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

This Document Relates To: ALL CASES

MEMORANDUM IN SUPPORT OF UNITED STATES' MOTION TO EXCLUDE PLAINTIFFS' PHASE I EXPERT TESTIMONY IN SUPPORT OF USING ATSDR'S WATER MODELS TO DETERMINE EXPOSURE LEVELS FOR INDVIDUAL PLAINTIFFS

INTRODUCTION

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"[S]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993). The Agency for Toxic Substance and Disease Registry ("ATSDR") developed water models to estimate monthly mean contaminant concentration levels in the Tarawa Terrace, Hadnot Point, and Holcomb Boulevard water distribution systems at Camp Lejeune. ATSDR's water models relied on the limited contaminant concentration sampling data that was available from the early to mid-1980s to simulate estimated contaminant concentration levels in drinking water at Camp Lejeune for more than 30 years into the past.¹ ATSDR's water models were developed for the intended purpose of determining relative exposure levels for population level epidemiological studies, not for the purpose of accurately or reliably determining absolute concentration levels for individual exposure. These water models and epidemiological studies were used to inform policy decisions related to presumptions for service-connected VA benefits.²

Nevertheless, the Plaintiffs' Leadership Group ("PLG") wants to use ATSDR's water models for the purpose of determining absolute exposure levels for individual plaintiffs in this litigation. PLG disclosed

¹ Models that attempt to recreate past conditions are referred to as "hindcasting models." **Ex. 1**, Mary P. Anderson & William W. Woessner, *Applied Groundwater Modeling: Simulation of Flow and Advective Transport* (2d ed. 2015) (hereinafter, "Anderson & Woessner Textbook"), p. 9; **Ex. 2**, Davis Dep., 304:17-19 ("Like the Anderson Woessner book, that's a reliable -- that's a reliable book.").

² As PLG noted at the March 25, 2025, Phase I Hearing, "the Department of Veterans Affairs, is relying at least in part on this water model to make determinations about was something service connected, who should receive disability benefits." Mar. 25, 2025, Hr'g Tr., D.E. <u>343</u> at 16:6-12; **Ex. 3**, Jan. 16, 2013 Letter from ATSDR to Veteran Affairs; **Ex. 4**, Aug. 3, 2015, Veterans Affairs Press Release.

five Phase I water modeling experts that offer broad and sweeping opinions about the correctness, accuracy, reliability, and soundness of ATSDR's water models without regard to the intended purpose, uncertainty, and limitations of the water models. The opinions of PLG's Phase I water modeling experts do not fit this case because ATSDR's water models were not intended for individual exposure determinations in litigation.

ATSDR's water models are unreliable, scientifically invalid, and not sufficiently accurate for the purpose of determining absolute concentration levels over particular time periods for individual exposure determinations. ATSDR's water models are based on insufficient contaminant concentration sampling data, which prevents them from providing reliable or accurate estimate contaminant concentrations for determining absolute concentration levels for individual exposures. ATSDR's water models also relied on conservative, health-protective assumptions that resulted in higher estimated contaminant concentration levels over longer timeframes. These assumptions were appropriate for ATSDR's mission as a public health agency, but they do not reflect real world conditions, making ATSDR's water models unreliable for determining absolute concentration levels or timeframes for individual exposures.

Accordingly, the Court should exclude the broad and sweeping opinions of PLG's Phase I experts about the correctness, accuracy, reliability, and soundness of ATSDR's water models and preclude use of ATSDR's water models for individual exposure determinations in this litigation.

STATEMENT OF FACTS

I. PLG Disclosed Five Phase I Water Modeling Experts to Support the Use of ATSDR's Water Models for Determining Exposure Levels for Individual Plaintiffs.

Phase I is focused on resolving the "toxic chemical exposure from the water at Camp Lejeune" and "the alleged chemicals in the water at Camp Lejeune from 1953 to 1987." June 24, 2024 Order, D.E. <u>247</u>, p. 1. To resolve these issues, PLG has asked the Court to adopt water models developed by ATSDR to provide mean monthly contaminant concentration levels in the Tarawa Terrace, Hadnot Point, and Holcomb Boulevard water distribution systems at Camp Lejeune for the purpose of making exposure determinations for individual plaintiffs. Mar. 25, 2025, Hr'g Tr., D.E. <u>343</u> at 16:13-20. To support using ATSDR's water

models to determine exposure levels for individual plaintiffs over particular periods of time, PLG disclosed the following five Phase I water modeling experts.

Morris Maslia: Mr. Maslia was Project Officer for ATSDR's Exposure-Dose Reconstruction Program from 1992 to 2017, and he oversaw and managed ATSDR's water modeling efforts for Tarawa Terrace and Hadnot Point/Holcomb Boulevard. **Ex. 5**, Maslia Report, p. 10, 145; **Ex. 6**, Maslia Rebuttal Report. Both the Tarawa Terrace and Hadnot Point/Holcomb Boulevard models are memorialized in multiple chapters or volumes of ATSDR reports. **Ex. 5**, Maslia Report, p. 145. Mr. Maslia was an author or managed and coordinated the drafting of each chapter report for both the Tarawa Terrace and Hadnot Point/Holcomb Boulevard models, and he is senior author of the "Chapter A: Summary of Findings" reports for both water models. *Id.* at 45-46, 145. Mr. Maslia also hosted and participated in ATSDR Expert Panels to discuss the development of ATSDR's water models for Tarawa Terrace and Hadnot Point/Holcomb Boulevard in 2005 and 2009, respectively. **Ex. 7**, 2005 Expert Panel (Day 1); **Ex. 8**, 2005 Expert Panel (Day 2); **Ex. 9**, 2009 Expert Panel (Day 1); **Ex. 10**, 2009 Expert Panel (Day 2).

Mustafa Aral: Dr. Aral is a Professor Emeritus and Director of the Multimedia Environmental Simulations Laboratory (MESL), a research center at the School of Civil and Environmental Engineering at Georgia Tech University. In the early 2000s, the MESL entered into a cooperative agreement with ATSDR to provide technical support for ATSDR's water modeling efforts for Tarawa Terrace and Hadnot Point/Holcomb Boulevard. **Ex. 11**, Aral Report, p. 4; **Ex. 5**, Maslia Report, p. 13. Dr. Aral was a contributing author for the "Chapter A: Summary of Findings" reports for both the Tarawa Terrace and Hadnot Point/Holcomb Boulevard models. **Ex. 5**, Maslia Report, p. 145. Dr. Aral also participated in the 2005 and 2009 ATSDR Expert Panels. **Ex. 12**, Konikow Dep., 32:9-15 ("Q. Okay. In what context have you met Dr. Aral? A. Serving on expert peer review panels for ATSDR in 2005 and 2009.").

Leonard Konikow: Dr. Konikow participated in the 2005 and 2009 ATSDR Expert Panels. He was invited to provide input during the development of ATSDR's water models for Tarawa Terrace and

Hadnot Point/Holcomb Boulevard due to his reputation in the field of groundwater modeling.³ Ex. 15, Konikow Rebuttal Report, p. 1.

Jeffery Davis & Norman Jones: Mr. Davis and Dr. Jones were not involved in the development of ATSDR's water models. They performed what is known as a "post-audit" on ATSDR's Tarawa Terrace water model to purportedly assess its accuracy. *See generally* **Ex. 16**, Davis/Jones Report; **Ex. 17**, Davis/Jones Rebuttal Report.

II. PLG's Phase I Experts Agree that A Model's Intended Purpose Informs the Foundation for Building the Model.

In a book chapter he co-authored, Dr. Konikow wrote that "[t]he first step in model design and application is to define the nature of the problem and the purpose of the model." **Ex. 18**, *The Handbook of Groundwater Engineering*, Chap. 20, Groundwater Modeling, p. 20-18. In explaining what he meant by these words, Dr. Konikow testified about the importance of the purpose of a model in deciding the best form of the model:

Q. Okay. Why is defining the nature of the problem and the purpose of the model the first step?

A. Well, you have to know the nature of problems to know before you decide what the best form of a model is to simulate it. Knowing the purpose of the model, what it would be used for, helps you assess what factors should be included and what could be safely ignored.

Ex. 12, Konikow Dep., 129:15-21-23 (emphasis added); see also Ex. 12, Konikow Dep., 213:14-18 ("So

in the sense of being aware of the use of it, you want to know what the ultimate -- the end users need and

what they're going to need, and that certainly can affect how you design the model.").

Like Dr. Konikow, Mr. Davis testified during his deposition that the foundation for building a

model is how the model is going to be used:

³ See, e.g., **Ex. 13**, Jones Dep., 83:16-20 ("Q. BY MR. ANTONUCCI: And what's your opinion of Dr. Konikow? A. Well, he's -- he's one of the most widely respected experts in groundwater modeling."); **Ex. 2**, Davis Dep., 115:3-6 ("Q. Would you agree that Dr. Konikow is an expert in the field of hydrologic modeling? A. Yes."); **Ex. 14**, Maslia Dep. (Mar 13, 2025), 87:19-88:1 ("Q. Okay. Did you introduce the plaintiffs' lawyers to -- in this case to Dr. Konikow? A. Yes, I did. When I say introduced, let me clarify. I think they were looking for a name of somebody who was nationally renowned in fate and transport modeling, and so from my days at USGS, I knew Dr. Konikow.").

Q. Do you -- is it important to understand the purpose of a model before you create the model?

THE WITNESS: Yes. Q. BY MS. SILVERSTEIN: Why? A. That's -- in my experience, that's the foundation for building a model, especially in a groundwater model, is how it's going to be used.

Ex. 2, Davis Dep., 69:11-21; see also Ex. 13, Jones Dep., 211:1-6. ("[T]he level of complexity in your

model warranted by the purpose of the model and what it's going to be used for and the – the nature of the

site that you're modeling."); Ex. 1, Anderson & Woessner Textbook, p. 9 ("The starting point of every

groundwater modeling application is to identify the purpose of the model.").

III. ATSDR's Water Models for Tarawa Terrace and Hadnot Point/Holcomb Boulevard Were Developed for the Intended Purpose of Determining Relative Exposure Levels for Epidemiological Studies and Not for Determining Absolute Concentrations for Individual Exposure.

A. <u>The Tarawa Terrace Water Model Was Intended to Support an Epidemiological Study on</u> <u>Birth Defects and Childhood Cancers from 1968-1985.</u>

The 2007 "Chapter A: Summary of Findings" report for ATSDR's Tarawa Terrace model stated that the intended purpose was to estimate historical exposure data needed for a population level, case control epidemiological study related to birth defects and childhood cancers occurring between 1968 and 1985. **Ex. 19**, TT Ch. A, p. iii; **Ex. 20**, Frank Bove, Morris Maslia et al., *Evaluation of exposure to contaminated drinking water and specific birth defects and childhood cancers at Marine Corps Base Camp Lejeune, North Carolina: a case–control study* 12 Env't Health 104 (2013) (hereinafter, "ATSDR Childhood Birth Defects and Cancer Study"). The primary contaminant of concern in Tarawa Terrace was perchloroethylene ("PCE"), and the source of the contamination was the ABC One Hour Cleaners, an off-base dry cleaner. The only available contaminant concentration sampling data was taken between 1982 and 1986. **Ex. 19**, TT Ch. A, p. A27. Nonetheless, the Tarawa Terrace model attempted to estimate monthly mean concentration levels of PCE and its degradation by-products in drinking water between 1951 and 1987. *Id., passim.*

The 2007 "Chapter A: Summary of Findings" report for the Tarawa Terrace water model makes clear that "ATSDR's exposure assessment cannot be used to determine whether you, or your family,

suffered any health effects as a result of past exposure to PCE-contaminated drinking water at Camp

Lejeune." **Ex. 19**, TT Ch. A, p. A98 (emphasis added). Moreover, in a response written or signed off on by Mr. Maslia to concerns from the Navy about the reliability and accuracy of the Tarawa Terrace model in simulating concentration levels 30 years into the past, ATSDR explained that a population level epidemiological study places little emphasis on absolute exposure levels and emphasizes the relative level of exposure. It specifically stated:

To address the issue of the intended use of the water-modeling results by the current ATSDR epidemiological study, the DON should be advised that a successful epidemiological study places little emphasis on the actual (absolute) estimate of concentration and, rather, emphasizes the <u>relative</u> level of exposure. That is, exposed individuals are, in effect, ranked by exposure level and maintain their rank order of exposure level regardless of how far off the estimated concentration is to the "true" (measured) PCE concentration.

Ex. 23, ATSDR Response to Navy (emphasis added), p. 6; **Ex. 14**, Maslia Dep. (Mar. 13, 2025), 86:16-24 ("Q. Okay. And you did respond to the Navy's comments or critiques, correct? A. That is public information on the ATSDR website, yes.") & 161:17-162:3; **Ex. 21**, Jun. 19, 2008, Navy Letter.⁴ By ranking groups with different relative exposure levels, an epidemiologist can determine whether groups with greater levels of exposure experience greater incidence of disease, which helps inform the study's analysis of whether the exposure can cause the disease in exposed populations. *See* **Ex. 20**, ATSDR Childhood Birth Defects and Cancer Study.

Consistent with the focus of ATSDR's water models on relative exposures for population level epidemiological studies rather than absolute concentration levels for individual exposures, ATSDR issued a disclaimer notifying the public that the Tarawa Terrace model's results may not reflect actual exposure of specific individuals to contaminants in the water system. **Ex. 24**, ATSDR TT Disclaimer ("**Disclaimer**:

⁴ Between 2007 and 2009, the timeframe that the Tarawa Terrace model was developed and completed, ATSDR took down a public webpage that generated estimated monthly contaminant concentrations based on an individual's address. Mr. Maslia testified that "in working with the Department of Navy, they expressed some reservations that there were insufficient qualifiers on the data, not the table itself. But when somebody just put in an address and got a value out, it did not explain to them the limits of the data or the simulated data." **Ex. 22**, Maslia Dep. (Jun. 30, 2010), 79:25-80:5.

... [t]he results however, may not reflect actual exposure of specific individuals to contaminants in the water system.") (emphasis added).

B. <u>The Hadnot Point/Holcomb Boulevard Water Model Was Intended to Support Additional</u> <u>Epidemiological Studies.</u>

As with the Tarawa Terrace model, the 2013 "Chapter A: Summary of Findings" report for the Hadnot Point/Holcomb Boulevard water model informed that the intended purpose of the Hadnot Point/Holcomb Boulevard model was to estimate historical exposure data needed for additional population level epidemiological studies. **Ex. 25**, HP/HB Ch. A, p. iii; **Ex. 5**, Maslia Report, p. 145. The primary contaminant of concern in Hadnot Point was trichloroethylene ("TCE"), and Holcomb Boulevard intermittently received water from Hadnot Point during the dry spring and summer months between June 1972 to December 1985. **Ex. 25**, HP/HB Ch. A, p. A27, A64. The sources of the contaminants were underground storage tanks ("USTs") and an on-base landfill at Camp Lejeune which affected certain wells that supplied water to Hadnot Point Water Treatment Plant. **Ex. 25**, HP/HB Ch. A, p. A27. As with the Tarawa Terrace system, the only available contaminant concentration sampling data was first taken in the early 1980s. *Id.* at A22, A26, A62. Thus, the Hadnot Point/Holcomb Boulevard model, like the Tarawa Terrace model, attempted to estimate monthly mean concentration levels for more than 30 years into the past to inform a "core period of interest for the epidemiological studies" of 1968 to 1985. *Id.* at A1.

The "Chapter A: Summary of Findings" report for the Hadnot Point/Holcomb Boulevard water model also made clear that "ATSDR's exposure estimates cannot be used alone to determine whether you, or your family, suffered any health effects as a result of past exposure to TCE-contaminated drinking water at USMCB Camp Lejeune." *Id.* at A182 (emphasis added).

IV. Prior to Becoming Litigation Experts, Mr. Maslia and Dr. Konikow Acknowledged that Analysis of the Water Models' Uncertainty and Reliability Was Limited, and the Models' Contemporary Reviewers Raised Concerns that the Models' Results Suggested Greater Accuracy and Precision Than Existed.

Mr. Maslia, Dr. Aral, Dr. Konikow, and ATSDR's lead epidemiologists, Dr. Frank Bove and Perri Ruckert, participated in the 2005 and 2009 ATSDR expert panels to discuss the development of ATSDR's water models in the context of epidemiological studies that were being performed. *See* **Ex.** 7, 2005 Expert

Panel (Day 1); **Ex. 8**, 2005 Expert Panel (Day 2); **Ex. 9**, 2009 Expert Panel (Day 1); **Ex. 10**, 2009 Expert Panel (Day 2). During both expert panels, Dr. Konikow repeatedly raised the issue of ATSDR's water models' inability to accurately and reliably estimate contaminant concentrations before the early to mid-1980s because there was no contaminant concentration sampling data before that time. For example, during the 2005 ATSDR Expert Panel, which focused on the development of the Tarawa Terrace model, Dr. Konikow noted that there was "very limited data," that "there's going to be speculation upon assumption built into that," and that qualitatively evaluating exposure is "probably the best you could hope from [sic] all of these models." He stated:

DR. KONIKOW: Well, you have very limited data against which to calibrate your model. Okay. And you know, in the period that you were collecting data, the wells were contaminated. Okay. So if you're going to run the groundwater model, it's a question of how do you get from zero to that level of concentration that you're calibrating. You start with an initial condition of no PCE in 1954. Okay.

And then you start your model running. And there's going to be speculation upon assumption built into that, and you'll get a range of responses. My hypothesis or my guess would be that all roads will lead to contamination by 1968. You want to do the modeling to demonstrate it. Maybe I'm wrong.

But you want – the only possible outcome that would differ would be a later arrival, and that may be the first few years there's no exposure. I think that's unlikely, but that's what you want to evaluate, and that's probably the best you could hope [for] from all of these models.

Ex. 8, 2005 Expert Panel (Day 2), 47:25-48:18 (emphasis added). Later in the same 2005 ATSDR Expert

Panel, Dr. Konikow reiterated his view about the inability to accurately or reliably estimate contaminant

concentrations before the early 1980s. He specifically stated:

Dr. Konikow: I again just reiterate with the groundwater modeling and transport modeling that ultimately we're limited in what we can do in terms of the available data. I mean, you know, we don't have concentration data before 1980 or '82. And so everything we do for looking at distribution before then is going to be a little fuzzy.

Ex. 8, 2005 Expert Panel (Day 2), Page 193:12-25 (emphasis added); see also Ex. 26, GAO Camp Lejeune

Report (2007), p. 55 (noting that "all of the panel experts raised concerns about the limited historical record"

and that "with limited historical data there would be minimal potential for water modeling to provide

accurate information about the level of concentration of the contamination and thus about each individual's total amount of exposure.").

In 2009, Dr. Konikow provided written comments for a draft report related to the Hadnot Point/Holcomb Boulevard model before the 2009 ATSDR Expert Panel. **Ex. 27**, 2009 Expert Panel Summary, p. 99. Dr. Konikow raised his concerns about the accuracy of the Hadnot Point/Holcomb Boulevard model given the limited data and complexity of the contaminant sources. He stated:

The approach taken appears to be quite reasonable, as far as can be told from the available information and with exceptions noted or discussed below, but indeed the level of accuracy and precision may still not be adequate because of the paucity of data and complexity of contaminant sources during the time period when the history is to be reconstructed. The adequacy will depend in large part on the reliability and soundness of the groundwater flow and transport models that will be developed (but which have not been adequately described in the reviewed documents). As noted in comments below, the approach used to estimate reaction rates appears to lack a firm theoretical basis for providing confidence in the accuracy and precision of the calculated values.

Id. at 99 (emphasis added). Dr. Konikow further described the task of building the Hadnot

Point/Holcomb Boulevard water model as "an enormously difficult and challenging one." He stated:

Overall, the task at hand is an enormously difficult and challenging one, and there are numerous difficulties confronting a successful completion. There are numerous sources of uncertainty both in the data analysis and the modeling results. Attempts should be made throughout the course of the project to quantify, as well as possible, the degree of uncertainty in each stage of the work.

Id. at 100 (emphasis added).

In a report chapter authored by Mr. Maslia, the ATSDR acknowledged that these challenges

prevented "a robust and comprehensive uncertainty analysis" of the Hadnot Point/Holcomb Boulevard

model. ATSDR stated:

For contaminant fate and transport modeling reported herein, however, insufficient waterquality data existed to conduct a statistical analysis for assessment of model calibration fit.

Conducting a robust uncertainty analysis using Monte Carlo analysis (e.g., Maslia et al. 2009) requires simulating thousands of realizations. When using available computational equipment, the HPIA and HPLF models have a simulation time of about 6-8 hours for each simulation. The lengthy simulation times and the substantial data limitations therefore make a comprehensive uncertainty analysis computationally prohibitive based on available resources and time limitations. Thus, the ranges of values presented in the sensitivity analysis section of this report assess a limited number of input and output model

parameters. The results (i.e., range of concentration) presented in the sensitivity analysis reported herein should not be considered or interpreted as the results of a robust and comprehensive uncertainty analysis, but do provide insight into parameter sensitivity and uncertainty in a qualitative sense."

Ex. 28, HP/HB Ch. A Supp. 6, p. S6.45 (emphasis added).⁵

The ATSDR's limited uncertainty analysis on the Hadnot Point/Holcomb Boulevard model actually consisted of a sensitivity analysis rather than an uncertainty analysis, but it nonetheless revealed that the contaminant concentrations predicted by the model varied dramatically with changes in well cycling schedules, which were assumed, rather than based on historical data. **Ex. 25**, HP/HB Ch. A pp. A93-A94 & Fig. A41. The ATSDR's analysis of the model's sensitivity to changes in the times when contaminants first leaked into the aquifer, which were also assumed rather than based on any historical data, showed that varying these times by eighteen years resulted in possible scenarios under the model where contamination at Hadnot Point could have started as early as 1948 or as late as 1967. **Ex. 25**, HP/HB Ch. A p. A84-A85 & Fig. A37; **Ex. 14**, Maslia Dep. (Mar. 13, 2025), 226:12-228:3. As a result, the ATSDR could not distinguish which dates were more accurate based on the model's "fit" to measured contaminant concentrations. *Id.* at 227:24-228:10 ("Q. But doesn't the sensitivity analysis show that plus or minus nine years or five years from the calibrated source release date, that's possible? A. It's a possibility.").

Mr. Maslia and Dr. Konikow's statements before becoming litigation experts are in line with the concerns that the Navy expressed and conclusions reached by the National Research Council ("NRC") of the National Academy of Sciences. **Ex. 21**, Jun. 18, 2008, Navy Letter, p. 6 ("[T]he goal of the Tarawa Terrace model is to reconstruct PCE concentrations on a monthly basis over approximately 30 years in order to conduct a health study. This is an extremely difficult goal since measured PCE concentrations are not available prior to 1982.") In 2009, the NRC issued a report entitled *Contaminated Water Supplies at Camp Lejeune: Assessing Potential Health Effects.* **Ex. 29**, NRC Report. The NRC was mandated by

⁵ Uncertainty analysis "includes assessment of measurement error, errors in the design of the model, and uncertainty in future (or past) hydrologic conditions important to the forecast (or hindcast)." **Ex. 1**, Anderson & Woessner Textbook, p. 18.

Congress to review evidence on whether adverse health outcomes were associated with past contamination at the water supply at Camp Lejeune. *Id.* The review included an evaluation of ATSDR's water model for Tarawa Terrace. The NRC concluded that ATSDR's Tarawa Terrace water model was not suitable for estimating monthly mean contaminant concentrations. The report specifically stated:

The ultimate outcome of the modeling was averaged monthly predictions of the concentrations of contaminants in the water supply to which people could have been exposed. Although ATSDR recognized and tried to account for the limitations and uncertainties associated with developing its models, it is extremely difficult to obtain quantitative estimates of historical levels of exposure to PCE and its degradation products reliably on a monthly basis. Reporting such model predictions without clear error bounds gives the impression that the exposure of former residents and workers at Tarawa Terrace during specific periods within a given year can be accurately defined.

Id. at 65 (emphasis added). The NRC further concluded that developing a water model for Hadnot

Point/Holcomb Boulevard would be even more problematic due to inherent complexities, stating:

Efforts at historical reconstruction of exposures at Hadnot Point will be even more problematic. The contamination scenario at Hadnot Point is so complex that the committee judges that only crude estimates of contaminant concentrations in the water supply can be obtained.

The history of water-supply contamination at Hadnot Point is much more complex than the history of that at Tarawa Terrace because of the multiplicity of sources and contaminants and the ill-defined period of contamination [that] the committee recommends the use of simpler approaches...[s]impler approaches may yield the same kind of uncertain results as complex models but are a better alternative because they can be performed more quickly and with relatively less resources, which would help speed-up the decision-making process.

Id. (emphasis added).

Prabhakhar Clement is the groundwater modeling expert who served on the NRC Committee and evaluated ATSDR's water model for Tarawa Terrace. *Id.* at v.; **Ex. 2**, Davis Dep., 307:17-22; **Ex. 13**, Jones Dep., 101:14-22. Following the publication of the NRC report, Dr. Clement published an issue paper in the journal *Groundwater* entitled "Complexities in Hindcasting Models – When Should We Say Enough Is Enough?" **Ex. 30**, 2011 Clement Issue Paper. Dr. Clement's issue paper noted that the NRC Panel consisted of "14 experts who volunteered their time to study various aspects of the problem for 2 years and prepared

a report, which was reviewed by 10 external peer-reviewers." *Id.* at 7. With respect to ATSDR's water models, Dr. Clement stated:

For the CLJ problem, for example, the site only had a limited number of PCE data points, which were short-term averaged random grab measurements made in the early 1980s (Figure 2). The calibration exercises were aimed toward fitting the monthly-averaged model predictions to these limited data points, within a predefined fixed target level, with an assumption that the calibrated model would be able to hindcast the historical levels of PCE and its byproducts in the 1950s, 1960s, and 1970s. However, due to limitations in our understanding of natural processes and due to inaccuracies in measurement methods, several complex models with many different model structures and initial conditions might fit these observations equally well.

Id. at 6. In response to Dr. Clement's questions about the complexity and accuracy of ATSDR's models, Mr. Maslia and his colleagues stated, "the water model was requested by ATSDR epidemiologists" and that "ATSDR is a public health agency." **Ex. 31**, ATSDR Response to Clement, p. 12, 14 (emphasis omitted). Referencing the debate between Dr. Clement and Mr. Maslia about ATSDR's water models, the Anderson & Woessner Textbook states "[h]indcasting applications are 'uniquely challenging' (Clement, 2011) because it is not possible to collect additional observations to augment the existing historical dataset, which is often meager." **Ex. 1**, Anderson & Woessner Textbook, p. 11.

V. PLG's Phase I Experts Declined to Opine about the Reliability or Accuracy of ATSDR's Water Models for Determining Absolute Concentrations for Individual Exposure Determinations.

Despite the stated health-protective purpose and the significant limitations of ATSDR's water models, PLG's Phase I experts have offered broad and sweeping opinions about the correctness, accuracy, reliability, and soundness of ATSDR's water models without regard for their intended purpose, uncertainty, and limitations. *See, e.g.*, **Ex. 5**, Maslia Report, p. 18; **Ex. 6**, Maslia Rebuttal Report, p. 50; **Ex. 11**, Aral Report., p. 13; **Ex. 16**, Jones/Davis Report, p. 6-1; **Ex. 17**, Jones/Davis Rebuttal Report, p. 3-13; **Ex. 15**, Konikow Rebuttal Report, pp. 32-33.

During their depositions, however, PLG's Phase I experts declined to unequivocally opine that ATSDR's water models are sufficiently correct, accurate, reliable, or sound for determining absolute concentration levels for individual exposures. Specifically, Mr. Davis testified:

Q. BY MS. SILVERSTEIN: In your report regarding the Tarawa Terrace model, you opined that the model used sound methodology and provided reliable insights to the migration of PCE contamination; is that correct? A. Yes.

Q. Are you opining that the model reliably or accurately estimates monthly contaminant concentration levels for individuals? MS. BAUGHMAN: Objection. Form.

THE WITNESS: No.

Ex. 2, Davis Dep., 72:14–73:2 (emphasis added). Similarly, Dr. Jones testified:

Q. BY MR. ANTONUCCI: You're not offering the opinion that the Tarawa Terrace model is a sufficiently reliable model for determining quantitative levels of contaminant exposure for an individual; right?

THE WITNESS: The – the opinions we've rendered on the model was that in terms of the -- how the model simulates concentrations at the water treatment plant, it -- it is a reasonably accurate model developed using sound scientific and engineering principles. How that – concentrations resulting from that are then incorporated in an epidemiological study is outside my scope of expertise -- expertise. Q. BY MR. ANTONUCCI: So that is not an opinion you're offering?

Q. BY MR. AN IONUCCI: So that is not an opinion you're offering? MS. BAUGHMAN: Objection. Form.

THE WITNESS: No, that's not an opinion I'm offering.

Ex. 13, Jones Dep., 231:18–232:19 (emphasis added).

Dr. Aral disclaimed knowledge about whether ATSDR's water models were intended for

determining an individual's exposure and about the level of detail required for the epidemiological studies

they were meant to support. Dr. Aral testified:

Q Okay. And then the next paragraph says, "Historical exposure data needed for the epidemiological case control study are limited. To obtain estimates of historical exposure, ATSDR is using water modeling techniques and the process of historical reconstruction. These methods are used to quantify concentrations of particular contaminants in finished water and to compute the level and duration of human exposure to contaminated drinking water." Did I read that correctly?

A Yeah. That's correct.

Q When you were working on the Tarawa Terrace water modeling, were you aware that the modeling work you were doing was intended for this epidemiological study?

A Yes.

Q And were you aware that it was not intended for estimating an individual's exposure?

MR. DEAN: Object to the form of the question. A I -- I am -- I don't have any idea on that –

Q So are you saying you don't know?

A What it is going to be used for --

Q You --

A -- I don't know what the models are going to be used for. Is -- is it for a public exposure? Individual exposure? Community exposure? I have no idea.

Ex. 32, Aral Dep., 42:11-19; 85:19-86:16; 87:14-20 (emphasis added).

Dr. Konikow could not point to anywhere in ATSDR's water modeling reports where it is stated

that the water models were intended to be used in litigation as part of a causation analysis for individual

plaintiffs. Dr. Konikow testified:

Q. Okay. And can you point me to anywhere in the ATSDR reports stating that the Tarawa Terrace model was intended to be used in litigation as part of a causation analysis for individual plaintiffs?

MR. DEAN: Object to the form of the question.

THE WITNESS: I do not recall seeing any mention of litigation in there.

Okay. Can you point me to anywhere in the -- in the Hadnot Point/Holcomb Boulevard reports that states that particular model was intended to be used in litigation as part of a causation analysis for individual plaintiffs?

THE WITNESS: I don't recall seeing anywhere in the reports that litigation was mentioned. So I would have to say no.

Ex. 12, Konikow Dep., 139:6-15; 147:15-148:3. Dr. Konikow further testified that he did not know whether

ATSDR's water models were good models for the purpose of estimating individual exposure.

Q. Okay. And when you say the model was successful, ATSDR was successful, and it was a good model, are you saying that it was successful and a good model for the purpose of estimating exposure in individuals? A. I don't know.

THE WITNESS: I don't know how it was used for exposure. I didn't look at the exposure studies or the epidemiological studies. So I really can't –

Ex. 12, Konikow Dep., 352:7-19 (emphasis added). Nevertheless, Dr. Konikow maintained that

"from the modeling perspective, [he] felt that the mean monthly concentrations were estimated on

the basis of reasonable, adequate models and so that they could be relied on for other purposes."

He testified:

Q. So what is -- what is the basis for your opinion that the simulated concentrations from the ATSDR models are -- do not preclude the use by health professionals to estimate past exposure of residents?

A. Well, from the health perspective, I have no basis for saying that. But from the modeling perspective, I felt that the mean monthly concentrations were estimated on the basis of reasonable, adequate models and so that they could be relied on for other purposes. But it's certainly not meant to imply I understood the health studies.

Ex. 12, Konikow Dep., 233:11-23 (emphasis added).

Mr. Maslia acknowledged that "we were not asked...to apply [ATSDR's water models] to

individuals." Mr. Maslia testified:

Q. In any of the ATSDR modeling reports for Tarawa Terrace, Hadnot Point or Holcomb Boulevard, any of the expert panel summaries that you put together, any of the transcripts from the expert panels, 2005 and 2009, can you point me to a single statement from any of those experts at the time or in any of your reports, the numerous voluminous reports, stating that the results of the models are sufficiently reliable and accurate to be used for exposure determinations in specific individuals?

THE WITNESS: We express in numerous places that they are reliable, acceptable. Again, we were not asked or -- nor were we ever asked to apply them to individuals.

Ex. 14, Maslia Dep. (Mar. 13, 2025), 127:6-22 (emphasis added). Nevertheless, Mr. Maslia maintained

that ATSDR's water models could be used "for whatever purpose." Mr. Maslia testified:

Q. And if you're asked by a lawyer or one of the judges that -- whether or not the Court should use the model for making exposure determinations for individual plaintiffs in the case, what would your answer be?

THE WITNESS: My response would be, from my standpoint, my professional and expert standpoint, that the model results are reliable based on our assessment of model calibration, model results, and that the -- as long as the models are sufficiently calibrated, in my mind, a**nyone can use them for whatever purpose** they want to use them for. In other words, we did not calibrate the models with the end result of exposure assessment. Again, we were, at ATSDR, blinded to anything with the epidemiology in terms of cases, controls, people, anything like that, other than the five objectives that I believe I listed in my expert report as to what the epidemiologists requested us to meet.

Ex. 14, Maslia Dep. (Mar. 13, 2025), 47:9-48:11.

LEGAL STANDARD

Under Fed. R. Evid 702, expert testimony is admissible if it (a) "will help the trier of fact to understand the evidence or to determine a fact in issue," (b) "is based on sufficient facts or data," (c) "is the product of reliable principles and methods," and (d) "reflects a reliable application of the principles and methods to the facts of the case." Expert testimony is only admissible if "it rests on a reliable foundation and is relevant to the task at hand." *Belville v. Ford Motor Co.*, 919 F.3d 224, 232 (4th Cir. 2019) (citing *Daubert, Inc.*, 509 U.S. at 597). The Court must assess "whether the reasoning or methodology underling the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Belville*, 919 F.3d at 232 (citing *Daubert*, 509 U.S. at 592–93). Moreover, "[f]it is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Daubert*, 509 U.S. at 591 (internal quotations omitted). "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92.

ARGUMENT

ATSDR's water models were intended to determine relative exposure levels for **population** level epidemiological studies, not to determine absolute concentration levels for **individual** exposure determinations. As such, PLG's opinions about ATSDR's water models do not fit this case where the question at issue relates to individual exposure. Moreover, ATSDR's water models are unreliable and scientifically invalid for the specific purpose of determining absolute concentration levels for individual exposure determinations over particular timeframes. ATSDR's water models are unreliable due to insufficient sampling data to determine contaminant concentration levels over 30 years into the past. Moreover, ATSDR's water models relied on conservative, health-protective assumptions that resulted in higher contaminant concentration levels over a long period of time. These assumptions do not reflect real world conditions, making ATSDR's water models unreliable for the purpose of reliably or accurately determining absolute exposure concentration levels for individual exposure determining absolute exposure determining absolute exposure determinations.

I. ATSDR's Water Models Do Not Fit This Case and Will Not Be Helpful to the Trier of Fact.

In *Coleman v. Union Carbide Corp.*, No. 2:11–0366, 2013 WL 5461855 (S.D. W.V. Sept. 30, 2013) (Copenhaver, J.), in a 42-page decision, a district court excluded an air model offered by an expert to show emissions exposure in a toxic tort case. In excluding the air model based on fit or relevancy, the district court determined that the model was designed to produce a worst-case scenario in a public safety setting

for a given community, but that it failed to address whether the proposed class of individuals suffered significant exposure to a proven hazardous substance. *Id.* Specifically, the district court held:

Mr. Haunschild and the plaintiffs unapologetically concede that his study "did not intend to prove a specific level of harm." (Pls.' *Daub.* Resp. at 10); (Haunschild Mar. Aff. ¶ 5 ("The purpose of my study was not to prove a specific level of harm.")). The difficulty with his approach, however, is quite apparent. It is designed to produce a hypothetical and prospective worst case scenario. His permit-based approach is understandable in the public safety setting for which it is intended, namely, where a regulator desires to know the possible effects that a facility's emissions may have on a given community. It tells the fact finder in a medical monitoring case very little, if anything, however, about whether a class of individuals suffered significant exposure to a proven hazardous substance. For that reason, it is unhelpful to the trier of fact apart from the question of reliability.

Id. (emphasis added).

The issue in the CLJA litigation is "toxic chemical exposure from the water at Camp Lejeune" with respect to individual plaintiffs. *See* June 24, 2024 Order, D.E. <u>247</u>, p. 1. However, ATSDR's water models were developed for the intended purpose of determining relative exposure levels for population level epidemiological studies, not for determining absolute concentration levels for individual exposure. As discussed above, this is reflected throughout ATSDR's water modeling reports and in the technical discussions that took place at the 2005 and 2009 ATSDR expert panels among the water modelers and ATSDR's epidemiologists. Consistent with their intended purpose of supporting population level epidemiological studies and given the limited historical concentration data, ATSDR's water models made conservative, health-protective assumptions, as discussed further below.

Thus, like in *Coleman*, the Court should exclude the opinions of PLG's Phase I experts on ATSDR's water models as unhelpful to the trier of fact in this case because ATSDR's water models were not intended for determining individual exposure levels. Fed. R. Evid. 702(a).

II. ATSDR's Water Models Are Unreliable and Scientifically Invalid for Determining Absolute Concentration Levels for Individual Exposure Determinations.

In *Coleman*, the district court also excluded the air model at issue as unreliable. *Id.* at *25, 33 In doing so, the district court observed that "an air model has many moving parts. **The accuracy of the model** bears a strong positive relationship to the correct inputs being used—inputs that represent the actual

conditions at the facility and its emission sources." *Id.* at *23 (emphasis added). The district court walked through the air model's inputs and questioned multiple inputs used in the model, including "use of maximum emission estimates...without regard to what is actually being emitted," and "failure to consider how the plumes from the Alloy Plant depleted as a result of their depositing particles in the course of their travels away from the Alloy Plant." *Id.* at *24-33. Ultimately, the district court held:

Mr. Haunschild's model is a speculative conglomeration of data that is unreliable on the question of exposure in, around, and beyond the Alloy Plant. This basic methodological flaw infects his entire analysis. It makes for a patently unreliable measure of significant exposure to harmful substances, which is the central issue in this personal injury, ambient air case.

Based upon these and other considerations, the court concludes that Mr. Haunschild's opinions are inadmissible under Rule 702 and Daubert.

Id. at *24-25, 33 (emphasis added).

Similarly, in Sommerville v. Union Carbide Corp., 2:19-cv-00878, 2024 WL 1204094 (S.D. W.Va.

Mar. 20, 2024) (Goodwin, J.), a district court excluded another air model offered by an expert to show exposure to emissions in a toxic tort case. Among other factors, the district court pointed to the use of "unreliable or unvalidated emissions data for different years throughout the period he models" and the use of unrealistic assumptions, including "to assume [a manufacturing plant] operated historically in a static sense." *Id.* at 11. Citing the *Coleman* decision, the *Sommerville* court held that the air model offered by the expert was unreliable because (1) the data upon which the model relied was insufficient and (2) the assumptions made did not reflect real world conditions. *Id.* at 19. In doing so, the Sommerville court further noted:

[M]odels used in environmental-tort litigation present two additional issues. First, the adversarial process creates unfortunate incentives to misuse models in "unscientific" ways, perhaps taking advantage of their uncertain and impervious nature. Second, because models are particularly complex and enigmatic applications of science, they are even less accessible....

Id. at 8 (quoting Matthew W. Swinehart, Remedying Daubert's Inadequacy in Evaluating the Admissibility of Scientific Models Used in Environmental Tort Litigation, 86 Tex. L. Rev. 1281, 1283 (2008)); see also Castellow v. Chevron USA, 97 F.Supp.2d 780, 793 (S.D. Tex. 2000) (crediting expert testimony in

occupational benzene exposure case that "[m]odels are basically what people use in the absence of data. If you're going to project a risk in a regulatory setting that attempts or purports to characterize a risk that cannot be measured experimentally or with data, then modeling is the only thing you can do. It doesn't constitute evidence to use in determining causation. It's a policy, not a science.") (citation omitted); *Ramsey v. Consolidated Rail Corp.*, 111 F.Supp.2d 1030, 1037 (N.D. Ind. 2000) ("Use of the groundwater flow model as a comparatively accurate predictor of the general direction of VOC migration doesn't support a finding of reliability when the model is used to support an opinion that VOCs traveled from one point (anywhere on the rail yard) to a specific second point (the Ramseys' well) despite lack of support in years of actual testing.").

Here, PLG's Phase I experts were given every opportunity during their depositions to opine about the reliability and accuracy of ATSDR's water models for determining absolute concentration levels for individual exposures determinations, but they declined to do so. That is because ATSDR's water models are unreliable and scientifically invalid for the purpose of determining absolute concentration levels for individual exposures over discrete timeframes. ATSDR's water models are based on insufficient contaminant concentration sampling data, and they rely on conservative, health-protective assumptions that resulted in increased estimated contaminant concentration levels over a longer period of time. These assumptions do not reflect real world conditions, making ATSDR's water models unreliable for the purpose of accurately determining exposure levels for individuals. Accordingly, the opinions of PLG's Phase I experts about ATSDR's water models should be excluded as unreliable.

A. <u>ATSDR's Water Models Are Based on Insufficient Contaminant Concentration Sampling</u> <u>Data</u>.

As discussed above, before PLG's Phase I experts became litigation experts, they repeatedly acknowledged concerns about the reliability and accuracy of ATSDR's models due to insufficient contaminant concentration sampling data before the early to mid-1980s. *See, e.g.*, **Ex. 8**, 2005 Expert Panel (Day 2), 47:25-48:18, 193:12-25 (Dr. Konikow's comments on the Tarawa Terrace model: "Well, you have very limited data against which to calibrate your model;" "then you start your model running...there's going

to be speculation upon assumption built into that, and you'll get a range of responses;" and "we don't have concentration data before 1980 or 1982...so everything we do for looking at distribution before then is going to be a little fuzzy."); **Ex. 27**, 2009 Expert Panel Summary, p. 99, 100 (Dr. Konikow's comments on the Hadnot Point/Holcomb Boulevard model: "the level of accuracy and precision may still not be adequate because of the paucity of data and complexity of contaminant sources during the time period when the history is to be reconstructed" and "the task at hand is an enormously difficult and challenging one, and there are numerous difficulties confronting a successful completion."); **Ex. 28**, HP/HB Ch. A Supp. 6, p. S6.45 (Mr. Maslia's comments on the Hadnot Point/Holcomb Boulevard model: "[f]or contaminant fate and transport modeling reported herein, however, insufficient water-quality data existed to conduct a statistical analysis for assessment of model calibration fit" and "[t]he results (i.e., range of concentration) presented in the sensitivity analysis reported herein should not be considered or interpreted as the results of a robust and comprehensive uncertainty analysis....").

Outside reviewers of ATSDR's water models expressed similar concerns about the models' reliability and accuracy due to insufficient historical sampling data. **Ex. 21**, Jun. 19, 2008, Navy Letter; **Ex. 29**, 2009 NRC Report, p. 65 ([I]t is extremely difficult to obtain quantitative estimates of historical levels of exposure to PCE and its degradation products reliably on a monthly basis. Reporting such model predictions without clear error bounds gives the impression that the exposure of former residents and workers at Tarawa Terrace during specific periods within a given year can be accurately defined."); **Ex. 30**, 2011 Clement Issue Paper, p. 6 ("For the CLJ problem, for example, the site only had a limited number of PCE data points....").

In short, ATSDR attempted to reconstruct average monthly concentrations of contaminants in drinking water over a period greater than thirty years based on limited sampling data from the very end of that timeframe in the early to mid-1980s. **Ex. 19**, TT. Ch. A, p. A27. Because ATSDR's water models are based on insufficient historical sampling data, the opinions of PLG's Phase I experts about ATSDR's water models should be excluded as unreliable for the purpose of determining absolute concentration levels for individual exposure determinations. *See Coleman*, 2013 WL 5461855 at *24-25 ("Mr. Haunschild's

model is a speculative conglomeration of data that is unreliable on the question of exposure in, around, and beyond the Alloy Plant."); *Sommerville*, 2024 WL 1204094 at *1 ("I find that the opinions of Dr. Sahu are not based upon sufficient facts or data....").

B. <u>ATSDR's Water Models Relied on Conservative, Health-Protective Assumptions that Do</u> Not Reflect Real-World Conditions.

In excluding the exposure air models, the district courts in *Coleman* and *Sommerville* also pointed to reliance of the models on assumptions that did not reflect real world conditions. *See Coleman*, 2013 WL 5461855 at *25 ("He has emission sources borrowing data from one another, across many years, and then combining them with the unexplained assumption that the target maximum emission rates all occurred in the same year."); *Sommerville*, 2024 WL 1204094 at *1 ("[T]he inputs he uses in the air model are speculative and are premised on assumptions that do not accurately represent the Defendants' operations in South Charleston.").

Similarly, ATSDR's water models made a number of conservative, health-protective assumptions that did not reflect reality. **Ex. 8**, 2005 Expert Panel (Day 2), 49:20-50:4 ("MR. MASLIA: Then from a standpoint of being conservative, from a public health standpoint...."). These assumptions resulted in the models predicting biased-high estimated contaminant concentration levels. Moreover, ATSDR's health-protective assumptions led them to conclude that drinking water contamination was present over a longer timeframe than what actually occurred. These assumptions do not reflect real world conditions, making ATSDR's water models unreliable for the purpose of accurately determining absolute concentration levels for individual exposure. The following is a discussion of some of the conservative, health-protective assumptions made in ATSDR's water models that were not based in fact.

i. ATSDR's Water Models Make Layered and Unsupported Assumptions About the Start and Extent of Contamination.

a. The Tarawa Terrace Model

For Tarawa Terrace, the source of contamination and approximate starting time of the contamination was known. The source of PCE contamination in Tarawa Terrace was an off-base dry-cleaner. Based on the deposition testimony of the dry-cleaner's owner, ATSDR determined that the dry

cleaner opened on the first day of the year in 1953.⁶ In the absence of additional information or data, the Tarawa Terrace model conservatively assumed that used PCE was dumped outside on the first day that the dry-cleaner opened, and it assumed that the PCE immediately traveled through the ground into the subsurface water aquifer. **Ex. 14**, Maslia Dep. (March 13, 2025), 287:23-288:11.

In reality, however, it would take years for contaminants to seep through the ground to reach the aquifer, even if the dry-cleaner started dumping PCE on the first day that it opened. *See Id.* at 286:18-22 ("Q. Okay. In the real world, if contaminants on the surface were to start leaking, would they immediately reach the aquifer? A. They would within, in this case, probably a couple of years."). During the 2005 ATSDR Expert Panel, Dr. Konikow recognized that it could have taken up to 14 years for PCE dumped by the drycleaner to travel through the subsurface soil to the aquifer. He stated:

DR. KONIKOW: But the point – one of the points is that you really – your study isn't starting until 1965 --

MR. MASLIA: '68

DR. KONIKOW: '68. That gives you 14 years from the time ABC Cleaner [sic] started. So the value in doing the groundwater flow and transport model will be to, you know, start the – as best we know, they were introducing contaminants into the soil, at least, through the septic tanks very shortly after they started; maybe a year, maybe instantly, maybe a year, maybe two years at most.

That gives you 12 years for it to reach the water table and spread. The groundwater flow and transport models, accounting for uncertainty, heterogeneity, and so on, will give you range of arrival times. But I'm guessing that the bulk of your realizations will get contaminant reaching the wells in that 14-year period.

MR. MASLIA: **Oh, no question about it.**

DR. KONIKOW: I think all of the uncertainty is going to be the range -

MR. MASLIA: Right; range.

DR. KONIKOW: -- Is going to be before your 1968 starting time. So it's worth doing those flow and transport models just to demonstrate that[.]

Ex. 8, 2005 Expert Panel (Day 2), 46:14-47:11 (emphasis added).

Consistent with the purpose of ATSDR's water modeling, the focus of the discussion was to ensure

that the contaminants arrived in the water by the 1968 start of the epidemiological study period. This arrival

time depended on how long it took the PCE that entered the aquifer near the off-base dry cleaner to travel

to the on-base water supply wells. Id. Dr. Konikow commented that for the epidemiological study, more

⁶ The United States' historian expert has opined that the dry-cleaner more likely opened in mid-1954.

refined or complex modeling was not needed because "it's not going to yield anything more than that." He

specifically stated:

DR. KONIKOW: But I'm guessing the outcome is still going to be, from the start of your epidemiological study to the end, Tarawa Terrace residents were exposed, which if you could support that, it kind of mediates the need for more refined modeling **because it's not going to yield anything more than that.**

Ex. 8, 2005 Expert Panel (Day 2), 49:14-19 (emphasis added).

During the 2009 ATSDR Expert Panel, Dr. Konikow and Mr. Maslia discussed the fact that shifting

the contaminant start date and mass loading did not preclude the Tarawa Terrace model from still hitting

high concentration levels for the period where data exists in the early to mid-1980s. They stated:

DR. KONIKOW: The Tarawa Terrace with the first arrival in November in '57, if that was actually several years later, maybe even four or five years later, would that have any effect on the health study since the health study is '68 to '85? In other words would any inaccuracy in that first arrival— MR. MASLIA: We actually did, Mustafa Aral did some well scheduling optimization and did different scenarios with different wells other than the ones that we calibrated for the model. And you could shift the time from '57 to '60, but during the course of the study it did not significantly affect at all the higher concentrations.

Ex. 9, 2009 Expert Panel (Day 1), 89:7-89:21 (emphasis added). In other words, ATSDR conservatively

assumed that contamination in Tarawa Terrace started in 1953, but in reality, it likely started years later.

The Tarawa Terrace model also assumed that the amount of PCE entering the aquifer from the drycleaner remained constant for the entire period between 1953 and 1987. In reality, the amount of PCE entering the aquifer would have varied, but ATSDR's model was not detailed enough to reflect such variation. *See* **Ex. 32**, Aral Dep., 149:1-150:9 ("But ABC Cleaners is – I assume is a point in our modeling idealization."); *Sommerville*, 2024 WL 1204094 at *11 ("[I]t is methodologically unsound to assume [a manufacturing plant] operated historically in a static sense.").

Robert Faye, another groundwater modeling expert that worked with Mr. Maslia and Dr. Aral in developing ATSDR's water models, noted in response to concerns raised by Dr. Konikow that "the reviewer seems to assign a high degree of accuracy and credibility to the PCE mass computation that is unwarranted" when in reality "the computation of PCE mass was a highly interpretive and somewhat subjective process

frequently based on questionable data." Ex. 33, Feb. 21, 2007 Faye Comments to Konikow, p. 10; Ex. 5,

Maslia Report, p. 145; Ex. 12, Konikow Dep., 328:6-329:15.

b. The Hadnot Point/Holcomb Boulevard Model

For the Hadnot Point water distribution system, the general sources of the contamination were known (leaking fuel drums and other industrial waste), but the time when contaminants started leaking into the aquifer and the degree of leaking that occurred was entirely unknown. **Ex. 25**, HP/HB Ch. A., p. A84. During the 2009 ATSDR Expert Panel, Dr. Konikow commented with respect to Hadnot Point, "I'm not sure how you're going to reconstruct the history of mass loading." He stated:

DR. KONIKOW: So then the question is how do you go, you'll calculate a mass, but then how do you go back in time and use that to estimate what the mass loading rate is over the duration of the model? The Tarawa Terrace situation you had a essentially a point source with a known location and a fairly constant over time disposal rate. **Here I'm not sure how you're going to reconstruct the history of mass loading.**

Ex. 9, 2009 Expert Panel (Day 1), 201:6-16. Mr. Faye responded to Dr. Konikow's concerns, reasoning

that it is better to have a "flawed starting point" than no starting point. He explained:

MR. FAYE: The issue, Lenny is basically, you know, you take what you get.

And what it is, I mean, it's basically, you know, you've got a flawed starting point or you've got no starting point. So, I mean, that's really what it comes down to. Of course, it's better to have a flawed starting point in my opinion.

Ex. 9, 2009 Expert Panel (Day 1), 202:5-21. In describing a "flawed starting point," Mr. Faye is referencing the fact that for the Hadnot Point/Holcomb Boulevard model, ATSDR made layered assumptions that were untethered to historical data about when contaminants started leaking from multiple sources, and they layered onto those assumptions the amount of contaminants in each of those leaks that were similarly unconnected to historical data. **Ex. 25**, HP/HB Ch. A., p. A84; *see also* **Ex. 38**, Sept. 26, 2008, Barbara Anderson email (comparing immediate mass loading scenario for benzene, which was assumed in the Hadnot Point/Holcomb Boulevard model with more realistic scenario of gradual mass loading); **Ex. 14**, Maslia Dep. (Mar. 13, 2025), 289:16-290:12.

ii. ATSDR's Water Models Also Had to Make Assumptions About Well Pumping and Cycling Schedules.

For both Tarawa Terrace and Hadnot Point, information about well pumping and cycling schedules was limited. Dr. Aral acknowledged the uncertainty with respect to well pumping and cycling in a chapter he co-authored stating that "Uncertainties in the exposure outcome can have a significant effect on the epidemiological study. In particular, the uncertainty caused by the groundwater pumping schedule used in the simulations has been pointed out to be important." **Ex. 34**, TT Ch. H at H3. However, the assumptions the modelers made were important because only a few of the wells that supplied the systems were contaminated. According to Mr. Maslia, assumptions about well cycling or pumping for TT-26—the most contaminated well in Tarawa Terrace—did have a significant impact on the estimated contaminant concentrations that the Tarawa Terrace model produced. He stated:

If you shut down TT-26, both the data and the model would show that your finished water went down to practically no contaminant at Tarawa Terrace. But if you shift the cycling so that it didn't hit or arrive or pass the MCL [Maximum Contaminant Level] say, as you said, 59, 60, 61, whatever, did not significantly affect the higher concentrations in the finished water.

Ex. 9, 2009 Expert Panel (Day 1), 89:25-90:8 (emphasis added); *see also* **Ex. 12**, Konikow Dep., 272:5-13 ("TT-26. That was because that was the main source, not the only but the main source, of contaminated water to the Tarawa Terrace Water Treatment Plant. If that wasn't pumping, then there would be few, very few contaminants showing up in the Water Treatment Plant."); **Ex. 8**, 2005 Expert Panel (Day 2), 50:5-51:17 ("So the concentrations were going to vary considerably, depending on which well happened to be in service at a particular point in time."); **Ex. 32**, Aral Dep., 252:17-253:22 ("Q. Results of [the optimized pumping schedules] study indicate that variation of pumping schedules may cause significant changes in the contaminant concentration levels and MCL arrival times at the water treatment plant. . . . do you disagree with what you wrote about the major – A. No I don't – Q. – cause – A. – I don't disagree.").

Understanding there was a direct relationship between contaminant concentration levels and whether a contaminated well was pumping, the ATSDR made numerous conservative, health-protective assumptions with respect to well pumping and cycling. For example, the Tarawa Terrace model made the assumption that "[o]nce a well was put in service, it was assumed to operate continuously for modeling purposes until it was permanently taken off-line--the exception being temporary shut downs for long-term maintenance." **Ex. 19**, TT Ch. A, p. A18; **Ex. 35**, Maslia Dep. (Sept. 26, 2024), 205:17-23.

iii. ATSDR's Water Models for Tarawa Terrace and Hadnot Point/Holcomb Boulevard Also Assumed that There Were No Volatile Organic Compound Losses During the Water Treatment Process.

The topic of volatile organic compound (VOC) losses during water treatment was discussed during the 2005 ATSDR Expert Panel. The Panel acknowledged there were at least 10% VOC losses during the water treatment process. Ex. 7, 2005 Expert Panel (Day 1), 56:22-25. However, the Panel characterized those losses as "negligible" and decided that ATSDR's water models did not need to account for them. Id. ("So although we said it's probably negligible, and I agree with Tom's number here. At 90 percent, what's going in is coming out on the other end."); Ex. 12, Konikow Dep., 298:16-299:22 ("My recollection of the expert peer panels is that there were experts there in volatilization and water treatment processes, and they stated, as best I could recollect, that there was not significant volatilization or losses of the VOCs for these particular water treatment plants. And so seemed to me as an expert reviewer of the work that that seemed like a reasonable assumption."); Ex. 2, Davis Dep., 102:16-21 ("Q. BY MS. SILVERSTEIN: So it would be correct to say that the ATSDR Tarawa Terrace model did not include a calculation simulating contaminant losses during storage, treatment, or distribution? A. That's my understanding."); Ex. 13, Jones Dep., 129:11-18 ("Q. BY MR. ANTONUCCI: Okay. However, the model -- the model doesn't take that into account...A. The model does not explicitly simulate volatilization."); Ex. 32, Aral Dep., 131:7-11 ("Q: Okay. Would you agree that a simple mixing flow-weighted average does not have any calculation to simulate physical processes whereby contaminants could be loss in treatment? A: That's correct."); Ex. 14, Maslia Dep., 149:22-151:16.

Not accounting for VOC losses makes sense where the purpose of the water models was to estimate relative exposure for epidemiological studies. As Mr. Maslia stated, "a successful epidemiological study places little emphasis on the actual (absolute) estimate of concentration and, rather, emphasizes the <u>relative</u> level of exposure." **Ex. 23**, ATSDR Response to Navy, p. 6. Because all water that was contaminated

experienced consistent VOC losses during treatment, a failure to account for such losses did not impact the rank order of exposure quantity predicted by the models. *Id.* ("[E]xposed individuals are, in effect, ranked by exposure level and maintain their rank order of exposure level regardless how far off the estimated concentration is to the 'true' (measured) PCE concentration."). However, for the purpose of calculating absolute exposure assessments, not accounting for VOC losses resulted in higher estimated concentration levels that do not accurately reflect real world conditions.

In short, ATSDR's water models are unreliable and scientifically invalid for the purpose of determining exposure levels for individual plaintiffs because the models relied on numerous conservative, health-protective assumptions that do not reflect real-world conditions. *See Coleman*, 2013 WL 5461855 at *32 ("Another void in Mr. Haunschild's model arises from his failure to consider how the plumes from the Alloy Plant depleted as a result of their depositing particles in the course of their travels away from the Alloy Plant. His failure to do so leaves one with another significant question mark regarding his methodology."); *Sommerville*, 2024 WL 1204094 at *1.

III. ATSDR's Water Models Are Unreliable and Scientifically Invalid for Determining Absolute Exposure Levels for Individual Plaintiffs Because They Are Based on Arbitrary Selections of Model Input Parameters.

On January 12, 2007, Mr. Maslia sent an email to ATSDR's water modeling team, including Dr.

Aral, Dr. Bove, and Mr. Faye entitled "Finalizing Modeling Activities for Tarawa Terrace." Ex. 36, Jan.
12, 2007 Maslia Email. In that email, Mr. Maslia made an executive decision on parameters being debated for the Tarawa Terrace model. *Id.* Mr. Maslia stated:

"As the Agency is under tremendous pressure (if not outright criticism) to IMMEDIATELY provide a report on Tarawa Terrace, we no longer have the time to debate this matter any further (i.e., I am calling it a 'tie' in the battle of the models"). Therefore, as the project officer for this project, I have made the following decision and I am requesting that everyone involved abide by my decision."

*Id.*⁷ Among other parameters covered by Mr. Maslia's executive decision was selection of biodegradation rate for PCE. *Id.*; **Ex. 35**, Maslia Dep. (Sept. 26, 2024), 261:17-25. Mr. Maslia also made the decision that "NO quantitative comparisons will be made using NON-DETECT (ND) samples" because "using these values is a 'double edge' sword that will come back to 'attack' us, because those who review [our] modeling results will pick a ND value to 'justify' their point of view and contradict our results." *Id.*

The following day, on January 13, 2007, Mr. Faye emailed Mr. Maslia taking issue with the decisions made about certain parameters, including the biodegradation rate, and noting that "the results are only marginally acceptable and certainly do not represent our 'best' calibration." **Ex. 37**, Jan. 13, 2007 Faye Letter. Mr. Faye further stated that he would find it difficult to defend the model results "to my technical peers or in a court of law." He stated:

I will find it very difficult to defend these results to my technical peers or in a court of law. Consequently, I would like to write a letter to the record to you and to ERG explaining what has happened, why the results are why they are, and addressing my concerns. I will send a draft of this letter to you first and ask for your comments."

Id. (emphasis added). Mr. Faye went on state:

I believe we have violated a fundamental rule of good modeling procedure. We let the 'tail wag the dog' and assigned extraordinary credibility to simulated numbers rather than to well established concepts. When a choice must be made between accepting less than desirable model results or violating or compromising valid conceptual models, I believe we should accept the undesirable results and explain the limitations of the simulations in that context."

Id. Notably, the United States learned during Mr. Maslia's March 13, 2025, Deposition that PLG retained

Robert Faye as an expert. Ex. 14, Maslia Dep. (Mar. 13, 2025), 56:2-59:5. Mr. Faye started preparing a

rebuttal report in the case, but that report ultimately was not disclosed. Id. at 57:20-58:18.

⁷ On June 12, 2007, Mr. Maslia, Dr. Bove, and then ATSDR Deputy Director, Dr. Thomas Sinks, attended a Congressional hearing on Camp Lejeune. Poisoned Patriots: Contaminated Drinking Water at Camp Lejeune: Hearing Before the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, 110 Cong. 56 (2007). The "Chapter A: Summary of Findings" report for the Tarawa Terrace model was published in July 2007. **Ex. 19**, TT Ch. A, p. iii; *see also* Maslia Dep. (Sept. 26, 2024), 269:12-19 ("12 Q. Were you feeling political pressure when you're referring to the pressure in the e-mail? A. I did not have -- I was not in any direct communication with politicians, but our agency leadership probably were or at least got feedback from them, and so they were pressuring us to finish up.").

Mr. Faye is not the only scientist to express concern about the use of the models for litigation purposes. During ATSDR's Expert Panel in 2009, several of the experts raised concerns about the fact that many components of the model were novel, untested, and, to their understanding, would not meet the *Daubert* standard if they were to be used in litigation. *See, e.g.,* **Ex. 10**, 2009 Expert Panel (Day 2), 161:12–162:5 (explaining the scientist's understanding of the *Frye* and *Daubert* standards); 159:12–20 ("[P]eople ... have been expressing their discomfort with some, with what I perceive as some new method that other people haven't used yet. And so I'm just trying to figure out is if we can be comfortable with it because that new method has somehow been compared to the existing methods. And so they shouldn't be as comfortable about it."); 175:7–13 ("MR. MASLIA: Well, the answer is anyone can sue or sue anyone at any time of the day, but for anything, so no, we're not gearing our study for that. What we're gearing our study for is for to be able to provide the epidemiologists and the epidemiologists to be able to assess epi results.") (emphasis added).

Plaintiffs' own expert, Dr. Jones, testified at his deposition to the untested nature of some of the model's components, stating that he "[did not] recall seeing any other" groundwater modeling projects use TechFlowMP, a contaminant fate and transport model created for the purpose of the ATSDR models. **Ex. 13**, Jones Dep., 183:14-18. Moreover, Dr. Jones testified that he had not seen TechFlowMP used anywhere else in published studies or the literature. *Id.* at 183:22-184:1. Nonetheless, given Mr. Maslia's stated intent of supporting epidemiology studies and not creating a model for use in litigation, ATSDR moved forward with the "new methods."

In short, ATSDR's water models are unreliable and scientifically invalid for the purpose of determining exposure levels for individual plaintiffs because the models relied on parameter decisions that were based in part on project expediency, rather than sound scientific or engineering principles.

IV. Excluding ATSDR's Water Models Will Not Preclude the CLJA Litigation from Moving Forward.

In *Westberry v. Gislaved Gummi AB*, 178 F.3d 257 (4th Cir. 1999), the Fourth Circuit held that "while precise information concerning the exposure necessary to cause specific harm to humans and exact

details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans given substantial exposure and need not invariably provide the basis for an expert's opinion on causation." *Id.* at 264. Excluding the ATSDR's water models will not preclude the CLJA litigation from moving forward because the United States is offering expert testimony from Dr. Remy Hennet, an expert geochemist and hydrogeologist, on what can reliably be said about the extent and timing of water contamination at Camp Lejeune to determine whether a plaintiff was "substantially exposed" to contaminated water at Camp Lejeune. Among other things, Dr. Hennet will opine that the Tarawa Terrace water distribution system likely became contaminated in the 1970s when VOCs reached supply well TT-26, and that the Hadnot Point water distribution system likely became likely became is the supplemental water from the Hadnot Point water distribution system represented a small fraction of the water in the Holcomb Boulevard water distribution system and that contamination in all systems ended in February 1985, when the last contaminated wells were taken out of regular service.

CONCLUSION

The United States does not dispute the scientific validity of ATSDR's water models for the purpose of estimating relative exposure levels to support epidemiological studies. However, ATSDR's water models are not sufficiently reliable or accurate for determining absolute exposure estimates for individual plaintiffs. Accordingly, the ATSDR's models do not fit the individual causation issues in this case, and the Court should exclude the opinions of PLG's Phase I experts about the correctness, accuracy, reliability, and soundness of ATSDR's water models and preclude use of ATSDR's water models for individual exposure determinations in this litigation. Dated: April 29, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2025, I electronically filed the foregoing using the Court's

Electronic Case Filing system, which will send notice to all counsel of record.

<u>/s/ Haroon Anwar</u> HAROON ANWAR