MLA and AAHSL Comments to EPA on proposed rule, Strengthening Transparency in Regulatory Science

May 11, 2018

April 30, 2018 Federal Register Posting

Due Date: May 30, 2018

Document Citation: 83 FR 18768

CFR: 40 CFR 30

Agency/Docket Numbers:

• EPA-HQ-OA-2018-0259

• FRL-9977-40-ORD

RIN: 2080-AA14

Document Number: 2018-09078

Comments submitted by Mary M. Langman, Director, Information Issues and Policy on behalf of MLA and AAHSL at: https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-0001

The Medical Library Association (MLA) and Association of Academic Health Science Libraries (AAHSL) do not support the proposed rule, "Strengthening Transparency in Regulatory Science," because it contradicts our core values. MLA and AAHSL support the use of scientific evidence in making health care decisions, and believe that *Better Health Through Better Information* is accomplished through the practice of evidence-based medicine. These core values include environmental policymaking, which often directly impacts human health. The proposed rule, would limit EPA's ability to use the best available evidence on the effects of pollution by limiting its pool of resources and data to research studies where the underlying data are publicly available. Because many environmental studies involve examining effects on individual patients, by definition they require confidentiality. The rule change could also prevent use of data from high-quality studies whose data may be proprietary due to private funding. In both cases, alternate methods exist to ensure that expert reviewers can evaluate the studies for methodological rigor, as well obtaining confidential access to data where necessary and appropriate.

The EPA's proposal runs counter to the data policies and philosophies that are currently being implemented by other federal agencies within the Department of Health and Human Services which have demonstrated it is possible to reconcile the principles of access to, reliability of, and reproducibility of data while respecting the confidentiality of individual patient data.

MLA and AAHSL support federal initiatives and regulations that facilitate scientific collaboration, provide researchers with easier access to the results of scientific research and data, strengthen biomedical research, and support better patient care. Unfortunately, the proposed rule counteracts its aim and the mission of our organizations. Rather than increasing access to scientific evidence, it would reduce the EPA's ability to use it, with potentially dire consequences for the health of Americans. Further, there has been consensus within the scientific community that this proposal would be counterproductive and unnecessary, and would inhibit meaningful research on public health (1) (2).

For all these reasons reasons, MLA and AAHSL urge Secretary Pruitt to reconsider the proposed rule.

References

1. American Association for the Advancement of Science. AAAS Statement on EPA Administrator's Plan to Disallow Use of Scientific Evidence in Decision-Making. April 20, 2018.

- <Internet> accessed May 8, 2018. https://www.aaas.org/news/scientific-leaders-speak-out-epa-s-proposed-transparency-rule
- 2. Berg J et al. Joint statement on EPA proposed rule and public availability of data. Science April 30, 2018; <Internet> accessed May 8, 2018. http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

The Medical Library Association (MLA) is a nonprofit, educational organization with more than 3,000 health sciences information professional members worldwide. Founded in 1898, MLA provides lifelong educational opportunities, supports a knowledgebase of health information research, and works with a global network of partners to promote the importance of quality information for improved health to the health care community and the public.

The Association of Academic Health Sciences Libraries (AAHSL) supports academic health sciences libraries and directors in advancing the patient care, research, education and community service missions of academic health centers through visionary executive leadership and expertise in health information, scholarly communication, and knowledge management.