

Testimony of

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PROTECTING CHILDREN FROM ENVIRONMENTAL THREATS

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Introduction

Thank you for the opportunity to submit written testimony to this Committee. I am Gina Solomon, a physician and Senior Scientist at the Natural Resources Defense Council (NRDC) and an Associate Clinical Professor of Medicine at the University of California at San Francisco (UCSF) where I am also the Associate Director of the UCSF Pediatric Environmental Health Specialty Unit. NRDC is a national, nonprofit, public interest organization dedicated to protecting human health and the environment. We have over 1.2 million members and online activists in all 50 states. I have subspecialty training and expertise in environmental medicine, and have done research, education, and advocacy for over a decade to protect children from lead poisoning, from contaminants in their food, air and drinking water, and from hazardous pesticides.

Almost every day I speak with people – both patients and members of the public – about their health and about risks to their health from environmental pollution. One of the most frequent questions I hear is: “What can I do to protect myself and my family from contaminants in the air, water, food, and in my community?” It’s often difficult to answer that question. Many hazards that can affect the health of children and families are not things that individuals can protect themselves from, even with advice from their physician. Contaminants in the air we breathe, in the food we eat, or even chemicals in common household products, are things that we have little control over as individuals. It is the responsibility of government agencies such as the Environmental Protection Agency (EPA) to assure that our air and water are safe for the most vulnerable among us, including pregnant women and children.

Children are at High Risk from Environmental Contaminants

One reason that I’m concerned about children’s environmental health is that some childhood diseases and abnormal conditions are on the rise. For example, childhood leukemia and brain tumors – the two most common childhood cancers – have increased by more than 20% since 1975.¹ Asthma approximately doubled in prevalence between 1980 and 1995 and has stayed at the elevated rate.^{2 3} Certain birth defects of the penis and testes, such as cryptorchidism (undescended testes), have increased 200% between 1970 and 1993.⁴ And, of course, there is autism, the diagnosis of which has increased by more than 10-fold in the last 15 years.⁵

Another reason I’m concerned about children’s environmental health is that decades of powerful scientific evidence has accumulated demonstrating that children are more susceptible to contaminants in their environment. Children’s susceptibility stems from four basic conditions: first, when adjusted for body weight, children take in more air, water, and food than adults so they take in more of any contaminants in those media; second, children’s behavior can lead to higher exposures because they put their hands in their mouths, play on the ground, and run around outdoors; third, children’s physiology is different, especially during infancy, and they detoxify some chemicals less efficiently; finally, their developing brains, reproductive systems, and other organs are more susceptible to permanent disruption that can result in health problems during their life. In

fact, research is accumulating that indicates many diseases that occur in adulthood, including neuro-degenerative disorders and many cancers, may have their origins in exposures that occur in the womb and in infancy or childhood.^{6 7}

None of these facts are scientifically controversial. In fact, the National Academy of Sciences (NAS) laid out these issues clearly in their 1993 report, *Pesticides in the Diets of Infants and Children*.⁸ The NAS report found that EPA's existing approach to regulating pesticides failed to address the unique vulnerabilities of infants and children, including the likelihood that infants and children are more susceptible and more highly exposed to pesticides.

Protecting Children: The Example of Pesticide Law

Congress recognized the overwhelming scientific evidence on children's susceptibility by writing child-protective language into the Food Quality Protection Act (FQPA), which passed both Houses of Congress unanimously in 1996.⁹ Through the FQPA, Congress required EPA to review the safety of all pesticides used on food crops, and, for the first time in any environmental law, specifically ordered EPA to assure the safety of infants and children. Specifically, pesticide tolerances (for allowable residue levels on food) must ensure to a reasonable certainty that "no harm will result to infants and children from aggregate exposure. . ."¹⁰

One of the FQPA's most important provisions is that it requires EPA to use an additional ten-fold margin in risk assessments to protect infants and children. EPA must maintain this additional margin to "take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children."¹¹ EPA can depart from this requirement and use a different margin "only if, on the basis of reliable data, such margin will be safe for infants and children."

In ensuring that pesticide residues are safe for infants and children, EPA must base its decision on information about: "food consumption patterns unique to infants and children;" "special susceptibility of infants and children to pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure;" and the "cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity."¹² By definition, if there are no data or significant gaps in data, there cannot be "reliable data" sufficient to overturn the statutory presumption of an additional ten-fold margin to protect infants and children.

This approach would seem to be a model for how to assure children are protected from toxic chemicals in their food. But there are two important problems.

The first problem is that Congress left the job half-done in 1996. It was important to take steps to require that children be protected from pesticides, but there are many thousands of non-pesticide chemicals that contaminate food, water, air, and consumer products. To this day, there is no legal requirement that EPA take any additional steps to assure that children are protected from these industrial chemicals. Chemicals that are known to

disproportionately affect fetuses, infants, or children, such as bisphenol A, phthalates, brominated flame retardants, TCE, and even arsenic remain in a limbo where there is no clear directive to protect children's health. Accordingly, EPA actions to date on these chemicals have failed to adequately protect children.

The second problem is that EPA has honored the child-protective language in the FQPA in the breach. In 2006, an NAS committee, on which I served, reviewed EPA pesticide assessments.¹³ The committee reported that out of the 59 pesticides with assessments posted on EPA's website, EPA failed to apply a child-protective factor for 48 chemicals. For five pesticides, the agency applied the full factor of 10 for at least one exposure group and exposure circumstance, such as acute dietary exposure of women of childbearing age. For six pesticides, EPA reduced the factor to 3. In the five cases where the full child factor of 10 was applied, severe developmental toxicity end points, such as multiple malformations and fetal death, were observed in laboratory animals. An updated NRDC analysis focusing on pesticide assessments completed in the past three years found that among 14 recent food-use pesticide assessments, only 2 incorporated the full child-protective factor. Thus there has been little improvement in recent years.

Independent scientists, the EPA's Scientific Advisory Panel (SAP), the EPA Inspector General, and even EPA's own scientific staff, have criticized the Agency's implementation of the FQPA.¹⁴ The SAP expressed concern that the Pesticide Program's approaches "may not be sufficiently conservative, may underestimate the risks to infants and children, and do not adequately identify individuals that may be inherently sensitive to neurotoxicants".¹⁵ A letter from EPA staff scientists to then Administrator Johnson in May 2006¹⁶ stated: "EPA's risk assessments cannot state with confidence the degree to which any exposure of a fetus, infant or child to a pesticide will or will not adversely affect their neurological development." The EPA scientists continued by saying: "We are concerned that the Agency has lost sight of its regulatory responsibilities in trying to reach consensus with those that it regulates, and the result is that the integrity of the science upon which Agency decisions are based has been compromised." A January 2006 Inspector General report points out flaws in the EPA testing process that have yielded a less than "complete and reliable database on developmental neurotoxicity of pesticides... upon which to base any final tolerance reassessment decisions as required by the FQPA."¹⁷ EPA staff scientists specifically requested in their letter that: "Where developmental neurotoxicity studies are absent, it is imperative that the Agency continue to retain the 10-fold safety factor - if not increase it - as a precaution, when making final reregistration decisions for [organophosphate] and carbamate pesticides."

Unfortunately EPA proceeded to finalize their assessment of the organophosphate pesticides in August of 2006 without paying heed to the scientists. The Agency reduced or eliminated the child-protective factor in one-third of the assessments, even though these chemicals are known to be especially toxic to the developing brain, leaving potentially dangerous chemical residues on food, where they can harm infants and children.

I also want to note that Congress inserted child-protective language into the Safe Drinking Water Act amendments of 1996.¹⁸ This law specifies that, when setting maximum contaminant levels (MCLs) for drinking water, EPA must “analyze the effects on groups such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk...” Unfortunately, EPA has neither set a single new MCL, nor has the Agency updated any old MCLs within the last decade. So the child-protective provisions in drinking water law have yet to be implemented. A special concern is the bottle fed infant whose sole source of water can be from the tap and who consumes far more water than other age groups on a bodyweight basis.

We can learn from the example of the FQPA. Congress should apply child-protective requirements to non-pesticide chemicals, and make these requirements even clearer than those in the FQPA, so the Agency must abide by the science. Meanwhile, EPA can re-prioritize children’s health protection and can correct the mistakes that have been made in past years that put children at risk.

California Leadership on Carcinogens

A glaring example of EPA’s failure to use science to protect children is from cancer-causing chemicals. This is a situation where the State of California has shown real leadership and has adopted scientific principles that protect children’s health.

California has done two important things that U.S. EPA has not:

- 1) California incorporates a factor to protect for prenatal exposure to carcinogens, thereby assuring an extra margin of safety for mothers and children. EPA does not.
- 2) California considers children to be more sensitive to all carcinogens, unless shown otherwise, whereas EPA’s “Supplemental Guidance on Assessing Cancer Risk from Early Life Exposures” limits the child-protective factors to chemicals with a “mutagenic mode of action”. In order to decide which chemicals these might be, EPA published a “Framework for Determining a Mutagenic Mode of Action for Carcinogenicity” which requires the Agency to prove that the chemical acts through this specific mechanism based on data which are basically unobtainable for the vast majority of carcinogens.¹⁹ Thus, the two documents together limit any child-protective factors to only a tiny subset of carcinogens.

That last issue – about mutagenic carcinogens – barely passes the laugh test with scientists. EPA’s draft Framework has been roundly criticized by not one, but two, of EPA’s scientific advisory committees.^{20 21} Specifically, EPA’s scientific advisors have pointed out that requiring clear evidence that a carcinogen is also a mutagen creates a powerful disincentive to test chemicals for mutagenicity. In addition, the Framework shifts the burden of proof, such that no child-protective margin is incorporated to protect kids from carcinogens, unless there is clear proof of mutagenicity. Finally, the definition of mutagen in the Framework document is so narrow as to exclude many cancer-causing chemicals that are likely to disproportionately affect children. I am pleased that last fall

EPA announced that it will consider broadening the definition of mutagen, but the fundamental issue remains that the health-protective intent of employing a margin of safety to protect children from carcinogens is undermined by EPA's draft Framework.

In addition, California's Office of Environmental Health Hazard Assessment (OEHHA) has done an analysis of data on carcinogens that have actually been tested during different life stages for their potency in causing cancer. Their analysis of how age at exposure affects cancer showed that early life exposures were more potent for many carcinogens, not just those that have a mutagenic mode of action. Thus, California applies the child-protective factors to all carcinogens unless there is evidence to the contrary.

In addition, OEHHA analyzed differences in how an infant can detoxify and rid themselves of toxic chemicals compared to an adult. That analysis showed that infants and young children are much less able to rid themselves of some common chemicals including butadiene, methylene chloride, trichloroethylene (TCE) and benzo(a)pyrene. Thus, California requires a science-based factor of 30 instead of 10 be applied when assessing the risk from non-cancer toxicity to account for differences in the way young bodies handle chemicals (compared to adults).

California is also developing an approach to address cumulative impacts of environmental exposures that take into account vulnerable populations like infants and children. Since 2008 the state has been convening a workgroup on Cumulative Impacts and Precautionary Approaches and also collaborating with the University of California to develop methods. The goal is to come up with strategies for assessing the multiple exposures, stressors, and vulnerability factors that people face in their homes and communities. This is a tall order, but this important workgroup has made significant progress, and California's forthcoming report will be very useful. According to California's definition,

Cumulative impacts means exposures, public health, or environmental effects from the combined emissions and discharges in a geographic area, including environmental pollution from all sources, whether single or multi-media, routinely, accidentally, or otherwise released. Impacts will take into account sensitive populations and socio-economic factors, where applicable and to the extent data are available.

U.S. EPA should take a careful look at California's approach to protecting children from cumulative impacts in their environment, and should adopt these scientifically-founded strategies in their risk assessments.

National Academy of Sciences Recommendations

In 2008, the National Academies of Science (NAS) released two important reports that made recommendations about ways to better protect children from environmental harm.²²

²³ The report, Science and Decisions, contained the finding: "While consideration of

susceptible subpopulations has been included in a number of environmental risk assessments, the level of consideration and incorporation in EPA assessments could be much improved.” Recommendations included that:

- EPA develop methods for explicitly considering prenatal exposure in cancer risk assessments. (p. 112)
- EPA systematically evaluate human vulnerability in their assessments. This would include identifying underlying disease processes in the population to which chemicals may be contributing. (p. 9, 146, 181)
- EPA assess background exposures to xenobiotics and endogenous chemicals that may affect the processes by which the chemical produces toxicity and may result in low-dose linearity. (pp. 9, 180)
- EPA develop clear standards and criteria for departing from default assumptions: (1) an evidentiary standard that the alternative is clearly superior (that is, its plausibility clearly exceeds the plausibility of the default) and (2) issue-specific criteria to bridge inference gaps. (pp. 8, 201, 207)
- EPA develop a consistent unified approach for dose response modeling that includes formal and systematic assessment of background disease and exposure, possible vulnerable populations, and modes of action that may affect a chemical’s dose-response relationship in humans. (pp. 8-9, Figure 5-8, 179-182)
- EPA incorporate interactions between chemical and non-chemical stressors in risk assessment (in the short term require that they develop a database and default factors that allow for the incorporation of key non-chemical stressors). (pp. 10, 236)
- EPA develop explicitly stated defaults to take the place of implicit ones. “For example, chemicals that have not been examined sufficiently in epidemiologic or toxicologic studies are often insufficiently considered or are even excluded in risk assessments.” (pp. 8, 193, 207)

The NAS Report, “Phthalates and Cumulative Risk Assessment, The Task Ahead” described that “infants’ and children’s physiology, developmental stages, and age-appropriate behaviors all may increase exposure to phthalates.²⁴ Consequently, they may be especially vulnerable to phthalate exposures during critical stages of growth and development.” (p. 18). And also recognized that “There is good evidence that combinations of phthalates and of other antiandrogens produce combined effects at doses that when administered alone do not have significant effect.” (p. 97).

The committee went on to make the following recommendations to EPA:

- A physiologically based approach for establishing grouping criteria for phthalates and other antiandrogens is strongly recommended such that all chemicals that can induce some or all of the effects that make up the androgen-insufficiency syndrome should be subjected to cumulative risk assessment. (p 90).
- Assessments based solely on the effects of single phthalates and other antiandrogens may lead to considerable underestimation of risks to the developing fetus. (p. 97).

- The committee's detailed recommendations outlined possible ways of conducting cumulative risk assessments and conceptually could be used to deal with other groups of chemicals, such as neurodevelopmental toxicants (p. 97).

Data Needed to Protect Children's Health

The biggest threat to children's health, however, may not be from chemicals we know, such as lead, mercury, phthalates, and bisphenol A. The biggest threat may be from what we don't know. We are still dealing with the shameful reality that most of the chemicals in our air and water, and even in our children's toys, have not even been tested for their toxicity. I'm not just talking about a lack of testing for effects on infant development; I'm talking about basic testing to see if these chemicals cause genetic damage, neurologic damage, hormonal effects, allergic reactions, and any number of other preventable health effects. Basic safety assessments of all chemicals – not just pesticides – are needed in order to protect children and adults.

A few years ago, I served on a National Academy of Sciences panel on "Toxicity Testing in the 21st Century".²⁵ The panel issued a final report in 2007 which laid out a vision for how to screen tens of thousands of chemicals in a manner that is cost-effective, sparing of animals, and yet provides the depth of information necessary to assess risks and protect children's health. This approach means that Congress can feasibly require that all chemicals in commerce undergo testing and safety assessments. The scientific tools are within our reach.

Recommendations

EPA should:

1. re-assess the organophosphate pesticides and apply the full child-protective factor to all of these chemicals in order to protect children from adverse effects on neurological development.
2. use the full child-protective factor in most pesticide tolerance decisions as required by Congress.
3. reassess the Framework for a Mutagenic Mode of Action to substantially broaden the carcinogens against which children require special protection.
4. move more quickly to implement the Endocrine Disruptor Screening Program for chemicals in consumer products, air, food, and water.
5. use a child-protective approach, including an additional safety factor and cumulative risk assessment to assess risks of endocrine disrupting chemicals such as phthalates, bisphenol A, and various flame retardants; and move quickly to promulgate regulations to protect children's health.

Meanwhile, Congress should pass comprehensive chemical policy reform that includes testing of all untested chemicals in commerce, requiring manufacturers to prove safety, and the use of an approach that protects children and other vulnerable populations from cumulative risks. Our current system is broken. Only with sweeping chemical policy reform will parents be able to sleep soundly at night, knowing that their children are safe.

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- ¹ Tracey J. Woodruff, et al., *America's Children and the Environment*, Washington, DC: U.S. Environmental Protection Agency, 2008.
- ² Jeanne E. Moorman, et al., "National Surveillance for Asthma, United States 1980–2004," Centers for Disease Control and Prevention, <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5608a1.htm> (November 1, 2009).
- ³ Tracey J. Woodruff, et al., "Trends in Environmentally Related Childhood Illnesses," *Pediatrics*, 113, no. 4 (April 2004): 1133–1140.
- ⁴ Leonard J. Paulozzi, "International Trends in Rates of Hypospadias and Cryptorchidism," *Environmental Health Perspectives*, 107, no. 4, (1999): 297–302.
- ⁵ National Institute of Mental Health, "NIMH's Response to New Autism Prevalence Estimate," <http://www.nimh.nih.gov/about/director/updates/2009/nimhs-response-tonew-autism-prevalence-estimate.shtml>. (November 4, 2009).
- ⁶ Janet Gray, Nancy Evans, Brynn Taylor, Jeanne Rizzo, Marisa Walker. *State of the Evidence: The Connection Between Breast Cancer and the Environment*. *International Journal of Occupational and Environmental Health*, Vol 15, No 1 (2009).
- ⁷ Jill Stein MD, Ted Schettler MD, MPH, Maria Valenti, Ben Rohrer. *Environmental Threats to Healthy Aging*. Greater Boston Physicians for Social Responsibility. October 2008.
- ⁸ *Pesticides in the Diets of Infants and Children*, National Research Council, Washington DC, 1993. http://www.nap.edu/catalog.php?record_id=2126.
- ⁹ The Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).
- ¹⁰ 21 U.S.C. § 346a(b)(2)(C)(ii)(I).
- ¹¹ 21 U.S.C. § 346a(b)(2)(C).
- ¹² 21 U.S.C. §§ 346a(b)(2)(C)(i)(I-III).
- ¹³ *Toxicity Testing for Assessment of Environmental Agents: Interim Report*, National Academy of Sciences Press, Washington, DC, 2006, p. 132. <http://www.nap.edu/openbook.php?isbn=0309100925&page=132>.
- ¹⁴ Melissa L. Phillips. *Registering Skepticism: Does the EPA's Pesticide Review Protect Children?* *Environmental Health Perspectives* Volume 114, Number 10, October 2006.
- ¹⁵ May 25, 1999 SAP meeting.
- ¹⁶ Letter to Administrator Johnson from Presidents of EPA Unions representing scientists, risk managers, and related staff, May 24, 2006. <http://www.panna.org/documents/epaScientistsFqpa.pdf>.
- ¹⁷ *Opportunities to Improve Data Quality and Children's Health through the Food Quality Protection Act*. Report No. 2006-P-00009, January 10, 2006. <http://www.epa.gov/oig/reports/2006/20060110-2006-P-00009.pdf>.
- ¹⁸ 42 U.S.C. §§ 321, 331, 333, 342, 346a
- ¹⁹ *Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA's 2005 Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*. <http://www.epa.gov/osa/mmoaframework/>.
- ²⁰ *Summary Report of the Peer Review Meeting: EPA's Draft Framework for Determining a Mutagenic Mode of Action for Carcinogenicity*. Final Report May 23, 2008. http://www.epa.gov/osa/mmoaframework/pdfs/MMOA_Report_Final508_6-2-08.pdf.
- ²¹ Letter from the Children's Health Protection Advisory Committee, December 14, 2007. [http://yosemite.epa.gov/ochp/ochpWeb.nsf/content/12142007.htm/\\$file/12142007.pdf](http://yosemite.epa.gov/ochp/ochpWeb.nsf/content/12142007.htm/$file/12142007.pdf).
- ²² *Science and Decisions: Advancing Risk Assessment*, National Academies Press, Washington, D.C. 2008. <http://dels.nas.edu/dels/viewreport.cgi?id=5545>.
- ²³ *Phthalates and Cumulative Risk Assessment The Task Ahead*, National Academies Press, Washington, D.C. 2008. http://books.nap.edu/catalog.php?record_id=12528.
- ²⁴ *Phthalates and Cumulative Risk Assessment The Task Ahead*, The National Academies Press, Washington, DC, 2008. http://books.nap.edu/catalog.php?record_id=12528.
- ²⁵ *Toxicity Testing in the 21st Century: A Vision and a Strategy*, The National Academies Press, Washington, DC, 2007. http://www.nap.edu/catalog.php?record_id=11970.