MINNESOTA

May 15, 2018

The Honorable E. Scott Pruitt, Administrator
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Mail Code 1101A
Washington, D.C. 20460

Re: Comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018 at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Pruitt:

The Minnesota Pollution Control Agency (MPCA) and Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science," published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259. This proposed rule to "strengthen transparency" does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and it will threaten the lives of real people. EPA should withdraw this dangerous proposal.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are appalled by the specious and brazen attack on health sciences research and the field of epidemiology. The proposed rule was clearly designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, or soil. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research – and to create suspicion significant enough to deter future use of health-based studies in regulatory decision-making. EPA's proposal flagrantly ignores the reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields.

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analysis would effectively breach confidentiality requirements upheld by public and private research through Institutional Review Boards (IRB). It is well documented that privacy assurances are essential to including people in health studies.

From a risk assessment perspective, not including epidemiology studies in regulatory science is not sound or prudent. Laboratory, toxicology, and epidemiology are complementary and necessary pieces of understanding and quantifying effects of a pollutant on human health. Excluding evidence from one of these three essential disciplines threatens the science basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in an impossible situation of relying primarily on animal models or in-vivo models that cannot be directly extrapolated to human dose-response estimates.

Minnesota supports open data access and is a national leader in science and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data available, providing technical assistance for using data, and engaging partners across communities and research institutions

around effective dissemination and data utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state IRBs.

Based on the lack of meaningful information and articulated or demonstrated need for the proposed rule, EPA has not made the case for a new regulation at 40 CFR Part 30.

The promulgation of this proposed rule would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision-making. As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. The EPA should immediately announce that it is withdrawing this proposal.

Our agencies will be submitting additional, substantive comments to the rulemaking record.

Sincerely,

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