

July 16, 2018

## **Letter to Oppose the EPA Proposed Rule on Strengthening Transparency in Regulatory Science from Environmental Health Professionals and Organizations**

RIN: 2080-AA14

Submitted electronically to Docket ID: EPA-HQ-OA-2018-0259-0001

Dear EPA Administrator,

We are environmental health professionals and organizations with expertise and interest in protecting children and their families from exposures to toxic chemicals that could lead to neurodevelopmental harm. We strongly support EPA's mission to protect human health and the environment, including by setting exposure limits and clean-up standards for environmental pollutants.

This letter is to voice our opposition to the EPA Proposed Rule, *Strengthening Transparency in Regulatory Science*.<sup>1</sup> We are opposed to this proposal because it will hamstring the Agency's use of scientific information, which can only harm EPA's work quality and public credibility. The proposed rule prohibits the Agency from setting regulations that are supported, in part or whole, by data that is not publicly available for re-analysis or that cannot be replicated. Since the proposed rule is retroactive, it could lead to the dismantling of many important existing EPA regulations.

Moreover, its claims of increasing transparency are disingenuous because the Proposal may allow EPA to consider significant amounts of information submitted by industry to the agency, even though the information will be protected as Confidential Business Information (CBI) and shielded from the public. Because industry data are associated with CBI claims more so than public health researchers' work, the Proposal reveals its industry bias.

EPA regulations that reduce exposure to pollutants and chemicals that are toxic to the developing brain have for decades relied on studies that included data and information that was not made fully public, including longitudinal epidemiologic studies, human clinical studies, and animal toxicologic studies. In many cases, the original raw data does not exist or is no longer accessible. In other cases, individual participant's data cannot be made public because of confidentiality requirements legally mandated by Institutional Review Boards and/ or the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In some cases, the original studies cannot be replicated because the high exposure conditions no longer exist, thanks to successful EPA safeguards.

Some examples of existing EPA actions that have reduced people's exposures to toxic chemicals, that may be rolled back because of this rule are below:

### Air pollution

Most air pollution is the result of burning fossil fuels, such as coal, oil, natural gas, and gasoline to produce electricity and power vehicles.<sup>2</sup> Prenatal and early childhood exposure to air pollution increases the risk of developmental delays, reduced IQ, symptoms of anxiety, depression and inattention. Air pollution may also increase children's risk of developing autism. Thanks to EPA regulations since 1997 that relied on the Harvard Six Cities study (a longitudinal epidemiologic study of thousands of individuals begun in the 1970s) and American Cancer Society study, among others, EPA has determined that over 230,000 premature deaths will be prevented by 2020, with benefits exceeding the costs of the Clean Air Act by 30-fold.<sup>3</sup>

The Six Cities study has been reanalyzed many times, including by the Health Effects Institute (a public non-profit co-funded by EPA and the regulated industry) and the American Cancer Society, in published reports.<sup>4</sup> Despite rigorous and transparent expert review and approval, the Six Cities findings continue to be disputed by polluters and their allies in Congress.<sup>5,6</sup>

### Lead in drinking water

The damaging effects of early childhood lead exposure can last a lifetime, so prevention is the only effective and meaningful solution. EPA's Lead and Copper Rule (LCR) of 1991 does just that by establishing drinking water limits, monitoring, and protective actions if needed. The rules are based on epidemiology studies published in the 1990's that correlate childhood blood lead levels with impaired brain function and adverse behavioral effects.<sup>7</sup> Many of the published studies are longitudinal cohort studies that include measurements of lead in blood from children decades ago, and then follow them out over time to observe lasting effects.

Thanks to important EPA regulations and effective lead-reduction measures in gasoline and paint, overall blood lead levels have been reduced in many people. This makes it impossible to replicate the exposure conditions at the time the original children in the study cohort had their blood lead levels measured, nor would it be ethical to seek to do so.

### Neurotoxic pesticides like chlorpyrifos

Organophosphate pesticides like chlorpyrifos are widely used in agriculture, with over 5 million pounds of the insecticide applied annually across the U.S to a variety of crops including apples, oranges, broccoli and berries.<sup>8</sup> Symptoms of acute poisoning include nausea and vomiting, headaches, dizziness, seizures, paralysis, and in extreme cases, even death. Due to risks to children's health, in 2000, EPA banned household use of chlorpyrifos and most other organophosphate pesticides.<sup>9</sup> The studies can no longer be reproduced because – thanks to the Food Quality Protection Act (FQPA) and the ban on residential uses – pregnant women and

young children are no longer poisoned by indoor use of organophosphate pesticides at such high levels.

### Conclusion

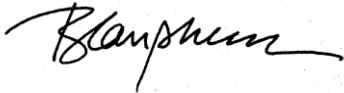
As scientists and health professionals we recognize the importance of data sharing and replicability in scientific practice and discourse. We would welcome an open dialogue to improve science-based decisions across the federal government, including at EPA. However, as The Economist pointed out in an editorial last month, this proposed rule is about stifling science used by EPA, not improving it.<sup>10</sup> The editors of Science, Nature, the PLOS journals and the Proceedings of the National Academies of Science have issued a joint statement of opposition of the Proposed Rule.<sup>11</sup> The EPA Chartered Science Advisory Board (SAB) identified many of the problems we've detailed in this letter, and recommended that it merits review by the SAB.<sup>12</sup> We share many of these concerns, and therefore strongly oppose the proposal.

Thank you for the opportunity to provide comments.

Respectfully,



Jennifer Sass, Ph.D.  
Senior Scientist, Natural Resources Defense Council,  
and, George Washington University



Bruce Lanphear, MD, MPH  
Simon Fraser University  
Vancouver BC, Canada



Learning Disabilities Association  
Maureen Swanson, MPA  
Director, Healthy Children Project

***Supported by the following (academic affiliations are for identification purposes only):***

Alaska Community Action on Toxics  
Pamela Miller, Executive Director  
and IPEN Co-Chair ([www.ipen.org](http://www.ipen.org)) and  
Anchorage, Alaska

Alliance of Nurses for Healthy Environments  
Katie Huffling, RN, MS, CNM  
Executive Director

Laura Anderko PhD RN  
Robert and Kathleen Scanlon Endowed Chair in Values Based Health Care & Professor  
Fellow, Center for Social Justice  
White House Champion of Change for Public Health and Climate Change  
Georgetown University  
Washington DC

Autism Science Foundation  
Alycia Halladay, PhD  
Chief Science Officer, New York, NY

John R. Balmes, MD  
Professor of Medicine, UCSF  
Professor of Environmental Health Sciences, School of Public Health, UC Berkeley  
Director, Northern California Center for Occupational and Environmental Health  
UC Berkeley-UC Davis-UCSF  
Director, UC Berkeley-UCSF Joint Medical Program

David Bellinger, Ph.D., MSc  
Professor of Neurology  
Harvard Medical School  
Boston Children's Hospital  
Boston, MA

Asa Bradman, PhD, MS  
Center for Environmental Research and Children's Health (CERCH)  
Associate Adj. Professor of Environmental Health Sciences  
School of Public Health/UC Berkeley  
Berkeley, CA

Carla Campbell, MD, MS, FAAP  
Associate Professor of Public Health  
MPH Program Director

Department of Public Health Sciences, Room 408  
College of Health Sciences  
University of Texas at El Paso  
El Paso, TX

Aimin Chen, MD, PhD  
Associate Professor  
Division of Epidemiology  
Department of Environmental Health  
University of Cincinnati College of Medicine  
Cincinnati, OH

Children's Environmental Health Network (CEHN)  
Nsedu Obot Witherspoon, MPH  
Executive Director

Jeanne A. Conry, MD, PhD, FACOG  
Past President  
The American College of Obstetricians and Gynecologists  
President  
The Environmental Health Leadership Foundation

Kristie Ellickson, PhD  
Division of Environmental Health  
School of Public Health, University of Minnesota

Stephanie M. Engel, PhD  
Professor of Epidemiology  
UNC Gillings School of Global Public Health  
University of North Carolina, Chapel Hill  
Chapel Hill, North Carolina

Brenda Eskenazi PhD  
Jennifer and Brian Maxwell Professor of Maternal and Child Health and Epidemiology  
School of Public Health  
UC Berkeley  
Berkeley, CA

Robert Gould, MD  
Associate Adjunct Professor  
Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology and Reproductive Sciences  
UCSF School of Medicine  
and Past President, Physicians for Social Responsibility

Russ Hauser MD, ScD, MPH  
Chair, Department of Environmental Health  
Frederick Lee Hisaw Professor of Reproductive Physiology  
Professor of Environmental and Occupational Epidemiology  
Harvard T.H. Chan School of Public Health  
Professor of Obstetrics, Gynecology and Reproductive Biology  
Harvard Medical School  
Boston, MA

Healthy Babies Bright Future  
Charlotte Brody, RN  
National Director

Irva Hertz-Picciotto  
Professor of Epidemiology, and Professor of Environmental Health  
Director, UC Davis Environmental Health Sciences Center  
School of Medicine  
University of California, Davis

Deborah Hirtz M.D.  
Professor, Neurological Sciences and Pediatrics  
University of Vermont School of Medicine  
Burlington, Vermont

Philip J. Landrigan, MD, MSc, FAAP  
Dean for Global Health  
Professor of Environmental Medicine, Public Health and Pediatrics  
Arnhold Institute for Global Health  
Icahn School of Medicine at Mount Sinai  
New York, NY

Juleen Lam, PhD MHS MS  
Associate Research Scientist  
Program on Reproductive Health and the Environment (PRHE)  
Department of OB/GYN & Reproductive Sciences  
University of California at San Francisco  
San Francisco, CA

Mark Miller MD, MPH  
President, International Society for Children's Health and the Environment  
Occupational Environmental Medicine  
University of California, San Francisco  
San Francisco, CA

Mark A. Mitchell, MD MPH FACPM  
Chair, National Medical Association Council on Medical Legislation  
Co-Chair, National Medical Association Commission on Environmental Health

Craig J. Newschaffer, Ph.D.  
Professor, Epidemiology and Biostatistics  
Dornsife School of Public Health  
Drexel University  
Philadelphia, PA

Heather B Patisaul, PhD  
Professor, Department of Biological Sciences  
Keck Center for Behavioral Biology  
Center for Human Health and the Environment  
NC State University

Devon Payne-Sturges, DrPH  
Assistant Professor  
Maryland Institute for Applied Environmental Health  
School of Public Health  
University of Maryland, College Park  
College Park, MD

Frederica P. Perera, DrPH, PhD  
Professor of Public Health  
Director, Columbia Center for Children's Environmental Health  
Mailman School of Public Health  
Columbia University  
New York, NY

Pesticide Action Network  
Emily Marquez, Ph.D.  
Staff scientist, Berkeley, CA

Physicians for Social Responsibility  
Barbara Gottlieb  
Director, Environment & Health

Beate Ritz MD, PhD  
Professor of Epidemiology  
Center for Occupational and Environmental Health  
FSPH, UC Los Angeles  
Los Angeles, CA

I Leslie Rubin MD  
Associate Professor, Department of Pediatrics, Morehouse School of Medicine  
Founder, Break the Cycle of Health Disparities, Inc.  
Medical Director, Developmental Pediatrics Specialists

Susan Schantz, PhD  
Neuroscience Program  
University of Illinois at Urbana-Champaign  
Urbana, IL

Science and Environmental Health Network  
Ted Schettler, MD, MPH, Science Director

Veena Singla, Ph.D.  
Associate Director, Science & Policy  
Program on Reproductive Health and the Environment (PRHE)  
University of California, San Francisco  
San Francisco, CA

Evelyn O. Talbott, DrPH, MPH  
Professor, Dept of Epidemiology  
University of Pittsburgh,  
Pittsburgh, PA

The Endocrine Disruption Exchange (TEDX)  
Carol Kwiatkowski, PhD, Executive Director,  
and Assistant Professor Adjunct, North Carolina State University and  
University of Colorado, Boulder

Tom Webster, DSc  
Dept Environmental Health  
Boston University School of Public Health  
Boston, MA

Robin M. Whyatt, Dr.PH  
Professor Emeritus  
Department of Environmental Health Sciences  
Mailman School of Public Health  
Columbia University  
New York, NY

Tracey J Woodruff, PhD, MPH  
Associate Professor and Director



Program on Reproductive Health and the Environment  
Department of Obstetrics, Gynecology, and Reproductive Sciences  
UC San Francisco  
San Francisco, CA

R. Thomas Zoeller, Professor  
Biology Department  
University of Massachusetts Amherst  
Amherst, MA

Ami Zota, ScD, MS  
Assistant Professor  
Department of Environmental and Occupational Health  
Milken Institute School of Public Health  
The George Washington University

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<sup>9</sup> U.S. Environmental Protection Agency. Chlorpyrifos: Ingredients Used in Pesticide Products. <https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos>. Published 2016

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<sup>10</sup> Swamp science: Scott Pruitt embarks on a campaign to stifle science at the EPA. The Economist. April 26, 2018. Available at <https://www.economist.com/news/united-states/21741140-new-policies-would-hamstring-clean-air-and-pesticide-standards-scott-pruitt-embarks>

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