiff’s reliance on regulatory agency statements to prove causation); *Yates v. Ford Motor Co.*, No. 12-752-FL, 2015 WL 2189774, at *23 (E.D.N.C.

May 11, 2015) (same).¹ None of Defendant's cases support Defendant's argument here, because whether regulatory thresholds *prove* causation does not indicate whether those regulatory thresholds relate to general vs. specific causation, which none of Defendant's cases assessed. Moreover, none of these cases considered an opinion like Dr. Bailey's that exposures *below* a regulatory threshold *disprove* causation, where the distinction between conservative regulatory assessment and tort causation does not apply in the same way. Dr. Bailey used these metrics as levels of toxic exposure that she said could not cause disease in humans generally, and arguments *against* general causation were subject to the same scheduling order deadlines as arguments for it. *See* [D.E. 685] at 4.

III. Defendant Admitted None of Its Phase II Experts Disclosed Dr. Bailey's Toxicity Criteria and Points of Departure, nor the Methodologies Dr. Bailey Used Them For.

Defendant also appeals the Order by arguing that even if Dr. Bailey's opinions included general causation testimony, that testimony was disclosed in Phase II. This is false, and contradicts Defendant's own prior statements, which Defendant omits from its appeal. When the Court asked: "Did any Phase II expert discuss points of departure or toxicity criteria in Phase II? If so, who and what's the report?" Defendant replied that "none of the United States Phase II experts disclosed these toxicity criteria." Feb. 13, 2026, Hr'g Tr. [D.E. 812] 73:18–74:4; *see also*

¹ *See also Sutura v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 664 (D. Mass. 1997) (considering plaintiff's expert's use of risk assessment and regulatory thresholds to prove causation); *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1186 (W.D. Okla. 2017) (considering plaintiff's expert's reliance on EPA report to prove causation); *Burst v. Shell Oil Co.*, No. 14-109, 2015 WL 3755953, at *8 (E.D. La. June 16, 2015) (considering plaintiff's expert's general causation opinion relying on regulatory guidance to prove causation); *Bd. of Cty. Comm'rs of Cny. of La Plata, Colo. v. Brown Grp. Retail, Inc.*, 768 F. Supp. 2d 1092, 1105 (D. Colo. 2011) (concluding that exceedance of regulatory levels did not support causation); *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 n.3 (10th Cir. 1999) (considering plaintiff's reliance on state classification as a carcinogen to prove general causation); *In re Johnson & Johnson Talcum Powder Prods. Mktg.*, No. 16-2738, 2026 WL 161184, at *221-22 (D.N.J. Jan. 20, 2026) (considering plaintiffs' expert's use of risk assessment to prove general causation).

id. at 74:9-10 (acknowledging the parties' dispute was not over whether the toxicity criteria were newly disclosed at Phase III, but whether they were "general causation material"). Defendant does not recant that admission on appeal, maintaining that "no Phase 2 expert relied on toxicity criteria or PODs to conduct a general causation analysis." [D.E. 829] at 5. These admissions confirm that Dr. Bailey's toxicity criteria (and related PODs) were not disclosed at Phase II.

In a last-ditch effort to save Dr. Bailey's untimely testimony, Defendant argues that the "EPA and ATSDR publications from which Dr. Bailey obtained the toxicity criteria and PODs were disclosed in the United States' Phase 2 reports" of Dr. Goodman and Dr. Lipscomb. [D.E. 829] at 7 & n.1. This argument, rejected by Judge Jones, should be rejected for many reasons. First, Defendant did not include it in its opposition to the motion that the Order granted. *See* [D.E. 790] at 4-6 (arguing Dr. Bailey relied on Dr. Goodman for epidemiology but relied on *agencies* to derive her toxicity criteria and PODs, and not mentioning Dr. Lipscomb at all). "Generally, the court will not consider issues raised for the first time on appeal." *Progressive Se. Ins. Co. v. Arbormax Tree Serv., LLC*, 2018 WL 2291297, at *2 (E.D.N.C. Feb. 16, 2018) (considering appeal from magistrate's order). No exception applies here, where Defendant had the opportunity to make this argument in its opposition to this motion and did not.²

Second, this position is directly contrary to one Defendant took when requesting that the Court adopt the rule that has now been applied to Dr. Bailey. Explaining the prejudice that results when Phase II experts are "deprived of any opportunity to evaluate, probe, or rebut" new general causation opinions smuggled into Phase III, Defendant argued that "the prejudice is not

² Following oral argument, without leave of Court, Defendant filed a "Notice" listing pages where its Phase II experts Dr. Goodman and Dr. Lipscomb cited the same reports Dr. Bailey cited to derive her toxicity criteria and PODs. [D.E. 815]. The PLG moved for leave to file a response, [D.E. 816], which the Order denied as moot.

alleviated by any assertion from counsel (i.e., PLG) that the opinions are not ‘new’ simply because they rely on previously disclosed literature or similar methodologies.” [D.E. 410] at 9. Defendant cannot now argue the opposite when the rule it requested is applied to its own experts.

Third, as explained in the PLG’s proposed response [D.E. 816-1] to Defendant’s post-argument “Notice” [D.E. 815], two of Defendant’s Phase II experts merely referenced other parts of lengthy agency reports for completely different purposes than Dr. Bailey, never offering the general causation methodologies or metrics Dr. Bailey relied on for her risk assessments or margins of exposure analyses. For example, Dr. Goodman cited the EPA’s thousand-page 2011 TCE study (JA Ex. 196 [D.E. 473-4], erroneously listed in Defendant’s Notice as 65 pages) for completely different facts and purposes than Dr. Bailey. *See* [D.E. 816-1] at 2 n.4 (listing examples). This was among the hundreds of references in Dr. Goodman’s bladder cancer report. Dr. Goodman merely citing a different part of a thousand-page study, among hundreds of citations, without mentioning toxicity criteria or PODs or risk assessment *at all*, did not disclose at Phase II that Dr. Bailey would use toxicity criteria or PODs, which ones she would choose, or how she would adjust them (or calculate them herself when needed). Dr. Goodman’s citations provided no basis for PLG to know the opinions Dr. Bailey would subsequently present and no opportunity for the PLG’s Phase II experts to rebut these general causation metrics or the methodologies used to derive them. Meanwhile, Dr. Lipscomb referenced the agency reports on which Dr. Bailey relied in order to opine that risk assessment and agency reference values are *inappropriate* for causation analyses, and did “not opin[e] on causation at all,” providing no general causation testimony on which Dr. Bailey could rely. *See* [D.E. 816-1] at 1-2 & nn.1-2. Dr. Bailey did not cite Dr. Lipscomb in her reports or deposition, and Defendant did not cite Dr. Lipscomb in its opposition the motion granted by the Order on appeal.

Finally, many of the toxicity criteria and PODs Dr. Bailey used could not have been disclosed in Phase II because she selected, adjusted, and/or calculated them herself. She did not just pull these off the shelf from the agencies, but made her own choices about which general causation benchmarks to apply. For example, because the EPA has no toxicity criteria for bladder cancer, Dr. Bailey chose to apply a mix of numbers from kidney, blood, and liver cancers. *See* [D.E. 800] at 2 & n.2. As Defendant admitted, she “extrapolated” and “modified” EPA data at times. [D.E. 790] at 5. And she calculated the benchmarks herself when unavailable from agencies. *See* [D.E. 800] at 2 & n.3 (citing examples of identical Appendix E in each bladder cancer report, disclosing Dr. Bailey’s own calculation of points of departure not available from the EPA). Dr. Bailey’s methodologies to select, adjust, and calculate these metrics were not in the references cited by Dr. Goodman and Dr. Lipscomb.

While Defendant now argues it should not have had to “effectively preview” the general causation benchmarks to which Dr. Bailey would compare Plaintiffs’ exposures, the Court’s July 22, 2025 Order barred Phase III experts from offering “novel threshold calculations” or “general causation methodologies that were not timely disclosed in Phase II.” [D.E. 444] at 5, 8. That is exactly what Dr. Bailey did, and those portions of her reports were properly excluded.³

CONCLUSION

Judge Jones correctly concluded that portions of Dr. Bailey’s Phase III reports contain new “general causation methodologies that were not timely disclosed in Phase II.” [D.E. 821] at 7 (quoting [D.E. 444] at 8). Judge Jones’s Order striking such portions should be affirmed.

³ Defendant does not appeal the July 22, 2025 order [D.E. 444], the March 5, 2026 order’s *Akeva* analysis [D.E. 821], or that the proper sanction for violations of the July 22, 2025 order is to strike the untimely testimony. *See also* [D.E. 410] at 9-10 (Defendant arguing for such exclusion). The Court may ignore Defendant’s rehashing of its prior arguments about Plaintiffs’ expert reports, which are not at issue in this appeal. [D.E. 829] at 8.

Dated: April 2, 2026.

/s/ J. Edward Bell, III
J. Edward Bell, III (admitted *pro hac vice*)
Bell Legal Group, LLC
219 Ridge St.
Georgetown, SC 29440
Telephone: (843) 546-2408
jeb@belllegalgroup.com

Lead Counsel for Plaintiffs

/s/ W. Michael Dowling
W. Michael Dowling (NC Bar No. 42790)
The Dowling Firm PLLC
Post Office Box 27843
Raleigh, NC 27611
Telephone: (919) 529-3351
mike@dowlingfirm.com

Co-Lead Counsel for Plaintiffs

/s/ James A. Roberts, III
James A. Roberts, III
Lewis & Roberts, PLLC
3700 Glenwood Ave., Ste. 410
Raleigh, NC 27612
Telephone: (919) 981-0191
jar@lewis-roberts.com

Co-Lead Counsel for Plaintiffs

/s/ Elizabeth J. Cabraser
Elizabeth J. Cabraser (admitted *pro hac vice*)
Lieff Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111
Telephone: (415) 956-1000
ecabraser@lchb.com

Co-Lead Counsel for Plaintiffs

/s/ Robin L. Greenwald
Robin L. Greenwald (admitted *pro hac vice*)
Weitz & Luxenberg, P.C.
700 Broadway
New York, NY 10003
Telephone: 212-558-5802
rgreenwald@weitzlux.com

Co-Lead Counsel for Plaintiffs

/s/ Mona Lisa Wallace
Mona Lisa Wallace (N.C. Bar No.: 009021)
Wallace & Graham, P.A.
525 North Main Street
Salisbury, NC 28144
Tel: 704-633-5244
mwallace@wallacegraham.com

Co-Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I, Elizabeth J. Cabraser, hereby certify that the foregoing document was electronically filed on the Court's CM/ECF system on this date, and that all counsel of record will be served with notice of the said filing via the CM/ECF system.

This 2nd day of April, 2026.

/s/ Elizabeth J. Cabraser
Elizabeth J. Cabraser (admitted *pro hac vice*)
Lief Cabraser Heimann & Bernstein, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111
Telephone: (415) 956-1000
ecabraser@lchb.com

Co-Lead Counsel for Plaintiffs