

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

IN RE:

CAMP LEJEUNE WATER LITIGATION

**UNITED STATES' STATEMENT OF
APPEAL REGARDING DOCKET ENTRY
821**

This Document Relates To:

ALL CASES

INTRODUCTION

Toxicity criteria are regulatory tools used to estimate risk; they do not prove general causation. Points of departure (“PODs”) are the starting points used to derive toxicity criteria; they likewise do not prove general causation. But D.E. [821](#) (the “Order”) treats them both as general causation testimony, striking parts of Dr. Lisa Bailey’s specific causation reports for discussing toxicity criteria and PODs, reasoning they are untimely general causation opinions under D.E. [444](#) (ruling that specific causation reports cannot include new general causation opinions). The Order is contrary to law and clearly erroneous.

In Section 6 of her reports, Dr. Bailey used toxicity criteria—which are used to derive exposure levels below which adverse health effects are not expected—to opine on the maximum potential increase in *risk* for each Plaintiff under conservative regulatory assumptions. In Section 7, she used PODs—the bases for toxicity criteria—to compare each Plaintiff’s exposure to a no effect level or low effect level identified in the publications from which the toxicity criteria are derived. Agencies perform similar comparisons for risk management decisions.

Neither toxicity criteria nor PODs are designed to determine whether an exposure can cause a disease. Courts distinguish between regulatory evaluations of risk and proof of causation required in tort litigation. *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 847 (E.D.N.C. 2015) (Flanagan, J.). By treating toxicity criteria and PODs as general causation methodologies, the Order collapses that settled distinction.

The Order also overlooks that specific causation experts “may reference general causation evidence, including Phase [2] opinions and published literature[.]” D.E. [444](#) at 8. Dr. Bailey’s reports used toxicity criteria and PODs from publications by the EPA and ATSDR cited in the United States’ Phase 2 expert reports. The Order presumes that Dr. Bailey can only use portions of these publications explicitly *discussed* in the body of a Phase 2 report. But D.E. [444](#) imposes

no such limitation. Because these publications were disclosed in Phase 2, Plaintiffs suffered no prejudice from Dr. Bailey's reliance on them. The Order should be reversed.

BACKGROUND

Expert discovery here is phased: Phase 1 (water contamination), Phase 2 (general causation), and Phase 3 (specific causation, damages, and residual issues). *See* D.E. [270](#); D.E. [312](#); D.E. [332](#); D.E. [414](#); D.E. [630](#). Dr. Bailey is a Phase 3 expert in human health risk assessment. *See generally* US Phase 3 Exp. Discl. (JA Ex. 328, D.E. [487-4](#)). In Section 6 of her reports, Dr. Bailey quantified the level of risk for each Track 1 trial Plaintiff using toxicity criteria from EPA and ATSDR publications. In Section 7, she compared each Plaintiff's exposure to the PODs from those same publications.

After Phase 3 disclosures, the United States moved to exclude the untimely Phase 2 general causation opinions in Plaintiffs' Phase 3 reports. *See* D.E. [409](#), [410](#). The Court granted the Motion in part and held that "Plaintiffs' Phase [3] experts may not introduce new, independent general causation analyses[.]" D.E. [444](#) at 8.

Plaintiffs unsuccessfully moved to apply that ruling to all experts. D.E. [515](#); D.E. [685](#) (denying motion). Plaintiffs then moved against Dr. Bailey only, arguing her use of toxicity criteria and PODs from EPA and ATSDR publications are new general causation analyses that should have been disclosed in Phase 2. *See* D.E. [787](#). The United States opposed, because toxicity criteria and PODs are not general causation evidence. *See* D.E. [790](#).

During a hearing, the Court asked whether the EPA and ATSDR publications underlying Dr. Bailey's analysis had been disclosed in Phase 2. *See* Ex. 1 at 73:13–15. The United States identified Phase 2 reports disclosing these publications. *See* D.E. [815](#). Still, the Order concluded that toxicity criteria and PODs are general causation methodologies not disclosed during Phase 2,

and it struck Sections 5.2, 6.3, 6.4, and 7, and Appendices D and E from Dr. Bailey's reports. *See* D.E. [821](#) at 6–8.

LEGAL STANDARD

A party may object to a Magistrate Judge's order within fourteen days after being served with a copy of the order. *See* Fed. R. Civ. P. 72(a); Local Civ. R. 72.4(a). "The [C]ourt shall 'consider timely objections and modify or set aside any portion of the order that is clearly erroneous or is contrary to law.'" *Cape Fear Pub. Util. Auth. v. Chemours Co. FC, LLC*, No. 7:17-cv-195, 2025 WL 899327, at *3 (E.D.N.C. Mar. 24, 2025) (citing Fed. R. Civ. P. 72(a)). "A factual finding is clearly erroneous when the [C]ourt is 'left with the definite and firm conviction that a mistake has been committed.'" *Cape Fear Pub. Util. Auth.*, 2025 WL 899327, at *3 (citations omitted). "A magistrate judge's order is contrary to law when 'the magistrate judge has misinterpreted or misapplied applicable law.'" *Id.* (citing *Trudell Med. Int'l v. D R Burton Healthcare, LLC*, No. 4:18-cv-9, 2021 WL 684200, at *3 (E.D.N.C. Feb. 22, 2021)). "Although the contrary to law standard permits plenary review of legal conclusions, decisions related to discovery disputes and scheduling are accorded greater deference." *Cape Fear Pub. Util. Auth.*, 2025 WL 899327, at *3 (quoting *Johnson v. City of Fayetteville*, No. 5:12-cv-456, 2013 WL 4039418, at *3 (E.D.N.C. Aug. 6, 2013)).

ARGUMENT

First, the Order erroneously treats Dr. Bailey's use of regulatory toxicity criteria and PODs as general causation methodologies. Courts, however, recognize that regulatory risk assessment and causation are distinct concepts with distinct purposes: the former guides policy-based decision making; the latter assesses cause and effect. *See Yates v. Ford Motor Co.*, No. 12-752-FL, 2015 WL 2189774, at *23 (E.D.N.C. May 11, 2015).

Second, the Order concludes that because Dr. Bailey’s toxicity criteria and associated PODs were not discussed in a Phase 2 report, they were not disclosed. But the EPA and ATSDR publications from which those values came were disclosed. *See* D.E. [815](#). The Order imposes a limit D.E. [444](#) does not contain.

I. The Order Erroneously Treats Regulatory Risk Assessment Concepts as General Causation Methodologies.

The Order errs by equating toxicity criteria and PODs with evidence of general causation. Courts consistently distinguish between regulatory evaluations of risk—which use toxicity criteria derived from PODs—and causation in tort law. Regulatory evaluations of risk guide health-protective policy decisions with conservative assumptions. Conversely, general causation in tort law asks what levels of exposure are hazardous to human beings generally. The Order collapses that settled distinction.

Toxicity criteria are regulatory values used to estimate potential human health risk. *See* Bailey Rep. (Tukes) at 10 (JA Ex. 427, D.E. [494-10](#)). They are used to develop exposure levels that agencies consider health-protective benchmarks. *Id.*; EPA 2020 TCE Risk Eval. at 226–28 (JA Ex. 199, D.E. [473-7](#)). They are derived from conservative assumptions to account for uncertainties, and are often based on PODs: the exposure levels associated with no effect, or the lowest exposure levels associated with *any* observed effects in animal or epidemiology studies. *See* Bailey Rep. (Tukes) at 10–11 (JA Ex. 427, D.E. [494-10](#)); EPA 2020 TCE Risk Eval. at 227, 254, 260, 304, 657–58 (JA Ex. 199, D.E. [473-7](#)); EPA 2011 Tox. Review of TCE at 5-6(d) (JA Ex. 196, D.E. [473-4](#)). Agency guidance documents that describe toxicity criteria also describe PODs and often make comparisons to PODs within a risk evaluation, alongside risk calculations, to guide risk management decisions. *See* EPA 2020 TCE Risk Eval. at 304–05 (JA Ex. 199, D.E. [473-7](#)); EPA 2011 Tox. Review of TCE at 5-143, 5-155 (JA Ex. 196, D.E. [473-4](#)).

Importantly, toxicity criteria are used to establish regulatory levels that are typically well below the associated PODs. *See* Bailey Rep. (Tukes) at 10–11 (JA Ex. 427, D.E. [494-10](#)). Thus, exposures at these regulatory levels are typically well below those associated with health effects in the epidemiology or animal studies (i.e., those that would be described in a general causation analysis). *See* EPA 2011 Tox. Review of TCE at 5-6(d), 5-143, 5-155 (JA Ex. 196, D.E. [473-4](#)).

In sum, regulatory evaluations do not use toxicity criteria or PODs to determine “the levels of exposure that are hazardous to human beings generally.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999). (In fact, no Phase 2 expert relied on toxicity criteria or PODs to conduct a general causation analysis.) Courts therefore recognize that regulatory thresholds and risk-based values do not establish causation. *See Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 664 (D. Mass. 1997) (stating that a regulatory standard is not “a measure of causation”). As this Court explained in *Yates v. Ford Motor Co.*, “while admittedly related, the terms ‘risk’ and ‘hazardous’ have critical differences in meaning.” 113 F. Supp. 3d at 853 (explaining that evidence showing an exposure “may increase the risk” of harm does not establish that the exposure “rises to the level of being hazardous to human beings generally”).

In fact, unlike a general causation threshold, exceeding regulatory screening levels, action levels, or standards “does not demonstrate a real or actual risk to human health.” *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1186 (W.D. Okla. 2017), *aff’d sub nom. Hall v. Conoco Inc.*, 886 F.3d 1308 (10th Cir. 2018); *see also Burst v. Shell Oil Co.*, No. 14-109, 2015 WL 3755953, at *8 (E.D. La. June 16, 2015), *aff’d*, 650 F. App’x 170 (5th Cir. 2016); *Bd. of Cnty. Comm’rs of Cnty. of La Plata, Colo. v. Brown Grp. Retail, Inc.*, 768 F. Supp. 2d 1092, 1105 (D. Colo. 2011). Because of the conservative nature of the toxicity criteria, the fact that an exposure falls above or below a level based on the criteria does not establish—or refute—general causation.

As this Court recognized in *Yates v. Ford Motor Co.*, regulatory decision-making follows a preventive principle under which agencies adopt conservative health-protective assumptions and lower evidentiary thresholds than those required to prove causation in tort law. 2015 WL 2189774, at *23 (citing *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 n.3 (10th Cir. 1999)). Indeed, *Yates* ruled that the plaintiff could not rely on a regulatory principle (the “each and every exposure” theory) to support its expert’s causation opinion. 113 F. Supp. 3d at 846–48. Thus, exposure levels associated with agency risk assessment outcomes cannot establish general causation. *See In re Johnson & Johnson Talcum Powder Prods. Mktg.*, No. 16-2738, 2026 WL 161184, at *221 (D.N.J. Jan. 20, 2026).

Here, the Order departs from this established distinction. After recognizing how toxicity criteria and PODs are defined, the Order holds that “[b]oth concepts plainly speak to ‘the levels of exposure that are hazardous to human beings generally,’ and therefore constitute general causation testimony.” D.E. [821](#) at 5–6 (citing *Westberry*, 178 F.3d at 263). But as discussed above, risk and hazard are distinct. *See Yates*, 113 F. Supp. 3d at 853. The Order assumes that because toxicity criteria are used to derive exposure levels expected to be protective of health, they necessarily answer the question of whether an exposure is “hazardous to human beings generally.” D.E. [821](#) at 5–6 (citing *Westberry*, 178 F.3d at 263). But that incorrectly equates regulatory risk assessment values with general causation.

Dr. Bailey did not use toxicity criteria to opine on levels of chemicals that could or could not cause disease in humans. Instead, she used them in plaintiff-specific risk assessments to evaluate the maximum risk of each Plaintiff’s estimated exposure under the conservative health-protective assumptions employed by the EPA and ATSDR in developing their regulatory risk-based standards. *See Bailey Rep. (Tukes)* at 6–7 (JA Ex. 427, D.E. [494-10](#)) (plaintiff-specific risk

calculation producing maximum excess lifetime cancer risk of 0.00008%, a risk lower than EPA's acceptable ELCR range).

By treating toxicity criteria and PODs as general causation methodologies, the Order ignores the distinction this Court recognized in *Yates*. It treats health-protective criteria (and the PODs from which they are derived) that inform regulatory values as general causation standards. This is clearly erroneous and contrary to law and an outlier decision conflating two distinct concepts.

II. The Order Conflicts with This Court's Prior Ruling Permitting Reliance on Published Literature Disclosed in Phase 2.

The Order also erred in holding that toxicity criteria and PODs should have been disclosed in Phase 2. Use of toxicity criteria and PODs, as noted above, are not general causation methodologies and thus were not required to be disclosed in Phase 2.

Nevertheless, D.E. [444](#) states that specific causation experts "may reference general causation evidence, including Phase 2 opinions and published literature[.]" D.E. [444](#) at 8. The EPA and ATSDR publications from which Dr. Bailey obtained the toxicity criteria and PODs were disclosed in the United States' Phase 2 reports. D.E. [815](#).¹

The Order fails to address this. Instead, it reasons that the toxicity criteria and PODs from these publications were not explicitly mentioned in Dr. Goodman's reports, so their use constitutes untimely general causation methodologies. D.E. [821](#) at 6. The Order erroneously assumes that

¹ The United States' expert, Dr. Lipscomb, relied on these publications to opine on the health-conservative nature of the agency's analysis. He also opined that such analysis precludes those values from serving as evidence of general causation. However, the same publications may serve different analytical purposes in different phases. Dr. Goodman relied on the EPA and ATSDR publications that reviewed the epidemiological and toxicological literature to ensure that all relevant publications were considered as part of her general causation analyses; Dr. Bailey relied on regulatory toxicity values reported in those same publications for purposes of risk assessment. Moreover, the fact that the same underlying publications inform two separate inquiries does not transform regulatory risk values into general causation methodologies.

Phase 2 experts must not only cite these publications but must specifically identify the precise toxicity criteria and PODs in expert reports before a Phase 3 expert may rely on them. This is beyond the requirements of D.E. [444](#).

Moreover, Plaintiffs knew of these publications. When the Court asked about the EPA and ATSDR publications, Plaintiffs conceded that “[c]ertainly those are studies the parties have known about and talked about for a long time.” Ex. 1 at 66:12–17. Yet Plaintiffs argued that the United States’ Phase II experts were required to identify the specific toxicity criteria and PODs Dr. Bailey would rely on and effectively preview how she would use those values in her reports. *See id.* at 66:17–19. Such a granular approach is inconsistent with D.E. [444](#), which allows Phase 3 experts to rely on “published literature” disclosed in Phase 2. D.E. [444](#) at 8.

Unlike Dr. Bailey’s use of previously disclosed published literature, the Plaintiffs’ Phase 3 reports disclosed what they themselves labeled as new general causation opinions:

Drs. Thomas Longo and John Sfakianos: Entire sections titled General Causation that address, “whether there is enough evidence to establish whether the chemicals in the water at Camp Lejeune are capable of causing bladder cancer as a general matter.” D.E. [410](#) at 2–3.

Drs. Yair Lotan, Joseph J. Del Pizzo, Richard Barbano, and Heidi Schwarz: Performed their own Bradford Hill analyses (methodology used for general causation). *Id.* at 4–5.

Drs. Kristin Andruska, Paul J. Michaels, and Armine Smith: Performed their own general causation literature review. *Id.*

Dr. Richard T. Hoppe: Testified that he offered his own general causation opinions. *Id.*

Dr. Bailey’s reports did not contain new general causation opinions. They (1) did not have a “General Causation” section; (2) did not address whether the alleged contaminants can cause a disease as a general matter; (3) did not address the Bradford Hill criteria; and (4) did not include an independent general causation literature review. And at deposition, Dr. Bailey was clear that she was not offering general causation opinions. *See* D.E. [627](#) at 8–9.

D.E. [444](#) permits specific causation experts to reference published literature that was disclosed in Phase 2. Dr. Bailey did exactly that. The Order should be reversed.

CONCLUSION

The Order collapses a distinction this Court and others have long recognized by equating regulatory risk concepts with general causation. Moreover, D.E. [444](#) permits Phase 3 experts to draw from published literature cited in Phase 2 reports. The United States respectfully requests that the Order be reversed.

Dated: March 19, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on March 19, 2026, I electronically filed the foregoing using the Court's Electronic Case Filing system, which will send notice to all counsel of record.

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