EXHIBIT B

Exhibit B

PLG's Response to Defendant's Substantive Argument in Defendant's Proposed Order

The PLG respectfully submits the attached response to rebut and contextualize what the Defendant filed labeled as a proposed order despite containing significant new substantive argument and citations. The PLG provides the following analysis to give the Court a complete understanding of the issues and statements regarding the experts identified in the Notice of Filing and PLG's proposed order. The analysis below is broken out by disease (and thus by judge). Because the admissibility of each expert opinion relating to each disease will be determined at separate trials by separate judges, certain information is repeated across sections to ensure each judge may consider the full context necessary before admitting testimony at trial.

I. Leukemia and NHL (Judge Dever)

A. Dr. Lukasz Gondek

Dr. Gondek applied the standard methodology of his fields (cancer genomics, hematology, and oncology), and held his opinions "to a reasonable degree of medical certainty."[1] He performed a documented, systematic PubMed-Medline search, "reviewed and considered all studies," and "followed the weight of the evidence approach" together with the Bradford Hill considerations.[2] He weighed both positive and negative studies—"I take both into consideration" and "I look at all the studies"—giving greater weight to better-designed studies with more granular data.[3] And consistent with modern causation science, he gave appropriate weight to mechanistic evidence: "biological evidence provides direct mechanistic insights, supporting the causal inference in

[1] Gondek GC Rep. at 3, 28 (JA Ex. 96, D.E. 465-1); Gondek GC Dep. Tr. at 262:9-19, 268:1-6, 269:5-17 (JA Ex. 160, D.E. 469-14); *see also* [D.E. 703] at 4 (describing Dr. Gondek's qualifications).
[2] Gondek GC Rep. at 4 (JA Ex. 96, D.E. 465-1); *see also* [D.E. 703] at 1, 7, 13; [D.E. 708] at 5; Gondek GC Rep. at 5-6, 19, 25.
[3] Gondek GC Dep. Tr. at 198:18-199:1, 200:14-201:2 (JA Ex. 160, D.E. 469-14); *see also* [D.E. 703] at 20-21.

observable and reproducible pathways, such as genetic mutations or cellular changes caused by the exposure."[4] That mechanistic analysis is the heart of his opinion.[5] On that basis Dr. Gondek concluded, "[t]o a reasonable degree of scientific certainty," that it is "at least as likely as not" that benzene, TCE, and PCE—individually and cumulatively—can cause leukemia.[6]

Defendant's proposed order does not make a single argument—or cite a single passage—showing that Dr. Gondek changed his scientific methodology because of the CLJA's burden of proof. The quotes show only that he understood the "at least as likely as not" burden and applied it to his ultimate conclusion, which Order 886 expressly permits. *See* [D.E. 886] ("Order 886") at 17. Each quote comes from the discrete "Standard Applied" section of his report or from deposition testimony about that legal standard—not from his methodology. His separate "Methodology" section, by contrast, sets out a documented, systematic PubMed-Medline search, his review of "all studies," a weight-of-the-evidence approach, the Bradford Hill considerations, and a focus on mechanistic evidence, and it never mentions the CLJA or any risk ratio.[7] Indeed, Dr. Gondek himself drew the very line the government erases, testifying that equipoise is "just a different standard of interpretation of the results." His equation of ATSDR's "equipoise and above" with the statute's "as likely as not" simply restates the burden in scientific terms; it does not show that he searched for, read, or weighed a single study differently because of it. In short, the CLJA's burden changed only the confidence expressed in Dr. Gondek's conclusion, never the method he used to reach it. The Defendant's request to strike Dr. Gondek's opinions under Order 886 is therefore unwarranted.

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[4] Gondek GC Rep. at 24 (JA Ex. 96, D.E. 465-1); *see also id.* at 4 ("the weight of evidence from mechanistic studies may, in some cases, outweigh purely epidemiological data"); [D.E. 708] at 24.
[5] Gondek GC Rep. at 8-14 (JA Ex. 96, D.E. 465-1); Gondek GC Rep. at 26.
[6] Gondek GC Rep. at 5, 11, 21, 22, 27 (JA Ex. 96, D.E. 465-1).
[7] Gondek GC Rep. at 4-5 (JA Ex. 96, D.E. 465-1).

B. Dr. Steven Bird (Leukemia and NHL)

Dr. Bird applied a reliable, standard methodology that he did not alter for this litigation. He "utilized scientifically valid and reliable methods to perform [his] research, followed by a consideration of the weight of the evidence and the Bradford Hill viewpoints," conducting documented PubMed and Google Scholar searches and reviewing cited references, toxicology texts, and EPA IRIS and ATSDR materials.[8] That methodology, he explained, "is identical to [his] methodology when seeing a patient and that which [he] teach[es] residents and fellows,"[9] and is the same one he follows in his peer-reviewed work—"I did the search. I reviewed the articles. It's the same."[10] He evaluated "the nine Bradford Hill viewpoints" through a "'weight of the evidence' approach"—"a qualitative assessment using [his] education, training, and 30 years of experience in evaluating all of the data."[11]

These methodologies led Dr. Bird to reach conclusions under a higher standard than equipoise. His "opinions in this report are provided under a 'more likely than not' standard, which necessarily exceeds the 'at least as likely as not' threshold established in the Camp Lejeune Justice Act," and he opined that "the water at Camp Lejeune more likely than not causes leukemia and NHL—comfortably exceeding the at least as likely standard set forth by Congress."[12] An expert who reached "more likely than not" did not lower his methodology as a result of the CLJA's "as likely as not" standard. There is thus no basis to exclude Dr. Bird's opinions under Order 886.

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[8] Bird GC Rep. (NHL-Leuk) at 6 (JA Ex. 103, D.E. 465-8); *see also* [D.E. 703] at 6-7, 13, 14; [D.E. 708] at 5-6; Bird GC Rep. (NHL-Leuk) at 8-9, 12-13, 16-17, 36).
[9] Bird GC Rep. (NHL-Leuk) at 6 (JA Ex. 103, D.E. 465-8).
[10] Bird GC Dep. Tr. at 88:15-20 (JA Ex. 148, D.E. 469-2).
[11] Bird GC Dep. Tr. at 139:10-22 (JA Ex. 148, D.E. 469-2); *see also* [D.E. 708] at 13; Bird GC Rep. (NHL-Leuk) at 14, 33-44, 46-47, 49-53, 61-63); Bird GC Rep. (NHL-Leuk) at 49-53.
[12] Bird GC Rep. (NHL-Leuk) at 8, 13 (JA Ex. 103, D.E. 465-8).

The government's contrary assertions rest on quotations stripped of their context. First, Dr. Bird's statement that the standard set by the CLJA "has significant implications for the analysis at issue" did not describe his methodology, as evidenced by his blood cancer report which resulted in a "more likely than not" conclusion using the same methodology.[13]

Second, the government tries to recast Dr. Bird's reference to "an odds ratio … of greater than 1.1" as a cutoff that mechanically lets a study "in" for consideration. It is no such thing. A relative risk near 1.1 reflects a positive—if only slightly positive—association; standing alone it is neither a finding of causation nor a gate. Dr. Bird examined every study regardless of its risk ratio, weighing each by its confidence interval, size, quality, and consistency with the body of evidence before asking whether causation was at least as likely as not. As the PLG's unchallenged epidemiologist Dr. Savitz explains, "studies that generate elevated relative risks (>1.0) provide some degree of support for an association and should not be misinterpreted as negative studies because the relative risk is not statistically significant."[14] Tellingly, the government neither moved to exclude Dr. Savitz nor includes him in its response to Order 886.

The government's position is also at war with its own agency. The very approach it derides—identifying a positive association by a risk ratio greater than 1.1, and weighing studies without using any particular risk estimate as a gatekeeper—is the approach of the 2017 ATSDR Assessment, the government's own report analyzing the very Camp Lejeune exposures at issue here.[15] That is not a litigation shortcut; it is mainstream epidemiology.[16] Defendant can challenge reliance on the weight of particular studies on cross-examination.

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[13] Bird GC Rep. (NHL-Leuk) at 7-8 (JA Ex. 103, D.E. 465-8).

[14] Savitz Rebuttal at 4 (JA Ex. 144, D.E. 468-10). Defendant also ignores that Order 886 recognized that results can be significantly significant so long as they do not have odds ratios "of 1.0 or below." Order 886 at 11.

[15] ATSDR 2017 Assessment at 8-9 (JA Ex. 182, D.E. 472-3) (citing Rothman 2008).

[16] *See* Savitz Rebuttal at 4 (JA Ex. 144, D.E. 468-10); [D.E. 708] at 17-20; [D.E. 703] at 5-13 (experts considered the full body of studies, including non-significant results).

More fundamentally, the government's premise—that the experts invoked the 1.1 figure only because of the equipoise standard—is refuted on the face of the ATSDR report. ATSDR applies the same positive-association consideration under its highest classification, "Sufficient Evidence for Causation" (where "the evidence is sufficient to conclude that a causal relationship exists"), expressly listing among its considerations "consistent positive associations (e.g., risk ratio or odds ratio greater than 1.1)."[17] ATSDR thus applies the very 1.1 consideration the government attacks not only at "equipoise and above," but at the higher "causation exists" level. The consideration does not change with the burden of proof; only the ultimate degree of confidence in causation does. That is precisely the point: the science is evaluated the same way regardless of the legal standard, so the experts' use of the same approach the government's own agency endorsed cannot be a Rule 702 defect.

Third, Defendant wrongly accuses Dr. Bird of relying on "a single non-significant study" (Aschengrau 1993) for PCE and leukemia. In fact, Dr. Bird reviewed the full body of PCE evidence for leukemia and NHL—including studies reporting statistically significant associations, together with mechanistic evidence—not a single study.[18]

C. Dr. Timothy Mallon

Defendant's proposed order to exclude Dr. Mallon's opinions on blood cancers ignores that he concluded that it is "more likely than not" that TCE causes leukemia, and "more likely than not" that benzene causes leukemia—each a conclusion that "exceeds the at least as likely as not standard of the CLJA."[19] Only his PCE opinion reached a conclusion of "at least as likely as not."[20] But that difference in conclusions does not support exclusion, because Dr. Mallon applied the same

[17] ATSDR 2017 Assessment at 6 (JA Ex. 182, D.E. 472-3).
[18] Bird GC Rep. (NHL-Leuk) at 33-44, 61-65 (JA Ex. 103, D.E. 465-8); [D.E. 708] at 17-18.
[19] Mallon GC Rep. (Leuk.) at 19 (TCE), 32 (benzene) (JA Ex. 98, D.E. 465-3).
[20] Mallon GC Rep. (Leuk.) at 3 (JA Ex. 98, D.E. 465-3).

methodology to all three opinions. A methodology that produced a conclusion *above* the equipoise burden for two of the three chemicals does not reflect reduced rigor (even if the same reliable methodology reached a lower conclusion in one instance). The Camp Lejeune Justice Act's standard changed only his ultimate conclusion (for one opinion)—never the way he searched for, read, and weighed the science to reach any of his conclusions. *See* Order 886 at 17 (distinguishing consideration of the CLJA's standard in the "ultimate conclusion").

Dr. Mallon employed a reliable, standard methodology that he did not devise for this litigation. His report sets out a single, documented method—a systematic literature search (PubMed, the Cochrane database, and the IARC, ATSDR, NTP, and EPA reports),[21] a "weight-of-the-evidence approach," and the Bradford Hill viewpoints[22]—applied uniformly to every opinion; it never mentions the CLJA or any risk-ratio figure, and he included every article his searches returned and weighed positive, negative, and null studies alike.[23] Indeed, he has applied the "at least as likely as not" framework in his Camp Lejeune work for the Department of Veterans Affairs since 2016—years before the Act—writing "[s]omewhere between 1600 and 2,000" such causation reports.[24]

Against this record, any claim that Dr. Mallon used an arbitrary risk estimate of 1.1 as evidence of causation is wrong on the face of his report and deposition. His methodology section mentions neither the CLJA nor any risk ratio,[25] and his treatment of a risk ratio above 1.1 as a positive association is grounded not in any legal standard but in the peer-reviewed literature and

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[21] Mallon GC Rep. (Leuk.) at 5, 9, 17, 19 (JA Ex. 98, D.E. 465-3); *see also* [D.E. 703] at 8, 13; [D.E. 708] at 6; Mallon GC Rep. (Leuk.) at 5, 9, 17, 19.

[22] Mallon GC Rep. (Leuk.) at 5-6, 17-19, 29-32, 37-40 (JA Ex. 98, D.E. 465-3); *see also* [D.E. 708] at 13; Mallon GC Rep. (Leuk.) at 32-39, 14; Mallon GC Rep. (Leuk.) at 41.

[23] Mallon GC Rep. (Leuk.) at 4-5, 12 (JA Ex. 98, D.E. 465-3); Mallon GC Dep. Tr. at 65:4-7 (JA Ex. 151, D.E. 469-5); *see also* [D.E. 703] at 21.

[24] Mallon GC Dep. Tr. at 47:14-22, 290:20-291:15 (JA Ex. 151, D.E. 469-5).

[25] Mallon GC Rep. (Leuk.) at 5-6 (JA Ex. 98, D.E. 465-3).

the government's own science: he testified that he "agree[s] with the Institute of Medicine and ATSDR," which "described risk ratios above 1.1 as being potentially causally associated with the health outcomes of interest," and traced that marker to the 2015 IOM review of the VA's criteria, the ATSDR's 2017 Assessment, and the work of Dr. Savitz.[26] When Dr. Mallon described a risk ratio of 1.1 as "evidence of causation," he was characterizing the summary estimate of one meta-analysis that he weighed against many others—not his methodology or his ultimate opinion.[27] Rather than apply any mechanical cutoff, Dr. Mallon weighs "the full range of the confidence interval" and "the distribution of all of the data under that confidence interval."[28] Defendant's claim that he "changed his methodology" thus mistakes a study-specific observation for a method. Dr. Mallon referenced the "equipoise and above" construct because it is ATSDR's, and his report addresses it in his separate causation-standard section, not his methodology.[29] Finally, the government's suggestion that Dr. Mallon's opinions rest only on studies lacking statistical significance is wrong: he grounded his conclusions in consistency across numerous studies and meta-analyses and in statistically significant positive results, including Cohn (1994), Purdue (2011), and the government's own Bove (2024) Camp Lejeune study.[30] In any event, statistical significance "goes to weight and not admissibility" and is no Bradford Hill prerequisite, as the Fourth Circuit confirmed in *In re Lipitor*, and the dispute is reserved for trial.[31]

[26] Mallon GC Dep. Tr. at 78:14–79:9, 81:21-82:3 (JA Ex. 151, D.E. 469-5).
[27] Mallon GC Dep. Tr. at 214:18-19, 215:7-9 (JA Ex. 151, D.E. 469-5).
[28] Mallon GC Dep. Tr. at 197:10-22 (JA Ex. 151, D.E. 469-5).
[29] Mallon GC Rep. (Leuk.) at 4-5 (JA Ex. 98, D.E. 465 -3).
[30] Mallon GC Rep. (Leuk.) at 9, 13, 17 (JA Ex. 98, D.E. 465-3); *see also* [D.E. 708] at 13-14.
[31] [D.E. 708] at 16, 18-20 (citing *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d. 641-42 (4th Cir. 2018); *see also* [D.E. 818].

II. Kidney Cancer (Judge Boyle)

As an initial matter, all of PLG's GC experts on kidney cancer are qualified to give these opinions. [D.E. 687] at 3 n.2.

A. PLG's Kidney Expert Methodologies Comply with Rule 702

All of the kidney cancer experts identified by Defendant utilized a proper methodology under Rule 702. Each expert performed a comprehensive literature search,[32] analyzed all of the evidence[33] (epidemiology, toxicology, mechanism of action, etc.), found statistically significant associations[34], utilized the Bradford Hill viewpoints[35] and performed a weight of the evidence analysis.[36] This is a reliable and valid methodology under Rule 702. *See* Order 886 at 10-13. None of the experts changed their methodology as a result of the CLJA's "at least as likely as not" burden of proof in this case. For example, Dr. Benjamin Hatten testified that his "methodology" is the "same in every case [he has] been an expert for[.]" Hatten GC Dep. Tr. at 240:8-15 (JA. Ex. 158, D.E. 469-12).[37] Similarly, Dr. Steven Bird's report states that his methodology in this case is

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[32] Hatten GC Rep. (Kidney) at 10 (JA Ex. 90, D.E. 464-11); Mallon GC Rep. (Kidney) at 8 (JA Ex. 92, D.E. 464-13); Bird GC Rep. (Kidney) at 5-6 (JA Ex. 83, D.E. 464-4); Freeman Dep. Tr. at 61:16-24, 64:4-16, 66:14-67:1 (JA Ex. 159, D.E. 469-13). In PLG's opposition to the Defendant's *Daubert* motion relating to PLG's expert's literature reviews, PLG detailed that its experts cited hundreds of studies relating to the chemicals at issue and relating to Camp Lejeune exposures (D.E. 707; D.E. 707-2). In fact, the Defendant did not challenge Dr. Freeman's literature review and stated it complied with Rule 702, even though he used the same literature review methodology as PLG's other experts. *See* [D.E. 575].

[33] Hatten GC Rep. (Kidney) at 3 (JA Ex. 90, D.E. 464-11); Mallon GC Rep. (Kidney) at 8 (JA Ex. 92, D.E. 464-13); Bird GC Rep. (Kidney) at 16-17, 31-41 (JA Ex. 83, D.E. 464-4); Freeman Rep. (Kidney) at 36-43, 45-50, 52-54, 56-60 (JA Ex. 86, D.E. 464-7).

[34] Hatten GC Rep. (Kidney) at 5, 14, 19, 21, 25-27, 29-31, 34 (JA Ex. 90, D.E. 464-11); Mallon GC Rep. (Kidney) at 10-13, 16-21, 27-29, 33-37, 42-43 (JA Ex. 92, D.E. 464-13); Bird GC Rep. (Kidney) at 13-16, 38 (JA Ex. 83, D.E. 464-4); Freeman Rep. (Kidney) at 32-41, 45-46, 52-53, 56-59 (JA Ex. 86, D.E. 464-7).

[35] Hatten GC Rep. (Kidney) at 14-16, 21-24, 27-29, 31-36 (JA Ex. 90, D.E. 464-11); Hatten GC Dep. Tr. at 86: 13-21 (JA. Ex. 158, D.E. 469-12); Mallon GC Rep. (Kidney) at 13-16, 23-26, 31-33, 39-42, 45-47 (JA Ex. 92, D.E. 464-13); Mallon GC Dep. Tr. at 91:8-92:5 (JA Ex. 151, D.E. 469-5); Bird GC Rep. (Kidney) at 45-55 (JA Ex. 83, D.E. 464-4); Bird GC Dep. Tr. at 138:1-140:15 (JA Ex. 148, D.E. 469-2); Freeman Rep. (Kidney) at 43-45, 50-52, 55-56, 60-64 (JA Ex. 86, D.E. 464-7).

[36] Hatten GC Dep. Tr. at 137:22-25 (JA Ex. 158, D.E. 469-12); Mallon GC Rep. (Kidney) at 8 (JA Ex. 92, D.E. 464-13); Bird GC Rep. (Kidney) at 5 (JA Ex. 83, D.E. 464-4); Freeman Dep. Tr. at 65:14-66:12 (JA Ex. 159, D.E. 469-13); Bird GC Dep. Tr. at 139:6-17 (JA Ex. 148, 469-2).

[37] *See also id.* at 239:6-239:23 (testifying that if he had a patient in his toxicology clinic he would use the same methodology as he used in this case for opinions about the causation of a chemical and a disease); 237:19-238:3 ("…

"identical" to his methodology when seeing a patient and when teaching his residents and fellows. Bird GC Rep. (Kidney) at 6 (JA Ex. 83, D.E. 464-4).[38] PLG's other two kidney cancer general causation experts make similar statements regarding their methodology.[39]

B. Defendant Seeks to Exclude Opinions Given to a More Likely Than Not Standard

Each challenged kidney cancer expert concluded for a majority of their opinions that the causal associations at issue met the traditional "more likely than not" or "preponderance of the evidence" standards.[40] The expert's methodology for these opinions cannot have been altered as a result of the reduced burden of proof in the CLJA if they were not even using the "as likely as not" standard for their opinions. For example, Dr. Hatten states the following in his report regarding his "discussion" of the "at least as likely as not" standard:

> This discussion is moot in the discussion of kidney cancer as it is clear that the body of evidence supports a determination of sufficient evidence for causation following exposures to the contaminated water at Camp Lejeune. The causal relationship between kidney cancer and the toxins in the water at Camp Lejeune would meet a more stringent "more likely than not" standard.[41]

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the reasonable degree of scientific certainty has to do with how as a scientist you evaluate the evidence. As likely as not is the means of framing and evaluating that evidence with respect to a specific[] exposure-response relationship.").

[38] In fact, Dr. Bird stated that he used the same methodology in this case as the peer-reviewed article he was questioned on at his deposition. Bird GC Dep. Tr. at 88:15-20 (JA Ex. 148, 469-2) ("I did the search. I reviewed the articles. It's the same.").

[39] Mallon GC Rep. (Kidney) at 8 (JA Ex. 92, D.E. 464-13) ("The methodology I used to form my opinions in this case aligns with the standard practices that I and other experts utilize when conducting similar analyses."); Freeman Rep. (Kidney) at 2 (JA Ex. 86, D.E. 464-7). ("The methods applied in this report are consistent with those outlined in the Reference Guide on Epidemiology, from the Reference Manual on Scientific Evidence, published by the Federal Judicial Center and the National Academies of Science (3rd Edition, 2011), as well as in the text Forensic Epidemiology: Principles and Practice, published by Elsevier (2016).").

[40] Hatten GC Rep. (Kidney) at 10, 16, 23-24, 28 (JA Ex. 90, D.E. 464-11); Mallon GC Rep. (Kidney) at 6, 15-16, 26, 41, 49 (JA Ex. 92, D.E. 464-13); Bird GC Rep. (Kidney) at 47, 49, 55 (JA Ex. 83, D.E. 464-4); Freeman Rep. (Kidney) at 45, 63-64 (JA Ex. 86, D.E. 464-7).

[41] Hatten GC Rep. (Kidney) at 6 (JA Ex. 90, D.E. 464-11).

Drs. Hatten, Bird and Mallon all found that the weight of the evidence was sufficient for causation under a "more likely than not" analysis for opinions relating to kidney cancer and (1) the Camp Lejeune water (TVOC – Total Volatile Organic Compounds), (2) TCE and (3) PCE."[42]

C. The Defendant's Proposed Order Incorrectly Frames Expert Opinions

The Defendant's proposed order disregards these facts. Instead, the Defendant has made inaccurate statements and conclusions based on citations that are taken out of context or incorrect.

1. Dr. Benjamin Hatten

Defendant states that PLG expert Dr. Benjamin Hatten "assumed that the CLJA's legal standard permitted him to forego the use of confidence intervals or statistical significance," [D.E. 890-3] at 8, but this is simply incorrect. First, Dr. Hatten never made any statement to this effect in his report or deposition testimony. The one citation used by the Defendant is to Dr. Hatten's report quoting the ATSDR and the fact that the ATSDR chose not to use these methods, not Dr. Hatten. Defendant omitted the following testimony from Dr. Hatten on this exact topic:

> Q: In forming your opinion as it relates to kidney cancer and bladder cancer on general causation in the Camp Lejeune litigation, did you consider confidence intervals when determining whether a study was statistically significant?
>
> A: As identified by the authors in each individual study with respect to their study methodology, I considered confidence intervals as to whether that was statistically significant in the study.[43]

Defendant also omitted testimony from Dr. Hatten where he specifically details that statistical significance was a factor in his analysis as to evaluating each epidemiological study.[44]

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[42] Dr. Mallon additionally found a causal relationship "more likely than not" for his Benzene opinions. Mallon GC Rep. (Kidney) at 6, 39 (JA Ex. 92, D.E. 464-13). Dr. Freeman found that the evidence was sufficient for causation under a "more likely than not" traditional standard for TCE and TVOC, but not PCE. Freeman Rep. (Kidney) at 45, 52, 63 (JA Ex. 86, D.E. 464-7).
[43] Hatten GC Dep. Tr. at 57:20-58:4 (JA Ex. 158, D.E. 469-12).
[44] Hatten GC Dep. Tr. at 60:1-13 (JA. Ex. 158, D.E. 469-12).

Indeed, Dr. Hatten's report is replete with qualitative descriptions of studies that are statistically significant.[45]

The Defendant's other claims as to Dr. Hatten are similarly factually inaccurate. For example, the Defendant states "Dr. Hatten arbitrarily considered any effects estimate above 1.1 as 'elevated' because of the CLJA's legal standard." [D.E. 890-3] at 7. This is not true. Dr. Hatten testified:

> Q: Sure. Maybe I should reframe that. When you are analyzing studies to determine whether or not a positive association exists, what relative risk do you generally look for?
>
> A: I don't have a specific number that I look for, and I'm not aware of any consensus or scientific consensus on what a specific number that represents a positive association is other than the factual report of greater than 1 is positive, less than 1 is negative when you are discussing a measure such as relative risk.[46]

Dr. Hatten's GC deposition testimony makes clear that he does not have any specific number he looks to in terms of whether there is a positive association, contradicting the Defendant's proposed order.[47] The Defendant chose to cite an out-of-context quotation from Dr. Hatten's bladder cancer specific causation deposition, which reflected different circumstances, analyses, and a different disease. What is undisputed is that Dr. Hatten looked at all of the evidence in the case, including all epidemiology studies, regardless of whether there was a positive or

[45] *See e.g.*, Hatten GC Rep. (Kidney) at 17-18 (JA Ex. 90, D.E. 464-11) (identifying non-statistically significant results as "elevated measure[s] of association" and statistically significant results as "statistically significant elevated risk[s]" or "statistically significant association[s]").
[46] Hatten GC Dep. Tr. at 48:1-12 (JA. Ex. 158, D.E. 469-12).
[47] Dr. Hatten gave general causation opinions for both kidney cancer and bladder cancer. He then gave specific causation opinions only for the bladder cancer cases.

negative risk, in conducting his weight of the evidence analysis.[48] Defendant's proposed order attempts to recast ordinary scientific judgment as methodological error.[49]

2. Dr. Steven Bird

The Defendant makes similar inaccurate claims regarding Plaintiffs' expert Dr. Steven Bird. For example, the Defendant's proposed order argues that Dr. Bird does not require statistically significant associations before applying the Bradford Hill factors (an argument already subject to a pending motion and full briefing), and incorrectly claims that Dr. Bird cites "only a single non-significant result" for his analysis of the strength of association for kidney cancer and TVOC. [D.E. 890-3] at 6. This is an entirely inaccurate summary of Dr. Bird's report. Dr. Bird's Bradford Hill analysis for TVOCs specifically states: "This section is naturally a summary of the evidence on the many pages preceding. Not all of the studies and evidence will be repeated in full in each of the Hill considerations to which they pertain, but the evidence from the prior sections will be incorporated by reference." Bird GC Rep. (Kidney) at 54 (JA Ex. 83, D.E. 464-4). In the many pages preceding,[50] Dr. Bird detailed the studies relating to Camp Lejeune (2014a, 2014b, 2018, 2024a, 2024b and Rosenfeld),[51] which contained several statistically significant results. *Id.* at 34-40.[52]

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[48] Hatten GC Rep. (Kidney) at 3-4 (JA Ex. 90, D.E. 464-11) ("These studies must be evaluated with respect to individual study design along with assessing the totality of the body of literature relating to the specific exposure and outcome.").

[49] Defendant's proposed order also argues that Dr. Hatten "admitted the CLJA's legal standard was a 'different lens for evaluating the body of evidence,'" and that Dr. Hatten "evaluates the evidence to determine whether it is at least 'as likely as not' that this demonstrated association is causal." [D.E. 890-3] at 7. These statements follow the direction in the Court's order that experts can utilize the at least as likely as not burden of proof in the expert's ultimate conclusions. Order 886 at 17. They do not reflect the actual methodology Dr. Hatten used as explained.

[50] Dr. Bird found these associations prior to his Bradford Hill analysis. Bird GC Rep. (Kidney) at 31-41, 45-55 (JA Ex. 83, D.E. 464-4) (discussing associations found in the literature from pages 31-41 and engaging in a Bradford Hill analysis on pages 45-55).

[51] *See* [D.E. 707] for a larger analysis of the literature cited by PLG experts and their methodology for obtaining this literature.

[52] PLG has already detailed the significant and consistent elevated measures of association found in these Camp Lejeune studies conducted by the Defendant, including statistically significant associations. *See* [D.E. 687] at 6-14.

Defendant's proposed order also argues that Dr. Bird "defines the Bradford Hill factor of strength of association as requiring only an odds ratio of 1.1 'given the lower standard at issue…of 'as likely as not' or 'equipoise,'" [D.E. 890-3] at 6, cherry-picking one phrase out of Dr. Bird's fifty-six page kidney cancer report to argue that Dr. Bird altered his methodology. This is incorrect. Dr. Bird repeatedly stated that he utilizes and reviews all of the evidence in the case, regardless of whether there is an increased risk or not. *See* Bird GC Dep. Tr. at 28:2-29:20 (JA Ex. 148, 469-2); *see also* Bird GC Rep. (Kidney) at 31-41 (JA Ex. 83, D.E. 464-4) (reviewing positive *and* negative studies). For example, Dr. Bird did not eliminate any studies because they were either above or below 1.1. Dr. Bird did not use the risk ratio of 1.1 to prove causation. Rather, he only discussed the risk ratio of 1.1 in the context of whether there was a positive association. Additionally, Dr. Bird's Bradford Hill section states the following (omitted by the Defendant): "studies with confidence intervals that include 1.0 do not establish that an agent does not cause a given disease," and that the epidemiology studies, including the studies of individuals exposed to Camp Lejeune water "reliably demonstrate risks of greater than 1.1 for exposure to TCE and kidney cancer." Bird GC Rep. (Kidney) at 46 (JA Ex. 83, D.E. 464-4).[53] As the PLG's unchallenged epidemiologist Dr. Savitz explains, "studies that generate elevated relative risks (>1.0) provide some degree of support for an association and should not be misinterpreted as negative studies because the relative risk is not statistically significant."[54] Tellingly, the government neither moved to exclude Dr. Savitz nor includes him in its response to Order 886.

Finally, the Defendant claims that Dr. Bird "admitted that the CLJA's legal standard 'has significant implications for the analysis at issue," implying that this somehow changed his

[53] Additionally, PLG refers the Court to the PLG's opposition to the Defendant's motion regarding Bradford Hill wherein the PLG discuss issues of statistical significance, confidence intervals and that PLG's experts complied with Rule 702. *See* [D.E. 687].
[54] Savitz Rebuttal at 4 (JA Ex. 144, D.E. 468-10).

methodology. [D.E. 890-3] at 6. It did not. Dr. Bird explained that this statement went to the "determination of a causal relationship"—his ultimate conclusion—and not his methodology. Bird GC Rep. (Kidney) at 6-7 (JA Ex. 83, D.E. 464-4).

3. Dr. Timothy Mallon

Similar to Dr. Bird, Dr. Mallon gave the majority of his opinions to a "more likely than not" standard.[55] He did not use a less rigorous methodology and there is no basis to exclude his opinions under Order 886.

Nonetheless, Defendant's proposed order makes inaccurate statements about out-of-context citations from Dr. Timothy Mallon to argue otherwise. First, Dr. Mallon did not use "an arbitrary odds ratio of 1.1 or above as 'evidence of causation' in his methodology." [D.E. 890-3] at 6. Dr. Mallon does not mention the CLJA or risk ratios in the entirety of his "methodology" section of his report. Mallon GC Rep. (Kidney) at 8 (JA Ex. 92, D.E. 464-13). Additionally, Dr. Mallon was asked about this at his deposition and his answer details that his use of a 1.1 risk ratio was not "arbitrary" at all. Mallon GC Dep. Tr. at 77:19-78:17, 81:18-84:13 (JA Ex. 151, D.E. 469-5). Dr. Mallon cited several peer reviewed pieces of literature that served as support for the statement that 1.1 is an elevated risk, including the Defendant's own ATSDR 2017 assessment of the evidence as to Camp Lejeune exposures.[56] *Id.* It should not be a controversial issue in the field of epidemiology that 1.1 shows an elevated risk with a positive association. Regardless, disputes over the weight of the evidence are not grounds for exclusion of expert testimony. Dr. Mallon repeatedly states that these statements are consistent with the scientific literature and his education, training and experience over many decades in these fields. Consistent with all of PLG's experts,

[55] Dr. Mallon concluded that TVOC, TCE, PCE and benzene "more likely than not" could cause kidney cancer.
[56] Dr. Mallon also cites to the Institute of Medicine, PLG general causation expert Dr. Savitz, and other epidemiology associations in his deposition.

Dr. Mallon reviewed all of the literature found during his extensive literature review, regardless of the risk ratios involved.[57] Dr. Mallon did not include or disregard any studies from his review based upon any risk level.[58]

The Defendant takes other statements made by Dr. Mallon as to a 1.1 risk ratio out of context. Dr. Mallon stated that "SMRs/RRs above 1.1 meets my definition of equipoise and above." Mallon GC Rep. (Kidney) at 17. Dr. Mallon was not saying, as the Defendant seems to imply, that a 1.1 SMR/RR did *not* meet his definition for a positive association if he were using the "more likely than not standard." He was simply stating that 1.1 shows a positive association.[59] Defendant's disagreement with that scientific conclusion is a merits debate.

Rather than apply any mechanical cutoff for considering studies based on risk ratios, Dr. Mallon weighs "the full range of the confidence interval" and "the distribution of all of the data under that confidence interval."[60] Defendant's claim that he "changed his methodology" is thus mistaken. And Dr. Mallon referenced the "equipoise and above" construct because it is ATSDR's, and his report addresses it in his separate causation-standard section, not his methodology.[61]

Lastly, the Defendant claims Dr. Mallon "interpreted studies that did not have statistically significant risk evidence as evidence of causation," [D.E. 890-3] at 8, but ignores that Dr. Mallon cited statistically significant results for each of the chemicals at issue and his TVOC analysis.[62] And again, consistent with the proper methodology under Rule 702, he looked at all of the evidence in conducting his weight of the evidence analysis.

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[57] *See* Mallon GC Dep. Tr. at 64:4-65:7 (JA Ex. 151, D.E. 469-5) (testifying that he included all articles from his comprehensive literature search).
[58] Mallon GC Rep. (Kidney) at 10-13, 16-21, 27-29, 33-37, 42-43 (JA Ex. 92, D.E. 464-13) (reviewing both positive and negative results).
[59] Mallon GC Dep. Tr. at 217:22-218:8 (JA Ex. 151, D.E. 469-5) (Dr. Mallon testified that 1.1 provides evidence of a positive association that can provide evidence relevant to a causation analysis).
[60] Mallon GC Dep. Tr. at 197:10-22 (JA Ex. 151, D.E. 469-5).
[61] Mallon GC Rep. (Kidney) at 6-8 (JA Ex. 92, D.E. 464-13).
[62] Mallon GC Rep. (Kidney) at 11, 12, 16, 27, 34 and 43 (JA Ex. 92, D.E. 464-13).

4. Dr. Michael Freeman

Finally, the Defendant again cherry-picks limited quotations from the hundreds of pages of Dr. Michael Freeman's report and deposition. For example, the Defendant quotes Dr. Freeman as recognizing the unique nature of the Camp Lejeune litigation and the equipoise standard adopted by the statute in this case, but does not include the context showing he had been asked about how a public health agency makes a determination that evidence is equipoise or higher, not how he had evaluated the scientific evidence in this case. Freeman Dep. Tr. at 287:7-14 (JA Ex. 159, D.E. 469-13).

As with PLG's other experts, the Defendant misconstrues Dr. Freeman's statements as to a risk estimate of greater than 1.1 showing evidence of a positive association. The Defendant asserts that Dr. Freeman's consideration of evidence with risk estimates of 1.1 is based on the CLJA's reduced burden of proof, when in fact Dr. Freeman weighed this evidence along with *all* the relevant evidence in a reliable methodology and only incorporated the CLJA's burden of proof in his ultimate conclusion. Dr. Freeman cites to ATSDR (2017) as support for his statements regarding a 1.1 relative risk. Freeman Rep. (Kidney) at 22, 24 (JA Ex. 86, D.E. 464-7). He recognizes that ATSDR used 1.1 as a threshold for both its equipoise classification and its more stringent classification, "Sufficient evidence for causation." *Id.* at 22. Specifically, he quotes ATSDR's statement "consistent positive associations (e.g., risk ratio or odds ratio greater than 1.1)" should be considered in determining whether the evidence is sufficient for causation. *Id.* at 22. Therefore, even the sources Dr. Freeman says he reviewed as to this issue used 1.1 not because of a legal standard or differing burdens of proof, but rather because it is a reasonable elevated measure of association that should be considered when evaluating the evidence to determine causation. Ultimately, Dr. Freeman reached many conclusions that there was "Sufficient evidence for a causal

relationship"—higher than the "equipoise and above" standard that ATSDR considered equivalent to "as likely as not." *Id.* at 67. He did not reduce his methodological rigor to reach any of his conclusions.

Further, as acknowledged by the Defendant in its Literature Review Motion, Dr. Freeman conducted a "fulsome" review of the relevant literature and considered all the evidence, both positive and negative, in assessing causation. [D.E. 575] at 8-7.

III. Bladder Cancer (Chief Judge Myers)

The Government proposes an order that seeks to exclude *the entirety* of three PLG General Causation ("GC") expert's opinions for bladder cancer. The Government's proposed order makes demonstrably inaccurate statements that self-servingly frame PLG's GC experts as doing and saying things that do not exist in the record. It attempts to do so with only a few citations out of the many hundreds of pages of reports and the many thousands of pages of deposition testimony for these experts. All of these citations are either factually inaccurate or taken out of the proper context.

As an initial matter, all of PLG's GC experts on bladder cancer are qualified to give these opinions. [D.E. 687] at 3 n.2.

A. PLG's Bladder Expert Methodologies Comply with Rule 702

All of the bladder cancer experts identified by Defendant utilized a proper methodology under Rule 702. Each expert performed a comprehensive literature search,[63] analyzed all of the

[63] Hatten GC Rep. (Bladder) at 10 (JA Ex. 76, D.E. 463-15); Bird GC Rep. (Bladder) at 5-6 (JA Ex. 67, D.E. 463-6); Culp Rep. at 3 (JA Ex. 70, D.E. 463-9). In PLG's opposition to the Defendant's *Daubert* motion relating to PLG's expert's literature reviews, PLG detailed that its experts cited hundreds of studies relating to the chemicals at issue and relating to Camp Lejeune exposures (D.E. 707; D.E. 707-2). In fact, the Defendant did not challenge Dr. Freeman's literature review and stated it complied with Rule 702, even though he used the same literature review methodology as PLG's other experts. *See* [D.E. 575].

evidence[64] (epidemiology, toxicology, mechanism of action, etc.), found statistically significant and non-statistically significant associations,[65] utilized the Bradford Hill viewpoints,[66] and performed a weight of the evidence analysis.[67] This is a reliable and valid methodology under Rule 702. *See* Order 886 at 10-13. None of the experts changed their methodology as a result of the CLJA's "at least as likely as not" burden of proof in this case. For example, Dr. Benjamin Hatten testified that his "methodology" is the "same in every case [he has] been an expert for[.]" Hatten GC Dep. Tr. at 240:8-15 (JA. Ex. 158, D.E. 469-12).[68] Similarly, Dr. Steven Bird's report states that his methodology in this case is "identical" to his methodology when seeing a patient and when teaching his residents and fellows. Bird GC Rep. (Bladder) at 6 (JA Ex. 67, D.E. 463-6). In fact, Dr. Bird stated that he used the same methodology in this case as the peer-reviewed article he was questioned on at his deposition.[69] Dr. Culp additionally confirmed he "employed the same review as I would in my research and clinical practice." Culp Rep. (Bladder) at 3 (JA Ex. 70, D.E. 463-9).

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[64] Hatten GC Rep. (Bladder) at 3 (JA Ex. 76, D.E. 463-15); Bird GC Rep. (Bladder) at 34-40 (JA Ex. 67, D.E. 463-6);Culp GC Rep. at 3 (JA Ex. 70, D.E. 463-9).

[65] Hatten GC Rep. (Bladder) at 10, 13, 16-18, 23, 26-28 (JA Ex. 76, D.E. 463-15); Bird GC Rep. (Bladder) at 15, 28 (JA Ex. 67, D.E. 463-6); Culp GC Rep. at 13-15, 18, 19, 21, 24, 35, 37, 38, 39 (JA Ex. 70, D.E. 463-9).

[66] Hatten GC Rep. (Bladder) at 13-15 (JA Ex. 76, D.E. 463-15); Hatten GC Dep. Tr. at 86: 13-21 (JA. Ex. 158, D.E. 469-12); Bird GC Rep. (Bladder) at 44-53 (JA Ex. 67, D.E. 463-6); Bird GC Dep. Tr. at 138:1-140:15 (JA Ex. 148, D.E. 469-2); Culp GC Rep. 3-4 (JA Ex. 70, D.E. 463-9).

[67] Hatten GC Dep. Tr. at 137:22-25 (JA Ex. 158, D.E. 469-12); Bird GC Rep. (Bladder) at 6, 44, 46, 48, 50, 52 (JA Ex. 67, D.E. 463-6);Culp GC Dep. Tr. at 149:6-9 (JA Ex. 155, D.E. 469-9); Bird GC Dep. Tr. at 139:6-17 (JA Ex. 148, 469-2).

[68] *See also id.* at 239:6-239:23 (testifying that if he had a patient in his toxicology clinic he would use the same methodology as he used in this case for opinions about the causation of a chemical and a disease); 237:19-238:3 ("… the reasonable degree of scientific certainty has to do with how as a scientist you evaluate the evidence. As likely as not is the means of framing and evaluating that evidence with respect to a specific[] exposure-response relationship.").

[69] Bird GC Dep. Tr. at 88:15-20 (JA Ex. 148, 469-2) ("I did the search. I reviewed the articles. It's the same.").

B. Defendant Seeks to Exclude Opinions Given to a More Likely Than Not Standard

Each challenged bladder cancer expert concluded that some of the causal associations at issue met the traditional "more likely than not" or "preponderance of the evidence" standards.[70] The expert's methodology for these opinions cannot have been altered as a result of the reduced burden of proof in the CLJA if they were not even using the "as likely as not" standard for their opinions. For example, Dr. Hatten states the following in his report regarding his "discussion" of the "at least as likely as not" standard:

> This discussion is moot in the discussion of bladder cancer as it is clear that the body of evidence supports a determination of sufficient evidence for causation following exposures to the contaminated water at Camp Lejeune. The causal relationship between bladder cancer and the toxins in the water at Camp Lejeune would meet a more stringent "more likely than not" standard.[71]

C. The Defendant's Proposed Order Incorrectly Frames Expert Opinions

The Defendant's proposed order disregards these facts. Instead, the Defendant has made inaccurate statements and conclusions based on citations that are taken out of context or incorrect.

1. Dr. Benjamin Hatten

The Defendant's core premise for asking the Court to wholesale exclude the general causation opinions of Dr. Hatten is that Dr. Hatten allegedly utilized a legal burden of proof for his scientific analysis. A review of the full record, as opposed to the select quotes offered by the Defendant, forecloses that claim. The Defendant's proposed order relies on a few limited excerpts of Dr. Hatten's testimony. When those excerpts are reviewed in the context of his full testimony, the record reflects consistent application of accepted epidemiological methodology and does not support the Defendant's characterization of his opinions as violative of Rule 702 or Order 886.

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[70] Hatten GC Rep. (Bladder) at 10, 16, 23-24, 28 (JA Ex. 76, D.E. 463-15); Bird GC Rep. (Bladder) at 12 (JA Ex. 67, D.E. 463-6).
[71] Hatten GC Rep. (Bladder) at 6 (JA Ex. 76, D.E. 463-15).

Dr. Hatten explained that the "as likely as not" classification corresponds to a scientific framework used to characterize the *weight* of evidence after a full evaluation of the evidence, including frameworks applied by ATSDR and peer-reviewed publications by Defendant's own expert epidemiologist – Dr. Goodman. *See* Hatten Dep. 224:18–225:9. The testimony reflects that the phrase "as likely as not" describes the expert's conclusion as to the balance of the evidence, not a change in how scientific evidence is evaluated. The terminology is not presented as a modification of Dr. Hatten's scientific methodology, but as consistent with existing approaches to describing the final step of evaluating whether the evidence supports causation. Accordingly, the challenged terminology which appears in the quotations cherry-picked by the Defendant pertains to classification of conclusions, not the process by which Dr. Hatten analyzed data.

The remainder of Dr. Hatten's testimony, which is not reflected in the Defendant's submission, confirms that his analytical framework did not change. Dr. Hatten rejected any suggestion that he applied a reduced or fixed numerical "methodological threshold" Dr. Hatten testified:

> Q: Sure. Maybe I should reframe that. When you are analyzing studies to determine whether or not a positive association exists, what relative risk do you generally look for?
>
> A: I don't have a specific number that I look for, and I'm not aware of any consensus or scientific consensus on what a specific number that represents a positive association is other than the factual report of greater than 1 is positive, less than 1 is negative when you are discussing a measure such as relative risk.[72]

This testimony directly contradicts Defendant's assertion that Dr. Hatten substituted a reduced numerical threshold (such as a relative risk of 1.1) in place of sound and accepted scientific analysis. The Defendant chose to cite an out-of-context quotation from Dr. Hatten's specific causation deposition, which reflected different circumstances and analyses. The full record reflects

[72] Hatten GC Dep. Tr. at 48:1-12 (JA Ex. 158, D.E. 469-12).

that Dr. Hatten evaluated such findings in the context of the totality of the evidence, applying the same qualitative Bradford Hill framework he described throughout his testimony and that he applies in all cases, regardless of the legal burden of proof.

Similarly, Dr. Hatten confirmed that statistical measures such as p-values and confidence intervals are considered as part of the analysis but are not determinative, explaining that statistical significance is "a factor to consider" and that he did not exclude studies based on p-values or confidence intervals alone.[73] This testimony reflects standard epidemiological practice and does not support Defendant's argument that he imposed rigid numerical criteria as a prerequisite for admissibility. This also undermines the Defendant's attempt to recast ordinary and standard scientific judgment as methodological error. The Defendant's argument would require the Court to impose rigid numerical criteria and statistical rules that Dr. Hatten expressly did not apply and that are not required or prescribed by prevailing epidemiological standards.

Taken together, the Defendant's cited testimony reveals a consistent pattern: Defendant isolates phrases describing conclusions and recasts them as evidence of an overriding methodological shift. However, the record draws a clear distinction:

- Dr. Hatten's methodology: literature review, study evaluation, Bradford Hill analysis, qualitative synthesis
- Dr. Hatten's conclusion framing: whether the resulting body of evidence is sufficient to support causation

The "as likely as not" language, as utilized by Dr. Hatten and PLG's other cited experts, operates if at all only at the second stage. It does not alter their methodology. Instead, it reflects

[73] Hatten GC Dep. Tr. at 60:1-9; 110:17-20 (JA Ex. 158, D.E. 469-12).

recognized scientific framework for expressing evidentiary balance, consistent with peer-reviewed epidemiological classification of evidence standards.

The full record and deposition testimony demonstrates that Dr. Hatten applied a standard epidemiological, weight-of-the-evidence methodology, did not adopt any numerical threshold or relaxed scientific criteria, and used "as likely as not" as a scientific descriptor of evidentiary balance, not a substitute for methodology. The Defendant's select excerpts reflect a mischaracterization of language, not a defect in method. A review of Dr. Hatten's opinions in the full context of his reports and deposition testimony does not support exclusion under Rule 702 or Order 886.

2. Dr. Stephen Culp

With respect to the general causation opinions of Dr. Culp, the Defendant again improperly conflates the legal standard governing PLG's burden under the CLJA with the scientific methodology Dr. Culp employed. Dr. Culp's reference to the CLJA's "as likely as not" standard appears solely in the half page "Mandate" section of his report, where Dr. Culp quotes the CLJA and states the standard is consistent with the "equipoise and above" classification of the evidence described in the scientific literature. Using this standard ("equipoise and above" classification of the evidence) to frame his conclusions, Dr. Culp examined whether the published epidemiological literature provided sufficient evidence to conclude the water at Camp Lejeune is as likely as not a cause of bladder cancer.[74] Dr. Culp's discussion of the standard of proof applicable to CLJA claims merely defines the question he was asked to answer, not how he analyzed data or the methodology he employed, as set forth in the remaining forty plus pages of his report, to reach his opinions.

[74] Culp Rep. (Bladder) at 2 (JA Ex. 70, D.E. 463-9).

A review of Dr. Culp's report demonstrates that this framing is analytically distinct from his methodology. In the very next section of his report – titled "Methodology" – Dr. Culp describes a standard, disciplined scientific approach, stating: "I summarized all relevant studies, including a brief discussion of their strengths and weaknesses, below. My analysis of each study included an assessment of the quality of the study, the design of the study, and the study's power. I employed the same review as I would in my research and clinical practice."[75] Thus, a full review of the record within the appropriate context demonstrates that Dr. Culp's methodology is consistent with his customary research standards and clinical practice, and the structure of Dr. Culp's report demonstrates that the legal standard of the CLJA did not dictate, influence, or modify Dr. Culp's scientific analysis. Rather, it defined the ultimate causation question, which Dr. Culp answered only after applying accepted epidemiological methods. This complies with the Court's Order 886, which prohibited experts from lowering methodological rigor to match the legal burden, but it did not prohibit experts from answering a legal causation question after performing a scientifically valid analysis. *See* Order 886 at 17. Dr. Culp did precisely that.

The Defendant's assertion that Dr. Culp "ignored" statistical significance is incorrect. Dr. Culp did not ignore statistical significance. The record demonstrates the opposite. Dr. Culp's Report identifies reported confidence intervals across numerous studies, distinguished between statistically significant and non-significant findings, and explained limitations of studies lacking significance, including underpowering. In his testimony, Dr. Culp confirmed that statistical significance is "one of the factors" he considers, and he performs "statistical significance testing" in his published works.[76] His approach is consistent with accepted epidemiology, which recognizes that statistical significance is important but not dispositive. The Court's Order does not impose a

[75] Culp Rep. (Bladder) at 3 (JA Ex. 70, D.E. 463-9).
[76] Culp Dep. Tr. at 61:1-8 (JA Ex. 155, D.E. 469-9).

rigid statistical-significance requirement. It requires reliable application of methodology, not adherence to any single metric.

The Defendant incorrectly characterizes Dr. Culp as adopting ATSDR's approach wholesale, but the record again shows otherwise. Dr. Culp considered ATSDR as one source of a classification of evidence, but did not replace his methodology. He still evaluated studies individually using Bradford Hill and weight-of-the-evidence. At his deposition, he confirmed that statistical significance remains a factor in his analysis and that his conclusions are based on the literature as a whole, explaining that "ultimately you're weighing all the evidence, all the factors of the Bradford Hill criteria in forming the basis of my opinion."[77] Thus, the ATSDR served as supporting literature but did not substitute for sound scientific reasoning.

The Defendant's critique that Dr. Culp selectively references confidence intervals misstates Rule 702. The inquiry is whether the expert engaged with relevant data, identified strengths and limitations, and applied a reliable analytical framework. Dr. Culp did all three, and his report repeatedly discusses confidence intervals and imprecision, confounding, exposure misclassification, and underpowered studies. These are hallmarks of methodical rigor – not unreliability. Any dispute over emphasis or presentation goes to weight, not admissibility.

Both his report and sworn testimony confirm that Dr. Culp followed a conventional epidemiological framework, consistent with Rule 702. The Defendant offers no evidence that Dr. Culp altered his methodology to satisfy the CLJA burden, and his opinions comply with the Court's Order at DE 886.

[77] Culp Dep. Tr. at 149:6-9 (JA Ex. 155, D.E. 469-9).

3. Dr. Steven Bird

The Government's challenge to Dr. Bird fails under the Court's Order because it does not identify any instance where Dr. Bird reduced methodological rigor or substituted a litigation-driven standard for accepted scientific methods. Critically, Dr. Bird concluded that causation is established at a "more likely than not" level, exceeding the CLJA's equipoise standard.[78] An expert who reaches a greater-than-50% probability of causation has necessarily relied on evidence stronger than the statutory standard, negating any claim that his methodology was relaxed.

The Government mischaracterizes Dr. Bird's statement that the CLJA standard has "significant implications for the analysis." Bird GC 1st Suppl. MCL (Bladder) at 7 (JA Ex. 69, D.E. 463-8). That statement appears in a section defining the causation question he was asked to answer in his ultimate conclusion, not his methodology, and expressly distinguishes between the scientific evaluation of evidence and the legal standard applied to the ultimate conclusion.

Second, the government tries to recast Dr. Bird's reference to "an odds ratio … of greater than 1.1" as a cutoff that mechanically lets a study "in" for consideration. It is no such thing. A relative risk near 1.1 reflects a positive—if only slightly positive—association; standing alone it is neither a finding of causation nor a gate. Dr. Bird examined every study regardless of its risk ratio, weighing each by its confidence interval, size, quality, and consistency with the body of evidence before asking whether causation was at least as likely as not. As the PLG's unchallenged epidemiologist Dr. Savitz explains, "studies that generate elevated relative risks (>1.0) provide some degree of support for an association and should not be misinterpreted as negative studies

[78] Bird GC Rep. (Bladder) at 12 (JA Ex. 67, D.E. 463-6).

because the relative risk is not statistically significant."[79] Tellingly, the government neither moved to exclude Dr. Savitz nor includes him in its response to Order 886.

The government's position is also at war with its own agency. The very approach it derides—identifying a positive association by a risk ratio greater than 1.1, and weighing studies without using any particular risk estimate as a gatekeeper—is the approach of the 2017 ATSDR Assessment, the government's own report analyzing the very Camp Lejeune exposures at issue here.[80] That is not a litigation shortcut; it is mainstream epidemiology.[81] Defendant can challenge reliance on the weight of particular studies on cross-examination.

More fundamentally, the government's premise—that the experts invoked the 1.1 figure only because of the equipoise standard—is refuted on the face of the ATSDR report. ATSDR applies the same positive-association consideration under its highest classification, "Sufficient Evidence for Causation" (where "the evidence is sufficient to conclude that a causal relationship exists"), expressly listing among its considerations "consistent positive associations (e.g., risk ratio or odds ratio greater than 1.1)."[82] ATSDR thus applies the very 1.1 consideration the government attacks not only at "equipoise and above," but at the higher "causation exists" level. The consideration does not change with the burden of proof; only the ultimate degree of confidence in causation does. That is precisely the point: the science is evaluated the same way regardless of the legal standard, so the experts' use of the same approach the government's own agency endorsed cannot be a Rule 702 defect.

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[79] Savitz Rebuttal at 4 (JA Ex. 144, D.E. 468-10). Defendant also ignores that Order 886 recognized that results can be significantly significant so long as they do not have odds ratios "of 1.0 or below." Order 886 at 11.
[80] ATSDR 2017 Assessment at 8 (JA Ex. 182, D.E. 472-3) (citing Rothman 2008).
[81] *See* Savitz Rebuttal at 4 (JA Ex. 144, D.E. 468-10); [D.E. 708] at 17-20; [D.E. 703] at 5-13 (experts considered the full body of studies, including non-significant results).
[82] ATSDR 2017 Assessment at 6 (JA Ex. 182, D.E. 472-3).

Third, Defendant wrongly accuses Dr. Bird of relying on "a single non-significant study" for bladder cancer and vinyl chloride. In fact, Dr. Bird reviewed the full body of vinyl chloride evidence for bladder cancer not a single study.[83]

Dr. Bird did not invent a new litigation-driven methodology to be applied solely to this case or relax usual and customary scientific rigor. He applied established epidemiological tools to a body of literature. The Defendant's cherry-picked quotations amount to disagreements over interpretation and weight of evidence, not reliability under Rule 702. Dr. Bird's methodology is precisely the type of sound analysis routinely accepted in toxic tort litigation. Dr. Bird did not change how he analyzed science, he changed how he expressed the conclusion to match the legal question, which is exactly what experts are supposed to do.

[83] Bird GC Rep. (Bladder) at 19, 50-52 (JA Ex. 67, D.E. 463-6); *see also* [D.E. 708] at 25-27.