IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA

IN RE: CAMP LEJEUNE WATER LITIGATION	)))	Case No: 7:23-cv-897
This Document Relates To: ALL CASES	)))	UNITED STATES' OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

The Court should reject Plaintiffs' efforts to compel production of a draft of an ongoing Cancer Incidence Study ("CIS") by the Agency for Toxic Substances and Disease Registry ("ATSDR") and related material while it undergoes statutorily mandated peer review because the information is protected from disclosure by the deliberative process privilege. Plaintiffs seek to compel production of ATSDR's draft CIS and related material before the final report is issued. If successful, Plaintiffs' request for the draft report would have a chilling effect on the frank discussion of peer reviewers and government scientists necessary to ensure the scientific quality of important ATSDR work studying potential effects of exposure to contaminated Camp Lejeune water. Moreover, subjecting ATSDR's peer review process to scrutiny in litigation would set a precedent that would have a ripple effect on scientific peer review processes across United States government agencies. The Declaration of the Director of ATSDR, Dr. Aaron Bernstein, and an accompanying privilege log are attached as exhibits.[1] Ex. 1, Bernstein Decl.; Ex. 2, Privilege Log. As detailed in the Declaration and the log, the deliberative process privilege applies to the draft CIS including (i) all draft reports, analyses, results, and conclusions; (ii) related databases and analytic data files; (iii) peer review revisions and comments; and (iv) related communications. Dr. Bernstein has personally reviewed the materials identified in the privilege log and asserts that the deliberative process privilege applies. Ex. 1, Bernstein Decl.

BACKGROUND

Congress established ATSDR under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") to "effectuate and implement [CERCLA's]

[1] In response to the requests for production in this litigation, ATSDR is in the process of querying custodians and searching for additional materials and information, some of which may fall within the categories listed above related to the CIS. The United States reserves the right to supplement the Declaration and the accompanying privilege log.

health related authorities." 42 U.S.C. § 9604(i)(1). ATSDR's directive, in part, is to "establish and maintain inventory of literature, research, and studies on the health effects of toxic substances[.]" *Id.* § 9604(i)(1)(B). CERCLA mandates that "[a]ll studies and results of research conducted under this subsection . . . shall be reported or adopted *only after appropriate peer review*." *Id.* § 9604(i)(13) (emphasis added). The statute provides,

> such peer review shall be conducted by panels consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected for such purpose by the Administrator of ATSDR or the Administrator of EPA, as appropriate, on the basis of their reputation for scientific objectivity and the lack of institutional ties with any person involved in the conduct of the study or research under review.

Id. The peer reviewers are required to sign a non-disclosure agreement ensuring that the peer review process remains confidential and controlled.

In 1989, the Environmental Protection Agency placed US Marine Corps Base Camp Lejeune and ABC One-Hour Cleaners on the National Priorities List under CERCLA. As required by CERCLA, ATSDR began studying Camp Lejeune and ABC One-Hour Cleaners and has since published numerous studies regarding Camp Lejeune.[2] ATSDR continues to study Camp Lejeune. In determining which studies to conduct, ATSDR considers a variety of factors including "scientific importance" and whether studies will "provide new scientific knowledge or address key data gaps in [ASTDR's] knowledge."[3] In 2008, ATSDR reviewed the existing scientific literature, including its own prior studies, to evaluate the need and feasibility for additional health studies related to Camp Lejeune.[4] The report recommended a cancer incidence

[2] *See generally Health Studies*, Agency for Toxic Substances and Disease Registry (Oct. 30, 2019), https://www.atsdr.cdc.gov/sites/lejeune/health-studies.html.
[3] *An Assessment of the Feasibility of Conducting Future Epidemiological Studies at USMC Base Camp Lejeune*, Agency for Toxic Substances and Disease Registry (June 23, 2008), https://www.atsdr.cdc.gov/sites/lejeune/docs/feasibility_assessment_Lejeune.pdf.
[4] *Id.*

study, among several other studies.[5]

In 2016, ATSDR received approval for and began work on the CIS.[6] In the interest of keeping the public informed, ATSDR published information on its website about the CIS.[7] From the start, it was understood that the CIS was "very complex and involve[d] working with state and federal cancer registries."[8] Because of the level of effort needed, ATSDR represented that, as of December 2019, it expected the study "to take at least 5 years before the study [was] completed and results [were] available."[9] Currently, the draft CIS is undergoing the CERCLA-mandated review process. Peer reviewers are analyzing the draft study and providing comments while the study authors work to incorporate feedback to enhance the scientific quality of the study before releasing it to the scientific community and the public.

This discovery dispute arises from Plaintiffs' Second Request for Production ("RFP"). On October 29, 2023, Plaintiffs served their Second RFP, which included a broad request for "any past, current, draft, planned or future study or report (including any supporting data), whether completed or uncompleted, published or unpublished, approved for dissemination or not, . . . performed by: (1) a United States governmental entity including but not limited too [sic] ATSDR . . . ." Ex. 3, Plfs' Second RFP. On November 29, 2023, the United States served its Responses to the Second RFP asserting the deliberative process privilege over "any drafts of the ATSDR Cancer Incidence Study and related materials as the study undergoes the agency's

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[5] *Id.*
[6] *ATSDR Timeline of Public Health Activities at Camp Lejeune, North Carolina*, Agency for Toxic Substances and Disease Registry, (Jan. 2017), https://www.atsdr.cdc.gov/sites/lejeune/docs/camp_lejeune_timeline.pdf.
[7] Cancer Incidence Study, Agency for Toxic Substances and Disease Registry (Dec. 11, 2019), https://www.atsdr.cdc.gov/sites/lejeune/cancer-incidence-study.html.
[8] *Id.*
[9] *Id.*

standard peer review process[.]" Ex. 4, United States' Resps. to Plfs' Second RFP. The response to this RFP stated that "[t]he United States will make a formal privilege assertion related to the deliberative process privilege in conjunction with any other privilege assertions made pursuant to the stipulated ESI protocol." *Id.*[10] Before the United States had the opportunity to provide Plaintiffs with the declaration and formal privilege log, Plaintiffs filed the instant Motion.

ARGUMENT

Both the draft CIS and its underlying data fall squarely within the deliberative process privilege, and the assertion of the privilege has been properly supported by the Declaration of ATSDR Director Dr. Bernstein and a privilege log. *Pittman v. United States*, 878 F. Supp. 833, 836 (E.D.N.C. 1994) ("detailed affidavits may be used to satisfy the agency's burden of justifying the application of the privilege."); Ex. 1, Bernstein Decl.; Ex. 2, Privilege Log.

The deliberative process privilege protects information that is both predecisional and deliberative, and ATSDR's draft CIS and related materials fall squarely within this protection.[11] Predecisional materials are those "prepared in order to assist an agency decisionmaker in arriving at his decision." *Heyer v. U.S. Bureau of Prisons*, No. 5:11-CT-03118-D, 2014 WL 4545946, at *3 (E.D.N.C. Sept. 12, 2014); *see also City of Virginia Beach v. U.S. Dep't of Com.*, 995 F.2d 1247, 1253 (4th Cir. 1993). Deliberative material "reflects the give-and-take of the consultative

[10] To date, the Parties continue to meet-and-confer regarding electronically stored information ("ESI") and custodians.

[11] In *United States Fish & Wildlife Service v. Sierra Club, Inc.*, 141 S. Ct. 777, 785 (2021), the Supreme Court recognized that Exemption 5 to the Freedom of Information Act ("FOIA") incorporates the same privileges available to the United States in civil litigation, including the deliberative process privilege. Courts within the Fourth Circuit have also recognized this. *See generally Coleman v. U.S. Dep't of Health & Human Servs.*, 2022 WL 1837922, at *2 (E.D. Va. Jan. 20, 2022); *Murray Energy Corp. v. McCarthy*, 2016 WL 6902359, at *1 (N.D.W.Va. July 20, 2016). Consequently, contrary to Plaintiffs' assertion, cases applying Exemption 5 of FOIA are informative to this dispute.

process" and may reveal the manner in which policies or outcomes were evaluated. *City of Virginia Beach*, 995 F.2d at 1253 (citations omitted). The deliberative process privilege "encourages free-ranging discussion of alternatives; prevents public confusion that might result from the premature release of such nonbinding deliberations; and insulates against the chilling effect likely were officials to be judged not on the basis of their final decisions, but for matters they considered before making up their minds." *Id.* at 1252–53 (quotation omitted). An unfinished scientific study in the midst of statutorily mandated peer review is the very thing that the deliberative process privilege was intended to shield from disclosure in litigation. As shown below, the draft CIS and related materials are both predecisional and deliberative.

I. The Draft CIS and Related Materials are Preliminary Documents Prepared in Accordance with ATSDR's Mission and are, thus, Predecisional.

The CIS was prepared in furtherance of ATSDR's mission which is, in part, to "establish and maintain inventory of literature, research, and studies on the health effects of toxic substances[.]" 42 U.S.C. at § 9604(i)(1)(B). CERLCA mandates that those studies undergo peer review prior to report or publication. *Id.* at § 9604(i)(13). The draft CIS reflects the authors' scientific opinions without the benefit of a complete peer review process and any resulting re-evaluation of the facts and conclusions. ATSDR merely seeks to complete the peer review process rather than disclose a draft study with preliminary opinions.

Predecisional documents include "draft documents . . . and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency" *Heyer*, 2014 WL 4545946, at *3. Plaintiffs incorrectly argue that the CIS cannot be predecisional because, in their opinion, the CIS is unrelated to a decision. Contrary to Plaintiffs' assertion, the agency is not required to "identify a specific decision in connection with which a memorandum is prepared" for the privilege to apply. *See City of Virginia Beach*, 995 F.2d at 1253 (quoting

NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 151–52 nn. 18–19 (1975)); *Access Reps. v. Dep't of Just.*, 926 F.2d 1192, 1196 (D.C. Cir. 1991) ("Any requirement of a specific decision after the creation of the document would defeat the purpose of the exemption."). Instead, courts have found that peer review materials to scientific studies are predecisional because they "preceded the agency's decision whether to and in what form to publish the Report." *Formaldehyde Inst. v. Dep't of Health & Hum. Servs.*, 889 F.2d 1118, 1124 (D.C. Cir. 1989). Draft scientific studies in the peer review process may undergo substantial revision or be rejected for publication entirely; a final decision to publish involves determining what conclusions the study can draw and whether those conclusions are worthy of being added to the body of scientific literature.

ATSDR's draft CIS is currently undergoing the statutorily required peer review before it can be added to ATSDR's body of scientific literature on potential health effects of exposure to contaminated water at Camp Lejeune. This peer review is limited to a discrete number of reviewers who signed non-disclosure agreements. Requiring disclosure of a draft study with preliminary opinions, along with related peer review comments, not only would chill the peer review process but also could deter ATSDR from conducting future studies on Camp Lejeune for fear its work will be prematurely released.

II. The Draft CIS and Related Materials are Deliberative Because They are Subject to Further Review and Modification under the CERCLA-Mandated Peer Review Process.

ATSDR's draft CIS and related materials are deliberative because they are part of a statutorily mandated peer review process. By statute, Congress requires that ATSDR's "inventory of literature, research and studies" "shall be reported or *adopted only after appropriate peer review*." 42 U.S.C. §§ 9604(i)(1)(B); (i)(13) (emphasis added). Because the draft CIS is in the midst of this required peer review process, it is subject to further review and potential modification by the agency. *See Farmworkers Legal Servs. of N. C., Inc. v. U.S. Dep't*

of Lab., 639 F. Supp. 1368, 1373 (E.D.N.C. 1986) (applying deliberative process privilege). Releasing such materials would hinder ATSDR's efforts to fulfill its Congressional mandate.

In *Formaldehyde Inst. v. Dep't of Health & Hum. Servs.*, 889 F.2d at 1124, the D.C. Circuit stated it is "indisputable" that disclosure of materials in the peer review process would "seriously harm the deliberative process." There, the court upheld the government's assertion of the deliberative process privilege, reasoning that a peer review letter related to a draft scientific report was predecisional because "it preceded the agency's decision whether to and in what form to publish the Report" and deliberative because it included "commentary in order to make that decision." *Id.* at 1120. The court recognized that production would cause harm because "[g]overnment employees who must publish as part of their job responsibilities would no longer receive the candid, constructive advice that contributes to the author's efforts to produce the best product possible." *Id.* at 1125. Such harm would result in "the publication of inferior work." *Id.*

Likewise, compelling production of the draft CIS and related materials would harm ATSDR's quality review process and, potentially, the reputation of its scientists. The draft CIS is a complex scientific analysis. For that reason, peer review is both mandated by statute and critical to the scientific process. As ATSDR's Director stated in his declaration, premature production would "suppress the routine scientific review process and have a chilling effect on the deliberations." Ex. 1, Bernstein Decl. The purpose of peer review is to increase the quality and credibility of the documents that the government distributes to the scientific community and the public. Study authors, agency officials, and peer reviewers "will not communicate candidly among themselves if each remark is a potential item of discovery and front page news." *Solers, Inc. v. Internal Revenue Serv.*, 827 F.3d 323, 329 (4th Cir. 2016) (quoting *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8–9 (2001)).

Plaintiffs improperly rely on *Allocco Recycling, Ltd. v. Doherty*, 220 F.R.D. 407, 412 (S.D.N.Y. 2004), which involved an attempt to protect from disclosure the results of a private consultant's survey of private waste carters for the New York City Department of Sanitation. The documents requested were factual materials produced solely by the third-party consultant and, therefore, not part of a give-and-take deliberative process involving city officials. *Id.* This is clearly distinguishable from a statutorily mandated peer review process involving conclusions of a government scientific study and the solicitation of feedback from other scientists.

The deliberative process privilege protects not only the draft CIS study and peer review process but also the underlying analytical data that the authors are considering. The scientists' compilation of data is deliberative and subject to change until the final study is published. As this Court has explained, a "factual summary or list" used in the decision-making process is protected by the privilege because it is "composed of selective fact" and therefore disclosure "could reveal the deliberative process." *Farmworkers Legal Servs.*, 639 F. Supp. at 1373 (citations omitted). Here, the study authors compiled an analytical data set from a variety of data sources including state cancer registries across the country. The analytical data set is intertwined with the authors' deliberations because the collection, management, and assessment of the data is part of the authors' analysis in drafting the CIS. Disclosure of such data would prematurely reveal the authors' analysis and, thus, reveal an important part of the deliberative process. *See id*. As this Court has stated, the privilege "protects the deliberative process as well as deliberative materials." *Id.* Consequently, the privilege protects not only the draft CIS but also the analytical data used to reach the conclusions in the draft. *Id.*

III. The Deliberative Process Privilege is Not Overcome by the Need for a Draft CIS Study and Related Materials.

Once the Court determines that the deliberative process privilege applies, the Court may consider if the need for the information outweighs the harms of production by considering: (1) the relevance of the evidence to the lawsuit; (2) the availability of alternative evidence on the same matters; (3) the government's role, if any, in the litigation; and (4) the extent to which disclosure would harm open and frank communication within the agency. *Heyer*, 2014 WL 4545946, at *3. Here, the potential relevance of the evidence to the lawsuit does not outweigh the harms of production. The study is just one of numerous studies regarding potential health effects from exposure to water at Camp Lejeune. Numerous other studies exist regarding the chemicals detected in the Camp Lejeune water from which experts can reach opinions on the effect of the water on health. Moreover, it is questionable that such preliminary results would even be admissible under Federal Rule of Evidence 702, given that one of the indicia of reliability for admission is whether opinions have been subject to peer review and publication. *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 593 (1991) ("submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected."). On the other hand, to reach into the mandated peer review process and require production of preliminary opinions would have a chilling effect on the scientific review process. The release of an unfinished report would create confusion among stakeholders and potentially weaken the public's trust in the government's scientific research if the preliminary results are later shown to be flawed.

The draft CIS and related materials were not created to provide information for this lawsuit. ATSDR's mission is to maintain an inventory of scientific research and the purpose of the draft CIS is to comply with that Congressional directive. 42 U.S.C. § 9604(i)(1)(B). Regardless of the production of this one report, Plaintiffs must produce evidence of general and

specific causation to maintain a valid claim under the Camp Lejeune Justice Act. *See* D.E. 22, Order Denying Motion for Reconsideration (explaining that a plaintiff's case must survive an examination of "exposure, general causation, and specific causation").

Moreover, the United States is not in exclusive control of the data underpinning the draft CIS, which is separate and apart from the analytical datasets. The draft CIS relies, in part, on the data collected from each state's cancer registry, data which is not within the exclusive control of the United States government. In fact, the United States has already produced six data sets related to peer reviewed Camp Lejeune health studies.

Finally, compelling disclosure of the draft CIS and related materials would have far-reaching implications not only for the scientific work of ATSDR, but also for the scientific work of other federal agencies that have similar review processes.[12] Compelling production would: hinder the deliberative process by chilling the candid exchange of information that leads to sound scientific conclusions; lead to confusion through the release of preliminary findings; and weaken the public's trust in the federal government's scientific work product. The public interest favors quality science, not incomplete work. Accordingly, premature disclosure of the draft CIS and related materials in contravention of the CERCLA-mandated peer review process cannot outweigh the need to protect the integrity of the federal government's scientific review process.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion should be denied.

[12] *See e.g.*, 7 U.S.C. § 136w(e) (mandating peer review of major scientific studies concerning pesticides conducted by or for the EPA); 42 U.S.C. § 2039 (requiring review of license applications to the Nuclear Regulatory Commission to be reviewed by an advisory committee); 49 U.S.C. § 44912(c) (mandating a scientific advisory panel for the Federal Aviation Administration).

Dated: December 11, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2023, a copy of the foregoing document was served on all counsel of record by operation of the court's electronic filing system and can be accessed through that system.

/s/ Elizabeth K. Platt
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