July 17, 2018

I am Roy Gamse, formerly EPA Deputy Assistant Administrator, reading the comments of John Bachmann. He served EPA for 33 years and was the Associate Director for Science/Policy and New Programs for the Office of Air Quality Planning and Standards in Research Triangle Park, NC.

Comments of John Bachmann

I appreciate the opportunity to provide these comments on the proposed rulemaking "Strengthening Transparency in Regulatory Science" on behalf of the Environmental Protection Network (EPN). EPN will submit detailed written comments on the proposal later.

This proposal would *not* strengthen transparency of regulations. Instead it would preclude the assessment and use of the best scientific information available, as required by all major statutes administered by EPA. The process by which it was developed, the misuse of references that ultimately do not support its arguments, and the lack of specifics on what EPA actually intends to do are an embarrassment to the Agency. The new acting Administrator should withdraw it from consideration as soon as possible.

- EPA's Proposal is a Solution in Search of a Problem
  - The proposal asserts that it is dealing with a "replication crisis," but does not cite a single instance where a study used by EPA for any type of major rule was shown to be flawed due to a lack of access to the underlying data. In fact, EPA and industry funded an independent reanalysis of the two air pollution studies that were criticized for not releasing confidential health information to the public, and both were successfully *reproduced* with results published in 2000. Moreover, their key findings have been *replicated* dozens of times since then by other investigators using different health and air quality data.
  - The proposal to exclude important peer reviewed studies is wholly inconsistent with scientific practice and EPA's past use of science in

regulatory decisions. Where studies with novel results appear, EPA's assessments have noted limitations, and in some cases supported reanalyses. EPA's science/policy related assessments are themselves peer reviewed by SAB or CASAC to further ensure study evaluations consider all of the relevant scientific literature.

- As noted by an SAB workgroup, EPA's proposal downplays valid concerns about the risks of providing access to the confidential information of subjects in epidemiology studies. The SAB group noted:
  - Some of the largest and/or most useful health effects data sets cannot be made fully public, because certain personal information on age, sex, health and location could be used to identify the participants, or because of agreements made with study participants in advance.
  - EPA failed to mention various ways to assess the validity of prior epidemiology studies without access to data, nor that the rule might preclude continued use of studies published many years ago.

- The proposal includes a provision for the Administrator to waive this requirement. No clear decision criteria are provided to allow EPA scientists and stakeholders to understand when and how such waivers might be granted. It thus appears that this requirement could be applied in an arbitrary and capricious manner that does not reflect sound science judgment.

- Critical decisions like these must be made on the basis of science, not politics. Otherwise highly relevant studies for which data cannot be publicly shared, even if published in the best peer reviewed journals and replicated, may be judged to be inherently untrustworthy.

- The rushed and mostly secret process EPA followed in developing this proposal displays a complete disinterest in transparency in public policy, much less in science. In developing this proposal, EPA leadership:
  - Did not provide a role for its own career scientific and science/policy experts in crafting the proposal or in assessing its potential impacts,
  - Never included the rule in its regulatory agenda,
  - Did not notify or consult with the SAB, much less request a review of the draft proposal as required by law,

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- Did not solicit the advice of the National Academy of Sciences on provisions that would change dose-response models used in risk assessment from those previously recommended by the NAS,
- Did not ask for a review to solicit the views of other Federal Agencies that conduct research and/or use health effects science in developing policies and regulations.
- Finally, the Agency originally allowed only a 30-day comment period on this remarkable, unvetted departure from decades of past practice in the assessment and use of science.

- In suggesting the potential costs of the rule would be minimal, EPA ignored the costs -
  - to researchers, who would have to pay to set up and maintain data sharing for their previously published studies to be considered,
  - to EPA for conducting the multiple reanalyses required in section 30.6 of the rule,
  - and to public health, for the disbenefits of undermining existing regulations.

  Having done no assessment, EPA has no basis for its claim that the benefits of the rule would exceed costs.

- Scientists and scientific publications that EPA cites as evidence of support for this rule have rejected the proposal's preemption of existing studies based on availability of raw data.

  - John Ioannidis reacted strongly to the proposal in an editorial, noting that "If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim."
  - Editors of four major scientific journals, whose policies EPA cited as support, jointly stated that "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them...Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."

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- EPA should immediately withdraw this flawed proposal from consideration. Given the fatal flaw of establishing an unnecessary regulation for science assessment that would elevate transparency over any other criterion, we are unable to offer any suggestions for improving it.