



It's not about transparency: politics is intruding into USEPA science and it could cost the public's health

Richard E. Peltier¹ · Gretchen T. Goldman²

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Uncertainty is key to science. As scientists, we are drawn to the edge of our knowledge and we seek to fill the gaps with new scientific understanding. But such gaps are vulnerable to interference from those who wish to capitalize on uncertainty for political gain. Right now, efforts are underway at the US Environmental Protection Agency (USEPA) to exploit uncertainty surrounding the health risk estimates at low pollution levels by mandating consideration of risk models that lack sufficient evidence. And public health may pay the price.

In March 2020, the USEPA released a Supplemental Notice on its draft rule Strengthening Transparency in Regulatory Science, first proposed in April 2018. The Supplemental Notice makes clear that the proposal, ostensibly about transparency, will restrict the science that EPA can use in decision-making. Specifically, we would like to draw attention to ways the proposal threatens the EPA's ability to follow science-based models to accurately assess risks from harmful pollutants.

Much has been said on this problematic proposal [1], but less focus has been placed on a provision buried in the draft rule that was sustained in the clarifying Supplement Notice. It reads, “[EPA]...should give appropriate consideration to high quality studies that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity...”.

The rule continues: ‘EPA should also incorporate the concept of model uncertainty when needed as a default to

optimize low dose risk estimation based on major competing models, including linear, threshold, and U-shaped, J-shaped, and bell-shaped models’.

To be clear, the EPA should and does consider a range of models when characterizing concentration-response functions, but the agency must rely on weight of evidence and the advice of experts to choose appropriate models. Good scientific justification comes from skepticism, rigor, and debate, and this is just what the USEPA's independent scientific reviews offer. However, in an agency that has sharply reduced its access to independent scientists [2], the mandated inclusion of these ‘competing models’ moves EPA closer to accepting the controversial theory of hormesis. This is a theory where exposures to environmental agents, that are typically harmful to health at higher doses, are thought to induce beneficial effects at low doses [3]. This may be an appropriate model for understanding responses where there is a biologically plausible mechanism (such as nutrients or exercise), but no evidence to date has shown its application to environmental pollutant exposure. This will endanger public health.

This rule, by contrast, pre-determines how science is incorporated into rulemaking by redefining how the agency considers risk estimation [4]. Rather than allow the agency to rely on expertise to determine appropriate models, the proposal forces EPA to consider ‘competing’ models, including those that are not evidence-based.

Introducing competing concentration-response model shapes without supporting scientific evidence will fundamentally redefine how science is used to inform policy. Assuming air pollution concentration-response functions follow a U-shaped curve, for example, would wrongly imply that low doses of pollution are beneficial to health, and that there is some ‘optimal’ level of pollution that balances the cost of control with public health benefit. Or it could mean that there is a threshold below which there is no public health harm.

The scientific literature simply does not support these conclusions for the vast majority of pollutants that the

✉ Richard E. Peltier
rpeltier@umass.edu

¹ Department of Environmental Health Science, University of Massachusetts, Amherst, MA, USA

² Center for Science and Democracy, Union of Concerned Scientists, Cambridge, MA, USA

EPA covers. In fact, there is growing evidence [5] that we are underestimating hazard ratio functions, and that the standards, such as those for particulate matter, need to be lower than previously thought to protect human health. Thus, a shift to these alternative models could harm sensitive populations, such as children, the elderly and those with lung diseases, which are populations more likely to be adversely affected by pollution at lower levels. If the USEPA fails to rely on the best available science about health effects at low concentrations, as the proposal suggests would be the case, these groups might not be protected from harmful pollution.

The proposed rule exploits scientific uncertainties in ways that tend toward less protective standards. For instance, the majority of studies linking ambient PM exposure with adverse health effects are derived from the most polluted locations. In order to determine the shape of the curve at lower concentrations, researchers must interpret the more limited scientific work on populations who breath lower concentrations. This is a challenge where the advice of experts is crucial and USEPA scientists should be able to take that advice and apply the concentration-response function that best fits the available evidence. Forcing the agency to use alternative models sets a dangerous precedent that replaces scientific assessment with political judgment.

This is a strong divergence from the USEPA's role in the four decades since it was created. The USEPA is charged with taking science-based and health-protective actions on everything from ambient air quality, to safe drinking water, to chemicals in consumer products. This commitment to rigorous, transparent science-based processes has protected the public from environmental threats for decades.

It is deeply worrisome that blind consideration of threshold concentrations and other alternative models for concentration-response could be incorporated into federal policy without adequate scientific review. And it is alarming that vulnerable populations' exposure to pollution could be perceived as beneficial. The USEPA proposal lends credibility to an idea far outside of the scientific mainstream that exposure to pollution is beneficial for humans. This is not

true for particulate matter or lead in drinking water or coal dust, and policy based on this idea puts public health at risk.

It is our view that efforts by USEPA political leaders to marginalize science will cause long-term damage to our nation's health. With the agency's willful neglect of scientific advice and increased reliance on ideas not supported by the body of evidence, we have profound and growing concern that the USEPA has abandoned its mission to protect the public's health both now, and well into the future.

The new USEPA Transparency proposal is out for public comment now and a final rule is slated to come by the end of 2020. Whether or not the final version includes the problematic concentration-response language buried in the proposal, it is clear that the agency's political leadership is keen on upending the mechanisms by which we understand the harms of environmental pollutants at low-levels. If they succeed, we will have eroded the science-informed processes used to protect public health. That we can say with certainty.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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