

Statement of Liz Borkowski, MPH
Submitted to: U.S. Environmental Protection Agency Science Advisory Board
Regarding EPA Proposed Rule “Strengthening Transparency in Regulatory Science”
May 31, 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 the impacts EPA’s proposed rule “Strengthening Transparency in Regulatory Science” (RIN 2080-AA14) would have for reproductive health, and we support the Science Advisory Board’s plan to review it.

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.^{1,2,3,4} It would not be ethical to publicly 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 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.⁵ 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.⁶ Given that the proposed rule does not appear to have undergone the required inter-agency review, these examples are worth considering.

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

¹ 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.

² 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.

³ 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.

⁴ 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.

⁵ 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/>

⁶ 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>

lower IQ and working memory to be associated with higher levels of prenatal chlorpyrifos exposure.⁷ 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.⁸ 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.

Endocrine-disrupting chemicals are also of particular concern in reproductive health, and EPA has regulated some of these, such as polybrominated diphenyl ethers (PBDEs)⁹ and polychlorinated biphenyls (PCBs),¹⁰ under the Toxic Substances Control Act (TSCA). Under reformed TSCA, EPA must make decisions based on the weight of the scientific evidence,¹¹ but it is not clear how it can do so if studies may be eliminated from consideration because data sets are not publicly available.

The Jacobs Institute of Women's Health encourages the Science Advisory Board to consider these examples of neurotoxicant and endocrine disruptor research and rulemaking activity when reviewing EPA's proposed rule. How would the studies that informed regulation of lead, mercury, chlorpyrifos, PBDEs, PCBs, or many other toxic substances be treated under this rule? Would specific criteria or provisions ensure that they could be considered even if, in order to preserve participants' privacy, their raw data could not be made publicly available?

⁷ 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.

⁸ 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.

⁹ 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>

¹⁰ 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>

¹¹ 15 USC §2625(i).