

Science

EDITORIAL

Getting the EPA back on track

1. Marie Lynn Miranda

See all authors and affiliations

Marie Lynn Miranda is a professor in the Department of Statistics at Rice University, Houston, TX, USA, and is the founding director of the Children's Environmental Health Initiative at Rice University.

mlm@rice.edu

Science 06 Dec 2019:
Vol. 366, Issue 6470, pp. 1173
DOI: 10.1126/science.aba3769

- [Article](#)
- [Info & Metrics](#)
- [eLetters](#)
- [PDF](#)

eLetters is an online forum for ongoing peer review. Submission of eLetters are open to all. eLetters are not edited, proofread, or indexed. Please read our [Terms of Service](#) before submitting your own eLetter.

[Submit a Response to This Article](#)

- **Criticism of Miranda Editorial and Joint Statement in December 6, 2019 Science Magazine**

James E. Enstrom, Epidemiologist and Physicist, UCLA and Scientific Integrity Institute

(13 December 2019)

The Miranda Editorial (1) and the Joint Statement (2) in the December 6 Science misrepresent the proposed EPA rule “Strengthening Transparency in Regulatory Science” (3). Its true purpose is to increase scientific rigor and transparency in the research findings used to justify EPA regulations. This rule is needed because certain EPA-related findings are etiologically implausible and the authors of these findings refuse to address criticism and/or to conduct requested reanalysis. I demonstrated the importance of this rule when I independently reanalyzed the ACS CPS II data underlying the seminal 1995 Pope analysis of these data. Pope 1995 (6) provided the primary justification for establishing the 1997 PM2.5 NAAQS. My reanalysis found NO

robust relationship between PM2.5 and total mortality (4,5) and it directly challenges the positive relationships in Pope 1995, HEI 2000 (7), and HEI 2009 (8). My reanalysis did not violate subject confidentiality and is a model for data sharing.

Unfortunately, Science does not publish null research findings that challenge the scientific validity of EPA air pollution regulations. In July 2016 I submitted my ACS CPS II reanalysis manuscript for peer review, but it was quickly rejected by both Science and Science Advances after initial screening and NO in-depth review. My manuscript was published on March 28, 2017 in Dose-Response (4), which includes the rejection history. Subsequently, it has been entirely ignored by Science, EPA PM Policy Assessment staff, and EPA-related investigators like Pope. In three recent articles on PM2.5 deaths (9-11), Pope has falsified the research record by not citing References 4-8 and by ignoring the 25-year PM2.5 deaths controversy. My comments to EPA CASAC regarding the current EPA PM PA make a strong case that there is NO causal relationship between PM2.5 and total mortality in the US and that the entire basis for the PM2.5 NAAQS needs to be reassessed (12-13). In the interest of objectivity, Science must publish evidence that supports the proposed EPA Transparency Rule and/or challenges existing EPA regulations.

For the record, this eLetter was originally submitted on December 11, 2019 as a Letter to the Editor (Science Manuscript aba5396) to be published in Science. The Letter to the Editor was rejected on December 13, 2019 by Science Editor Jennifer Sills after an initial reading and NO peer review. This immediate rejection is similar to the immediate rejection that I received in July 8, 2016 regarding Manuscript No. aah4744, which was eventually published on March 28, 2017 in Dose-Response, as explained in Reference 4 and Reference 13.

References

- 1) Marie Lynn Miranda. Getting the EPA back on track. Science 366:1173 (6 Dec 2019) (DOI: 10.1126/science.aba3769)
- 2) H. Holden Thorp, et al. Joint statement on EPA proposed rule and public availability of data. Science 366:eaba3197 (6 Dec 2019) (DOI: 10.1126/science.aba3197) N=545 words
- 3) U.S. Environmental Protection Agency, Science Advisor Programs, "Strengthening transparency in regulatory science" (30 Apr 2018) (<https://www.epa.gov/osa/strengthening-transparency-regulatory-science>)
- 4) James E. Enstrom. Dose-Response (28 Mar 2017) (<https://doi.org/10.1177/1559325817693345>)
- 5) James E. Enstrom. Dose-Response (29 May 2018) (<https://doi.org/10.1177/1559325818769728>)
- 6) C. Arden Pope III, et al. AJRCCM (1 Mar 1995) (<https://doi.org/10.1164/ajrccm/151.3 Pt 1.669>)

- 7) Health Effects Institute Special Report. (July 2000)
(<https://www.healtheffects.org/system/files/HEI-Reanalysis-2000.pdf>)
- 8) Health Effects Institute Research Report 140. (May 2009)
(<https://www.healtheffects.org/publication/extended-follow-and-spatial-an...>)
- 9) C. Arden Pope III, et al. Air Quality, Atmosphere & Health (1 Apr 2018)
(<https://doi.org/10.1007/s11869-017-0535-3>)
- 10) C. Arden Pope III, et al. EHP (24 Jul 2019) (<https://doi.org/10.1289/EHP4438>)
- 11) Jacob S. Lefler, et al. Environmental Health (21 Nov 2019)
(<https://doi.org/10.1186/s12940-019-0544-9>)
- 12) James E. Enstrom. EPA CASAC Comment (17 Oct 2019)
(<http://www.scientificintegrityinstitute.org/JEEPMPA102219.pdf>)
- 13) James E. Enstrom. EPA CASAC Comment (11 Dec 2019)
(<http://www.scientificintegrityinstitute.org/JEEPMPA120319.pdf>)

Show Less

Competing Interests: None declared.

- **RE: Getting the EPA onto the science track**

S. Stanley_Young, Statistician,CGStat

Other Contributors:

Warren Kindzierski, Epidemiologist,University of Alberta

(13 December 2019)

There are two sides to every coin. Miranda(1) takes one side: poor air quality is a killer, among other health effects, and any request for data access is a simple ruse to overturn established fact(2). Humans including scientists can get it wrong and stay wrong for a long time(3). In addition to two sides, there is the edge of the coin – we just don't know the answer. Two recent reports based on massive data sets find no association of air components with heart attacks or mortality(4,5). Contemporary with the Harvard Six Cities, a large and well-conducted study, also funded by the Environmental Protection Agency found no effect of air quality on mortality(6). Two reports in 1988(7,8) noted that for 56 health questions the literature was roughly equally divided for and against the claims and that selective reporting was a possible cause of the replication problem; we now call that p-hacking. If false positive studies are reported and negative studies are

suppressed, there can be a canonization of false claims(9). Reviews(10,11) of The Lancet and JAMA meta-analysis studies note that base papers in these studies provided contradictory evidence; many of the base papers had very small p-values whereas many others appeared to be completely random, a mixture. Both claims cannot be right. At best the results reported in these meta-analysis studies were ambiguous. An agency can support external research and base its decisions on this research and so long as it does not take possession of the data, freedom of information cannot reach through the agency to examine the data(12). Appeal to authority(2) is less trustworthy than transparency in data and methods. The citizen needs the protection of transparency; the EPA should be supported on opening up the science process.

References

1. M. L. Miranda, Getting the EPA back on track. *Science* 06Dec2019:1173
2. H. H. Thorp, Joint statement on EPA proposed rule and public availability of data. *Science* 06Dec2019: eaba3197 DOI: 10.1126/science.aba3197
3. MacKay C. *Extraordinary Popular Delusions and the Madness of Crowds*. BN Publishing. 1852 Edition.
4. A. Milojevic, P. Wilkinson, B. Armstrong, K. Bhaskaran, L. Smeeth, S. Hajat, Short-term effects of air pollution on a range of cardiovascular events in England and Wales: case-crossover analysis of the MINAP database, hospital admissions and mortality. *Heart*. 100, 1093–1098. doi:10.1136/heartjnl-2013-304963. (2014)
5. S. S. Young, R. L. Smith, K. K. Lopiano, Air quality and acute deaths in California, 2000-2012. *Reg Tox Pharm* 88, 173-184. (2017)
6. P. Styer, N. McMillan, F. Gao, J. Davis, J. Sacks, Effect of outdoor airborne particulate matter on daily death counts. *Env Health Perspec* 103, 490-497. (1995)
7. L. C. Mayes, R. I. Horwitz, A. R. Feinstein, A collection of 56 topics with contradictory results in case-control research. *Int. J. Epidemiol.* 17, 680–685. (1988)
8. A. R. Feinstein, Scientific standards in epidemiologic studies of the menace of daily life. *Science* 242, 1257–1263. (1988)
9. S. B. Nissen, T. Magidson, K. Gross, C. T. Bergstrom, Publication bias and the canonization of false facts. *eLife*. 5:e21451. doi:10.7554/eLife.21451. (2016)
10. S.S. Young, M.K. Acharjee, K. Das, The reliability of an environmental epidemiology meta-analysis, a case study. *Reg Tox Pharm*. 102, 47-52. (2018)
11. S. S. Young, K. B. Kindziarski, Evaluation of a meta-analysis of air quality and heart attacks, a case study, *Crit Rev Tox* doi: 10.1080/10408444.2019.1576587 (2019)
12. J. S. Cecil, E. Griffin, “The Role of Legal Polices in Data Sharing.” In *Sharing Research Data The National Academies Press* <http://www.nap.edu/catalog/2033.html> (1985)

Show Less

Competing Interests: None declared.

View Full Text

Getting the EPA back on track

Your information will be kept confidential, and the lessons learned from your participation will serve society—those are the promises made by researchers to participants in studies designed to inform environmental policies, from clean water and air to chemical exposure limits. The

United States Environmental Protection Agency (EPA) may well break this fundamental pact next year, putting the agency at odds with its very mission “to protect human health and the environment.” Hopefully, the EPA will realize that this would jeopardize regulations that keep the environment safe to live in, and correct course back to sound policy-making.

In January 2020, the EPA plans to issue a supplement to its 2018 proposed rule, Strengthening Transparency in Regulatory Science, which stated that in setting standards, the agency would only use research for which underlying raw data and models were made public. The rule could eliminate many public health studies from consideration. At a congressional hearing last month, the EPA claimed that the supplemental rule provides clarifications, but does it address major problems with the plan? Although the notion of depositing data and models from federally funded research into public databases is laudable, the rule as proposed poses substantial problems. This may account for why the majority of nearly 600,000 public responses to the 2018 proposed rule were critical.

In epidemiological and clinical studies, people provide information—their medical histories, behaviors, education, employment, and other personal details—under the condition that it will not be shared and their privacy will be protected. anonymizing data is already difficult, if not impossible. With geographically referenced data, a capable programmer can leverage machine learning and brute computational strength to determine the location, subsequently the identity, of a study participant. Similarly, facial recognition software has been applied to images reconstructed from cranial scans to identify study participants. Re-identification can jeopardize employment, insurance, or personal relationships for individuals, a scholarship, reputation, or funding for researchers. This will simply discourage people from participating in future health studies. Moreover, successfully recruiting and retaining participants depends on trusting relationships built on meaningful and sustained interaction between researchers and participants, especially with disad-

vantaged populations who are underrepresented in research. The EPA rule assumes that people will consent to their data residing in a repository where decisions about data use are made by persons unknown to them.

The proposed rule claims that additional analysis of raw data and models will improve science. Who will do this analysis? Most likely, vested interests will finance work slanted toward a particular outcome, rather than undertake scientific inquiry without an agenda. For example, lead paint industry defense attorneys have attributed children’s neurological deficits to landlord neglect and parental failure. The rule also disregards the power of the “weight of the evidence.” Imagine multiple studies done by different investigators on different populations using different techniques, yet reaching similar conclusions—that’s a powerful result. Ignoring the weight of evidence derived from the totality of relevant science, regardless of data availability, contravenes the EPA’s directive (stated in the Clean Air Act) to set standards “requisite to protect the public health with an adequate margin of safety.”

Many researchers already deposit code and data into open repositories. The U.S. National Institutes of Health and other federal funding agencies require data-sharing plans to support independent reanalysis within the scientific community without compromising confidentiality. The peer review process provides an additional check on the credibility of research results. Work by the Health Effects Institute, in which an industry-government-funded partnership reanalyzed data from the Harvard Six Cities Study and the American Cancer Society Study on the link between particulate matter pollution and mortality, represents an excellent model for evaluating the validity of research pivotal to environmental health regulations without compromising confidentiality or excluding studies.

The EPA’s proposed transparency rule does not ensure research rigor or improve transparency. It unquestionably excludes key science from policy-making. Once the supplemental rule is released in January 2020, there will be an open period for public comment—an opportunity for everyone to remind the EPA of its obligation to use the best science, as required in multiple environmental laws, to protect human health and the environment.

—Marie Lynn Miranda



Marie Lynn Miranda is a professor in the Department of Statistics at Rice University, Houston, TX, USA, and is the founding director of the Children’s Environmental Health Initiative at Rice University. mlm@rice.edu

“The EPA’s proposed transparency rule... unquestionably excludes key science from policy-making.”