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May 30, 2018

Mr. Tom Sinks, Office of the Science Advisor, Environmental Protection Agency
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Comments on “Strengthening Transparency in Regulatory Science” Docket ID No. EPA-HQ-OA-2018-0259

Dear Mr. Sinks;

This letter is sent on behalf of the Tribal Caucus members of EPA Region 10’s Tribal Operations Committee (RTOC). This letter is not sent on behalf of EPA Region 10 or any employees of EPA, but solely tribal government representatives of the RTOC. These comments are submitted in response to the request for public comment regarding “Strengthening Transparency in Regulatory Science,” Docket No. EPA-HQ-OA-2018-0259.

RTOC opposes the proposed rule. Insofar as scientists are required to show their work in order to satisfy the standards of peer-review that regulate the scientific profession, “lack of guile and of any attempt to hide damaging information” is a worthwhile objective.¹ However, this objective is not mutually exclusive with the ethical obligations that necessarily must inform research. The proposed rule asks researchers to sidestep their fiduciary duty to respect research subjects, and its implementation would exclude valuable science—actually hindering its own stated objectives.

The RTOC is called to protect the public interest at large in response to this proposed rule, which impacts the health of all citizens who are subject to the negligent omission of valuable data from consideration. We stand especially for tribal members who will be excluded as a matter of substantive representation. The proposed rule claims that it “will help ensure that EPA is pursuing its mission of protecting public health and the environment *in a manner that the public can trust and understand.*”² Where the rule would cause data affecting tribal members to be excluded as a matter of cause, we refute this claim of trust and understanding.

The unwillingness of Tribes to release information about tribal members stems in part from a heinous history of abuse by researchers. In the 17th and 18th centuries, American Indian body

¹ *Transparency*, BLACKS LAW DICTIONARY (10th ed. 2014).

² *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18769 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30) (emphasis added).

parts were taken from army hospitals and battle sites for phrenological research.³ In a 1950s study, Alaskan Natives were recruited to ingest radioactive iodine (I-131), but many of the research subjects—including children and pregnant women—could not provide meaningful consent.⁴ In the 1970s, 3,406 American Indian women and girls were forcibly sterilized by Federal officials.⁵ Also in the 1970s, the Barrows study in Alaska leaked sensationalized and stigmatizing findings without the consent of the Inupiat community.⁶ As recently as the 1990s, a researcher at Arizona State University obtained two hundred sacred blood samples from Havasupai people and wrongfully sent those samples overseas—the whereabouts of some samples remain unknown.⁷ Such abuse by research institutions is certainly not limited to Tribes and their members.⁸ In representing tribal governments who are understandably inclined to view data collection as an unsafe enterprise, we point to the troubling way in which the proposed rule implies that American people are a monolithic group in this sense. For purposes of so-called transparency, people without such histories of trauma are advantageously positioned. The RTOC questions the ability of the proposed rule to promote the “meaningful participation” of *all* Americans.⁹

Fish surveys demonstrate that the proposed rule results in inequitable data representation. The fish surveys demonstrate the distinctive relationship between Tribes and the health of our Nation’s waterways, and in so doing highlights the need for diverse representation in EPA data collection. While the general population eats 19-56 grams of fish and shellfish on average per day, tribal members in the Pacific Northwest can eat up to 797 grams (1.75 pounds) every day.¹⁰ This is a critical issue for RTOC, as the Region 10 includes Tribes across Alaska, Washington, Idaho, and Oregon. Tribal populations in our region are exposed to toxins that bioaccumulate in aquatic life due to factory effluent, urban wastewater, and runoff from agriculture and cities.¹¹ In light of our presentation of these concerns, tribal members voiced their willingness to facilitate updated fish studies in order to protect the health of their communities at a recent Affiliated Tribes of Northwest Indians conference.¹²

³ Felicia Schanche Hodge, *No Meaningful Apology for American Indian Unethical Research Abuses*, 22(6) ETHICS & BEHAVIOR 431, 434 (2012).

⁴ *Id.* (I-131 destroys thyroid gland cells, and because no records were kept, follow up iodine exposure health risk assessment of subjects and their offspring is impossible).

⁵ *Id.* at 433. (At least two American Indian 15-year-old girls awoke from what they believed to be surgeries removing their tonsils to find that their ovaries had been excised instead).

⁶ *Id.* at 435.

⁷ *Id.*

⁸ *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003) (Research ethics dispute involving children with Canavan, a disease mostly affecting people of Ashkenazi Jewish descent); Rebecca Skloot, *The Immortal Life of Henrietta Lacks* (Broadway Books 2011) (Henrietta Lacks was an African-American woman whose cancer cells were taken without her knowledge, used for medical research, and eventually sold for billions—yet neither she nor her family were ever compensated).

⁹ *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18769 (proposed Apr. 30, 2018) (to be codified at 40 C.F.R. pt. 30) (“By better informing the public, the Agency [is] enhancing the public’s ability to understand and *meaningfully participate* in the regulatory process.”) (emphasis added).

¹⁰ Nicole Wendee, *Meeting the Needs of the People: Fish Consumption Rates in the Pacific Northwest*, 121 Environmental Health Perspectives A334, A335 (2013).

¹¹ *Id.* (polychlorinated biphenyls, metals, dioxins, and others).

¹² RTOC Presentation at the ANTI Mid Year Convention 2018 (May 22, 2018).

The fish surveys are scientifically rigorous while also protecting the fiduciary interest between the researcher and the research subject. One fish survey provided by the Columbia River Inter-Tribal Fish Commission included a confidentiality agreement for instance—barring the release private information about tribal member participants—but also included limitations, peer review, procedural information, and quality control.¹³ Under the proposed rule, these fish surveys would be excluded. Almost no activity on the reservation has more potential for significantly affecting the economic and political integrity and the health and welfare of all reservation citizens than water use, quality, and regulation. The proposed rule threatens to silence tribal interests where it potentially prevents the use of the fish surveys. On our view, this seems contrary to “openness, clarity, [and] unobstructed access.”¹⁴

Where the issue of raw data collection has been raised, the courts have permitted the EPA to use studies like the fish surveys. In *Coal of Battery Recyclers*, the United States Court of Appeals for the District of Columbia Circuit held that the EPA could use non-public data in order to support its regulation of the amount of lead in ambient air.¹⁵ In that case the regulation at issue prevented adverse neurological effects in American youth.¹⁶ Failing to implement the proposed regulation would have resulted in average losses of more than two intelligence quotient (IQ) points in this country’s children.¹⁷ In another case using non-public data, epidemiological studies protected elderly Americans from cardiopulmonary disease caused by a contaminated respiratory environment.¹⁸ The Uinta Basin ozone concentrations in Colorado were found by the EPA to exceed the National Ambient Air Quality Standards on the basis of non-public data.¹⁹ Occasionally, studies use data that is not publicly available, often because the research focuses on medical issues and patient privacy is protected under other federal laws. Nonetheless—as in the cases *supra*—this research is reviewed by experts in the field before it is ever considered for policy development.

It is both pragmatic and efficient to recognize that the EPA delegates review of raw data to experts. It was for this reason that in *Coal of Battery Recyclers*, the court made a distinction between the EPA’s “reliance on a study’s results from its reliance on the raw data underlying such results.”²⁰ The proposed rule unrealistically suggests that the EPA cannot and will not utilize the peer review that it has delegated in cases like *Battery*. The existing inequitable distribution of environmental resources in America is a crisis of health and justice, and it is in the public interest that the EPA invest wisely.

¹³ Columbia River Inter-Tribal Fish Commission, *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakima, and Warm Springs Tribes of the Columbia River Basin*. Technical Report 94-3 (October 1994). Available: <http://www.deq.idaho.gov/media/895853-fish-consumption-survey-1994.pdf> (“following completion of the report, all relevant information was returned to CRITFC”).

¹⁴ *Transparency*, BLACKS LAW DICTIONARY (10th ed. 2014).

¹⁵ *Coal. of Battery Recyclers Ass’n v. EPA*, 390 U.S. App. D.C. 305, 315, 604 F.3d 613, 623 (2010) (The Lanphear study studied the relationship between blood lead levels and IQ changes, providing evidence for the effects of lead on IQ at blood lead levels below 10 [mu]g/dL and for the nonlinearity of these effects).

¹⁶ *Id.* at 307, 604 F.3d at 615.

¹⁷ *Id.* at 309, 604 F.3d at 617; See *National Ambient Air Quality Standards for Lead*, 73 Fed. Reg. 66,964 (Nov. 12, 2008).

¹⁸ *Am. Trucking Ass’ns v. EPA*, 283 F.3d 355, 370 (D.C. Cir. 2002).

¹⁹ *Miss. Comm’n on Env’tl. Quality v. EPA*, 416 U.S. App. D.C. 69, 86, 790 F.3d 138, 155 (2015).

²⁰ *Coal. of Battery Recyclers Ass’n v. EPA*, 390 U.S. App. D.C. 305, 315, 604 F.3d 613, 623 (2010).

The proposed rule seems to assume that “best available science” can be equivocated with raw data collection, albeit the fish surveys and *Battery* demonstrate that demanding raw data collection is at odds with best *available* science. “In a random sample of the biomedical literature (2000-2014), none of the 268 papers shared all of their raw data. Only one shared a full research protocol. The proportion of studies that have had all their raw data independently re-analyzed is probably less than one in a thousand.”²¹ It may be the case that moving toward open science is the best way forward, but as it stands this quixotic aspiration will stymie scientific progress in practice because much of existing science does not qualify. In regard to our Region 10 Tribes in particular, it is unlikely that tribal interests would benefit from the proposed Rule.

The RTOC encourages EPA to engage with Tribes in Region 10 in government-to-government consultation to further understand the significance of this proposal.

We appreciate your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "William (Billy) J. Maines". The signature is written in a cursive style with a large initial 'W'.

William (Billy) J. Maines
Region 10 RTOC, Tribal Caucus Co-chair

²¹ John P. A. Ioannidis, *All Science Should Inform Policy and Regulation*, PLOS MEDICINE (May 3, 2018) <http://doi.org/10.1371/journal.pmed/1002576>.