

**Statement of Liz Borkowski, MPH**  
**Regarding EPA Proposed Rule “Strengthening Transparency in Regulatory Science”**  
**July 17, 2018**

Thank you for the opportunity to present comments. My name is Liz Borkowski, and I am the managing director of the Jacobs Institute of Women’s Health, which is at the Milken Institute School of Public Health at the George Washington University. The Jacobs Institute is concerned about EPA’s proposed rule “Strengthening Transparency in Regulatory Science” (RIN 2080-AA14) due to the harmful impact it would have on women’s health and reproductive justice. We urge EPA to withdraw it based both on its detrimental impacts and on the lack of a demonstrated need for such a rule.

EPA has failed to demonstrate that its current processes for considering science in regulation are inadequate. It has not provided examples of any instances in which insufficient transparency has resulted in outcomes contrary to its statutory mandates or executive orders. Given extensive existing procedures used by EPA and the scientific community at large to assure the quality of research, EPA has failed to make a case that additional public access to data is necessary. The theoretical – but as yet undemonstrated – benefits of EPA’s proposal must be weighed against the extensive and unequally distributed costs of such an approach. Failing to consider the best available evidence because the underlying data are not publicly available would result in regulations that fail to sufficiently protect public health. The consequences would fall most severely on sensitive groups not adequately protected by current rules, which include racial and ethnic minorities, those with low socioeconomic status, the elderly, and pregnant individuals and their eventual children.<sup>1,2,3</sup> My comments provide a few examples related to reproductive health.

First, neurotoxicants are of particular concern to pregnant women and the parents of young children. In regulatory activities to reduce exposure to neurotoxicants such as lead and methylmercury, EPA has relied on an extensive body of research. This research includes longitudinal studies of individuals who were exposed in utero or as young children to higher levels of lead or methylmercury than would typically occur in the U.S. today.<sup>4,5,6,7</sup> It would not be ethical to publicly

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<sup>1</sup> Di Q, Wang Y, Zanobetti A, Wang Y, Koutrakis P, Choirat C, Dominici F, & Schwartz JD. (2017). Air Pollution and Mortality in the Medicare Population. *New England Journal of Medicine*, 376(26):2513-2522.

<sup>2</sup> Zhang M, Mueller NT, Wang H, Hong X, Appel LJ, & Wang X. (2018). Maternal Exposure to Ambient Particulate Matter  $\leq 2.5 \mu\text{m}$  During Pregnancy and the Risk for High Blood Pressure in Childhood. *Hypertension*, Epub ahead of print. doi: 10.1161/HYPERTENSIONAHA.117.10944.

<sup>3</sup> Rauh VA. (2018). Polluting Developing Brains - EPA Failure on Chlorpyrifos. *New England Journal of Medicine*, 378(13):1171-1174.

<sup>4</sup> Needleman HL, Gunnoe C, Leviton A, Reed R, Peresie H, Maher C, & Barrett P. (1979). Deficits in psychologic and classroom performance of children with elevated dentine lead levels. *New England Journal of Medicine*, 300(13):689-95.

<sup>5</sup> Bellinger D, Sloman J, Leviton A, Rabinowitz M, Needleman HL, & Waternaux C. (1991). Low-level lead exposure and children's cognitive function in the preschool years. *Pediatrics*, 87(2):219-27.

<sup>6</sup> Mazumdar M, Bellinger DC, Gregas M, Abanilla K, Bacic J, & Needleman HL. (2011). Low-level environmental lead exposure in childhood and adult intellectual function: a follow-up study. *Environmental Health*, 10:24.

<sup>7</sup> Debes F, Budtz-Jorgensen E, Weihe P, White RF, & Grandjean P. (2006). Impact of prenatal methylmercury exposure on neurobehavioral function at age 14 years. *Neurotoxicology and Teratology*, 28:536-47.

release data from these studies, and it would not be feasible, particularly for older studies that used incompatible storage media, to locate all participants and obtain their permission.

EPA's use of research on lead and methylmercury also has implications for other agencies that address these substances. For instance, the Department of Housing and Urban Development (HUD) relies on EPA's Renovation, Repair and Painting rule in its regulation of renovators working in housing units receiving HUD housing assistance where lead paint is present.<sup>8</sup> EPA calculated the reference dose for methylmercury that EPA and the Food and Drug Administration used to create guidelines on fish consumption, including recommendations for pregnant and breastfeeding women.<sup>9</sup> It does not appear that EPA has undertaken the required inter-agency review process to assess the implications of its rule for other agencies.

Another neurotoxicant of concern for reproductive health is the pesticide chlorpyrifos. Researchers followed a cohort of children exposed to this pesticide before the current ban on indoor use, and found lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.<sup>10</sup> In a rulemaking process regarding agricultural use of chlorpyrifos, EPA requested the underlying data from the Columbia Center for Children's Environmental Health. The response from Columbia University explained that because of the detailed sociodemographic and health-related elements their data set contains, they did not believe they could submit extensive individual-level data to EPA in a way that would ensure participants' confidentiality.<sup>11</sup> Such concerns are not uncommon with the kinds of longitudinal data sets that allow identification of long-term consequences of environmental exposures. Often, the combination of variables used in an analysis provides enough information to identify individual participants, and may include sensitive information, such as diagnosis of neurodevelopmental delays.

In addition, endocrine-disrupting chemicals are of great concern in reproductive health, and EPA has regulated some of these, such as polybrominated diphenyl ethers (PBDEs)<sup>12</sup> and polychlorinated biphenyls (PCBs),<sup>13</sup> under the Toxic Substances Control Act (TSCA). Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence,<sup>14</sup> but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

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<sup>8</sup> EPA Certified Renovation Firms and Certified Renovators: Additional Requirements of HUD's Lead Safe Housing Rule. (2009). Accessed May 25, 2018 at <https://www.hudexchange.info/resource/169/epa-certified-renovation-firms-and-certified-renovators-additional-requirements-of-huds-leadsafe-housing-rule/>

<sup>9</sup> Environmental Protection Agency. (no date). EPA-FDA Fish Advice: Technical Information. Accessed May 25, 2018 at <https://www.epa.gov/fish-tech/epa-fda-fish-advice-technical-information>

<sup>10</sup> Rauh V, Arunajadai S, Horton M, Perera F, Hoepner L, Barr DB, & Whyatt R. (2011). Seven-year neurodevelopmental scores and prenatal exposure to chlorpyrifos, a common agricultural pesticide. *Environmental Health Perspectives*, 119(8):1196-201.

<sup>11</sup> Fried, L. (2016). Letter from Linda P. Fried, Dean, Mailman School of Public Health, Columbia University, to Jack E. Housenger, Director, Office of Pesticide Programs, United States Environmental Protection Agency, dated May 18, 2016.

<sup>12</sup> Environmental Protection Agency. (no date). Assessing and Managing Chemicals under TSCA: Polybrominated Diphenyl Ethers (PBDEs). Accessed May 29, 2018 at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/polybrominated-diphenyl-ethers-pbdes>

<sup>13</sup> Environmental Protection Agency (no date). Learn about Polychlorinated Biphenyls (PCBs). Accessed May 30, 2018 at <https://www.epa.gov/pcbs/learn-about-polychlorinated-biphenyls-pcbs>

<sup>14</sup> 15 USC §2625(i).

If EPA moves forward with the rule it has proposed, it will undermine science in regulatory decisionmaking by making it impossible to consider the best available science. This will have detrimental impacts on reproductive justice, health equity, and women's health. The Jacobs Institute of Women's Health urges EPA to withdraw this rule.