

U.S. Senate Committee on Environment and Public Works

"Oversight Hearing on EPA'S Children's Health Protection Efforts"
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Testimony by
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Dear Madam Chair and Members of the Committee. Good morning. It is an honor to speak before you today about the importance of children's health and the environment, and the track record of the US Environmental Protection Agency (EPA) to address this vital issue. My name is Susan West Marmagas and I am the Director of Health Programs with Commonweal.

Today I am speaking as a former member of, but not representing, the Children's Health Protection Advisory Committee (CHPAC), a federal advisory committee that advises the Administrator of the Environmental Protection Agency by offering scientific review, guidance and technical assistance on children's environmental health. As defined by EPA, the CHPAC is

> "a body of researchers, academicians, health care providers, environmentalists, children's advocates, professionals, government employees, and members of the public who advise EPA on regulations, research, and communications issues relevant to children."[1]

The CHPAC is comprised of a broad swath of children's health experts, all decisions are made by consensus, and every member was appointed or re-appointed by the current administration, myself included. The Committee meets on an average 3 times each year, deliberates on key children's health issues, reaches consensus on its recommendations, and sends letters to the Administrator with advice, comment and recommendations for consideration. I served on the Committee from 2001-2007 during which time we brought numerous children's health concerns to the Agency. Committee rules require that members serve for a maximum of 6 years, therefore in 2007 my term on the Committee ended.

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[1] http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_advisory.htm

Today I would like to touch on the following main points:

Weakened Stature of the CHPAC:
The use of the CHPAC by the Administrator of EPA has changed considerably over the last eight years. At its inception, the Committee was seen as the "go-to" body of experts on children's environmental health for EPA, and the Administrator and key offices sought out the Committee for review, comment and advice on critical policy, regulatory, and science issues. Many of the CHPAC's recommendations were well received by the Agency, and many of them were incorporated into Agency decision-making. Over the last several years, the attention of EPA leadership to children's health overall has waned and the Committee has been seen less as a critical advisory body, and more as just another public commentator. However, that has not stopped the CHPAC from seeking out critical issues and offering its expertise to EPA. The Agency has increasingly ignored CHPAC's recommendations. This shift, I believe, has significantly weakened EPA's attention to children in its rule-making, research and policy affairs.

CHPAC Advice Not Heeded
While the CHPAC serves at the discretion of the Administrator, it is its role to offer the Agency the best scientific and policy advice regarding critical issues that impact the health of children. The Committee role is not solely one of "public comment", but rather is one of a federal advisory committee, set up under the FACA standards, to offer advice. However, the track record from the last several years clearly shows that many of the CHPAC recommendation letters have been viewed by the Agency as just another form of public comment, and not as the result of deliberative review by a body of experts from a broad swath of children's health expertise. In the last few years, the CHPAC has weighed in on such critical issues as the National Ambient Air Quality Standards for particulate matter, ozone and lead, mercury from coal-fired power plants, children's cancer risk assessment, regulation of toxic chemicals including the Voluntary Children's Chemical Evaluation (VCEEP) and High Production Volume Programs, and perchlorate. In numerous instances, the response from the Agency to the CHPAC's extensive and scientifically sound recommendations has been one of form letters, recommendations not heeded, or input treated as solely additional public comment. The problem is not only that the Committee has been ignored, but more importantly that critical children health concerns remain unaddressed.

Case Study I: Mercury and Children's Health
I would like to briefly highlight an example of CHPAC advice not being heeded with the example of the Clean Air Mercury Rule, a rule that has interestingly enough since been struck down by the courts. The CHPAC evaluated the issue of mercury from coal-fired power plants thoroughly and wrote not one, but four, letters to the Administration from January 2004 through January 2005. The recommendations made by the CHPAC were ignored by the Agency.

Beginning in January 2004, the CHPAC took up consideration of the proposed mercury from power plant rule. We reviewed the science on the health effects to children from mercury exposure, extensively questioned lead staff in EPA's Office of Air and Radiation about the EPA's proposed regulations to control mercury emissions from power plants, and examined the EPA's proposed preamble to the rule.

In our initial January 26, 2004 letter to Administrator Michael Leavitt, we outlined the significant health implications of low-dose methylmercury exposure for children. Based on our review of the extensive scientific record of toxicological and medical research on this subject, including an authoritative report by the National Research Council of the National Academy of Sciences, the CHPAC determined the following:

- Exposure to methylmercury in the womb can cause adverse developmental and cognitive effects in children, even at low doses that do not result in effects in the mother[2];
- Prenatal exposure from maternal consumption of fish can also cause impairments later on in the developing child. Recent epidemiologic studies have found that children exposed to even low levels of mercury before birth experience subtle symptoms of neurologic damage. Specific effects include poor performance on neuro-behavioral tests, particularly on tests of attention, fine motor function, language, visual-spatial abilities (e.g., drawing) and memory.[3]
- Infants and children have on-going dietary exposures to methylmercury. Children and infants are sensitive to mercury's effects because their nervous systems continue to develop until about age 20.[4]
- According to CDC's second National Report on Human Exposure to Environmental Chemicals, almost 8 percent of women of child bearing ages (16- 49) have levels of mercury that exceed what is considered safe for a fetus.[5]

Since this letter was written, continuing research in this field suggests that the actual number of infants exposed to methylmercury in utero at levels exceeding the EPA's safe reference dose may be much higher when data on maternal cord blood levels are also considered.[6]

Based on the CHPAC's review of the health effects science and the proposed rule, the Committee raised a number of key findings in our first letter[7] that we would continue to raise unsatisfactorily with the Agency over the next year:

- "This proposed action does not go as far as is feasible to reduce mercury emissions from power plants, and thereby does not sufficiently protect children."
- "From our understanding, the unique vulnerabilities of children, infants and women of child-bearing age were not adequately considered in the development of the EPA's proposed rules...we strongly recommend that EPA, when finalizing the rule, take into greater

[2] U.S. EPA, America's Children and the Environment, 2003.
[3] Toxicologial Effects of Methylmercury. National Academy Press, Washington, DC 2000. http://www.nap.edu.
[4] U.S. EPA. 1997b. Mercury Study Report to Congress, Volume VII: Characterization of Human and Wildlife Risks from Methylmercury Exposure in the United States. EPA-452/R-97-009.
[5] Schober SE, et.al. Blood mercury levels in US children and women of childbearing age, 1999-2000. JAMA 2003:289(13):1667-1674.
[6] Mahaffey KR, Clickner RP, Bodurow CC., Environ Health Perspect. 2004 Apr;112(5):562-70. http://ehp.niehs.nih.gov/members/2003/6587/6587.html
[7] January 26, 2004 from the CHPAC to Administrator Michael Leavitt.

consideration the health impacts on children and women of child-bearing age in as practicable a manner as possible given existing information"

- "Should EPA decide to move mercury regulations to Section 111, thereby changing the definition of mercury from power plants as a hazardous air pollutant, we are concerned about the unintended consequences of this re-classification for regulating mercury at the state level."
- "We recommend that EPA evaluate the possibility that hot spots could result and that the proposed regulation should be written to ensure that existing hot spots are reduced and no new ones created."
- We seek an integrated analysis from EPA with respect to whether emissions reductions under either of these proposals are the most child-protective, timely and cost effective." (including available technologies, costs, health implications, economic benefits)
- "We would like EPA to share the results of this integrated analysis with CHPAC for further consideration so that we may better advise EPA on the most child-protective regulatory options."

In response, political appointees indicated that EPA's strategy was the "the most cost effective and environmental beneficial". The Agency did not respond to the CHPAC's request for additional modeling or other impact analysis assessing the effect of the rule on children's health, or for integrated analysis on technology, costs, children's health impacts, or economic benefits. Upon further reiteration of our concerns, and our request for meetings with senior agency leadership, in two subsequent letters in June 2004 and November 2004, we received little additional responsive action from the Agency, and in January 2005 we sent our final letter to the Agency. Despite our repeated requests, no integrated impact analysis was ever provided to the CHPAC.

Three weeks before the release of the final rule, OAR Director Holmstead agreed to meet with the CHPAC. In the meeting on February 24, 2005, he stated that the Agency did not need to do specific analysis on children's health because the entire rule is about and for children. When asked about an integrated analysis that included children's health impacts, Holmstead promised that this analysis would be in the final rule.

In conclusion, the concerns raised by the EPA's own child health advisors were largely dismissed by the Agency in completing its rule-making on mercury emissions from power plants. The Agency did not conduct a comprehensive analysis on children's health impacts, although they did include a health benefits analysis in the final rule that was never made available for public comment prior to finalization of the mercury rule. The Agency never undertook an integrated analysis to assess technologies, costs, health impacts and economic benefits of more stringent reductions. And, in conclusion, as indicated in Mr. Holmstead's comments to the CHPAC in February 2005, the Agency downplayed or ignored the significant threat of mercury to children's health even in the face of persistent, evidence-based concerns voiced repeatedly by the leading children's health experts in the country.

Two Other Relevant and Timely Examples

National Ambient Air Quality Standards

Similar instances of EPA not heeding the advice of the CHPAC have occurred repeatedly in the last three years that have mirrored the experience with the Clean Air Mercury Rule. I would like briefly touch on the experience with the National Ambient Air Quality Standards. The CHPAC, in its letters to the Agency on particulate matter, ozone and lead, presented the documented health effects on children from all three contaminants. The CHPAC also made recommendations to the Agency about the standards for all three contaminants that would be protective of children. The EPA has not followed the recommendations of the CHPAC, nor the recommendations of the Clean Air Science Advisory Committee (CASAC), the federal committee charged with evaluating EPA's assessment of the science behind the standards. The Agency ultimately set standards that do not provide an adequate margin of safety for infants and children. In his testimony[8] of May 7, 2008 for the Senate Environment and Public Works Committee, Dr. John Balbus outlined the concerns of the CHPAC regarding the NAAQS for particulate matter and ozone, and the inadequate response from EPA.

Perchlorate

The main health risk of perchlorate is its effect on brain function, namely through the impact of perchlorate on the thyroid. The CHPAC in 2006 offered comments and recommendations on EPA's Office of Solid Waste & Emergency Response (OSWER) preliminary remediation Goal (PRG) on perchlorate.[9] The CHPAC letter stated that:

> "Perchlorate is a well-recognized endocrine disruptor at sufficiently high doses, targeting the thyroid and thus creating risk of neurodevelopmental toxicity. A key concern is the nursing infant because of the potentially high exposure rate associated with this pathway, and the high susceptibility at this life stage."

The CHPAC letter specifically outlined the risk to breast feeding infants, a population not considered in the development of the PRG, and yet the population deemed by the CHPAC to be most at risk from perchlorate exposure in breast milk. The CHPAC's review of the published literature concluded that a "nursing infant exposure is approximately 5 to 10 times higher than the perchlorate RfD." The CHPAC also outlined how infants are not only more exposed, but more susceptible to the neurodevelopmental effects of perchlorate because the central nervous system is still developing.

The CHPAC, after reviewing the PRG, concluded that:

> "The OSWER PRG ignores the higher exposure and susceptibility of infants, and could lead to nursing and bottle-fed infants being exposed to daily doses that are well above the perchlorate RfD; the PRG needs to protect this susceptible population."

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[8] Testimony of John M. Balbus, MD, MPH, Oversight Hearing on Science and Environmental Regulatory Decisions Public Sector Solutions to Global Warming, Oversight, and Children's Health Protection, Subcommittee of the U.S. Senate Environment and Public Works Committee (May 7, 2008)

[9] Letter from Melanie Marty to Administrator Stephen Johnson regarding perchlorate PRG and water contamination (March 8, 2006)

The extensive input from the CHPAC was not addressed by EPA, and the recommendations have yet to be incorporated into Agency action. Specifically, the OSWER did not consider the significant issue of transport of perchlorate into breast milk and the elevated exposure of a nursing infant.

Since that time, additional studies and analyses have been published that make an even more compelling case to protect infants by setting a stronger PRG, a more protective RfD, and an overall drinking water standard for perchlorate. Specifically, as outlined by Dr. Gary Ginsberg in his April 25, 2007 testimony for the House Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce[10], the following findings justify the need for protective policy on perchlorate.

Most notably from the 2006 CDC study, evidence has emerged that at low exposures common across our population, perchlorate appears to disrupt the thyroid gland in humans[11]. The CDC study found an association between perchlorate exposure in the general population and altered thyroid status, namely low thyroid hormone, high TSH. The effect was only seen in women and only in those women with low iodide intake. This increases the concern that pregnant women could be especially at risk. The CDC study is more powerful than the study used by NAS and EPA to set the RfD as it involved thousands of subjects, it divided the population based upon known risk factors including low iodide intake, and it included a reliable exposure measure, urinary levels of perchlorate.

The CDC study confirms concerns raised by Ginsberg and others about the RfD as the association between perchlorate exposure and impaired thyroid function occurred at background population exposures that are 10 fold below the RfD. Ginsberg, et.al[12] found that perchlorate effects in a key subgroup of the population (the 36% of women with low iodide intake) indicates that the concerns are greater than originally thought with perchlorate, The CDC study offers a compelling justification for an overhaul of the RfD so that it more fully reflects the human epidemiology and laboratory data.

In addition, recent publications also built an even more compelling case to recognize the special vulnerability of the nursing infant to perchlorate. In the Ginsberg, et.al[13], the authors also document the "double jeopardy for the nursing infant", both lower iodine intake and a substantial dose of perchlorate.

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[10] http://energycommerce.house.gov/cmte_mtgs/110-ehm-hrg.042507.Ginsberg-testimony.pdf

[11] Blount BC, Pirkle JL, Osterloh JD, Valentin-Blasini L, Caldwell KL. 2006a. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. Environ Health Perspect 114:1865-1871.

[12] Ginsberg, G.L., Hattis, D.B., Zoeller, R.T. and Rice, D.C. (2007) Evaluation of the USEPA/OSWER Preliminary Remediation Goal for perchlorate in groundwater: focus on exposure to nursing infants. Environ Health Perspect 115: 361-369.

[13] Ginsberg, et.al

Taken together with the CHPAC recommendations, these latest publications demonstrate a compelling justification for setting a child-protective drinking water standard for perchlorate.

Significant Decrease in EPA Leadership on Children's Health

Over the last eight years, there are specific examples of how the priority on children's health has been steadily decreasing. After having a permanent director running the Office of Children's Health Protection from 1997-2001, the Office was without a permanent director until just recently. During this time, the CHPAC repeatedly called in its letters to the Administrator to address this leadership gap, however the position remained empty. The CHPAC's December 16, 2002 highlighted that:

> "the Advisory Committee is deeply concerned that the OCHP is currently without a permanent director and has been for seven months. Consistent with your dedication to children's environmental health, we urge you to promptly fill this position with an energetic and well-qualified staff member."

At the same time, additional issue areas were added to the Office's mission without additional financial or staffing resources to support them. First, an aging initiative was added and most recently environmental education. In the same December 16, 2002 letter[14] the CHPAC expressed concern that:

> "expanding the mission of OCHP to cover environmental health concerns of both children and the aging will do justice to neither effort, thus diminish the effectiveness of both. We believe that OCHP should retain its present name and mission."

EPA Administrator Christine Todd Whitman responded[15] assuring the CHPAC that "additional resources are needed for the Aging Initiative and…. that EPA does not intend to reduce funding for children's health initiatives to meet that need."

However, the commitment of EPA leadership to children's health continues to diminish. Since the aging initiative was added, the office was more recently expanded the office to also include environmental education. And, once again, reduction in the budget and staff dedicated to children's environmental health has occurred.

The CHPAC most recently addressed this issue in its April 10, 2007 letter[16] to the Administration – in honor of the 10th anniversary of the Executive Order 13045: Protection of

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[14] Letter from Melanie Marty to Christine Todd Whitman supporting the Initiative on Aging, but suggesting that the aging initiative be established as an independent office or effort instead of expanding the name and mission of OCHP (December 16, 2002)

[15] Response from Christine Todd Whitman to Melanie Marty thanking the Committee for their input on the Aging Initiative and the need to select a permanent director for OCHP (May 2, 2003)

[16] Letter from Melanie Marty to Administrator Stephen Johnson regarding the ten year anniversary of the Children's Health Executive Order (April 10, 2007)

Children from Environmental Health Risks and Safety Risks**.** The letter called for EPA to make a renewed commitment, specifically stating that:

- We have a moral imperative to leave the world cleaner, healthier and safer for our children;
- EPA's focus on children's environmental health has diminished in recent years;
- Considerations of children are still not explicitly considered in all relevant and critical Agency decisions and policies;
- EPA has not capitalized on opportunity to tackle significant challenges.

The letter presented seven key elements for EPA's vision on children's environmental health, and called on EPA to work with other federal and state agencies to make these happen:

- Ensure healthy environments for our children, including the recommendation that all regulations should address the unique susceptibilities of children;
- Eliminate environmental health disparities in populations at risk;
- Expand critical research to address impacts on children, especially addressing multiple exposures at all life stages, and addressing ethnical considerations;
- Strengthen the national approach to regulating chemicals, address flaws in our chemical regulatory system and put children at the center of a comprehensive effort;
- Foster environmental preparedness and prevention by taking preventive steps to address the threat of climate change and impact on children from natural disasters and terrorism;
- Institute "environmental health literacy" through strong educational, right-to-know programs, and community programs;
- Commit necessary infrastructure, leadership and resources within EPA and help to lead inter-agency collaboration on pursuing this vision.

Even though the Administrator took issue with the CHPAC's conclusion that the EPA's focus on children's health had diminished, he did commit the Agency to convene key staff across the Agency to address the seven elements. What has happened to the efforts to move the recommendations forward? It seems that the initial effort has now stalled yet again within the Agency.

Turning now from the role of the CHPAC in advising EPA decision-making on children's environmental health, I believe that the 10th anniversary letter also offers a 'roap map" to other federal agencies and Congress.

In my role as a leader in the field of children's environmental health, I would like to briefly comment on an legislative opportunity to address critical gaps in protecting America's children from exposure to toxic chemicals.

Kid-Safe Chemicals Act

As has been significantly documented, the Toxic Substances Control Act is severely lacking in its ability to protect children, and our most vulnerable, from exposure to toxic chemicals. As a member of the CHPAC, it proved challenging to offer effective recommendations about EPA toxic chemicals program because it is so significantly limited by current law. Without a more comprehensive approach to regulating toxic chemicals, EPA and our nation cannot effectively address this critical children's health issue. I believe that the Kid-Safe Chemicals Act, by prioritizing children, will protect the public's health more broadly. The Act will ensure

publically available health and safety information for the vast majority of chemicals and will put the burden of proof on chemical manufacturers to demonstrate that their chemicals are safe for children. The Act also codifies inter-agency collaboration with the specific partnership between EPA and the Centers for Disease Control and Prevention in the collection of biomonitoring data. This Act offers a comprehensive solution to our current regulatory system and is supported by a broad swath of public health, health professional, environmental, and community-based organizations.

Observational Studies of Children

In 2005, EPA was in the process of quietly setting up an observational study of children's exposure to pesticides in Florida, when this effort came to the public's (and the US Senate's) attention. Significant ethical issues were evident in the study design, and questions were raised by ethics professionals, scientists and the public health community across the United States as to the validity and ethics of such a study. The study, known as CHEERS, was abandoned under pressure, and the Agency has since developed guidance for future observational studies. However the Agency has not thoroughly addressed the concerns expressed by the US Senate. In the interim, the EPA released new rules on human testing, and the rules are currently being challenged in court.

However, EPA this summer released a RFA for a new $2.5 million cooperative agreement on observational studies and children. While the RFA seemed to be addressing some of the concerns raised by the proposed CHEERS study, it left open the door for a similar study to be approved. The RFA was cancelled last week. It seems prudent to thoroughly address the concerns that have been raised about observational studies and to wait until the concerns about the human testing rule are resolved by the courts. Given the track record of this Administration, I believe it is important for the Administrator to thoroughly address the concerns raised before new efforts are undertaken.

In conclusion, I would like to thank you for addressing vital children's health issues facing EPA and the nation. It has been my honor to present testimony about issues facing our children. I am happy to provide more specific detail, or answer any specific questions that you may have.

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Susan West Marmagas, MPH is the Director of Health Programs with Commonweal where she co-leads the Women's Health and Environment Initiative – an emerging national network of health, women's and environment leaders and organizations undertaking collaborative projects to improve the health of women in the US and globally. Based in Blacksburg, VA, West Marmagas recently returned to her rural roots to also help improve local public health in southwestern Virginia and Appalachia. She currently advises the Appalachia Community Cancer Network to address potential environmental determinants of cancer in the region.

West Marmagas has over fifteen years of experience in the public health field, most notably in the area of children's and women's environmental health. She joined Commonweal after serving as the Director of Environment & Health Programs at Physicians for Social Responsibility (PSR) in its national office in Washington, DC. In this position, she led PSR's national environmental health program, focusing on toxics and children's health, clean air and climate change, environmental public health tracking, and the emerging links between the environment and chronic disease. She has also held senior positions with the Children's Environmental Health Network and the National Environmental Education Foundation.

She received her Master of Public Health with a concentration in Community Health Education from the University of California at Berkeley and her Bachelor of Arts in International Studies from Earlham College. Her career has focused on engaging health professionals and scientists in protective public policy, facilitating strategic planning discussions across the health and environment fields, and implementing evidence-based policy efforts. West Marmagas has testified before the US Congress and has served as media spokesperson on national issues such as fish consumption, mercury pollution, and children's health. She served on the U.S. Environmental Protection Agency's Children's Health Protection Advisory Committee and co-chaired its Regulatory Work Group. She is a Site Visitor for the Council on Education for Public Health and a Fellow with the National Public Health Leadership Institute. West Marmagas serves in leadership with the American Public Health Association, including as former Chair of its Environmental Health Section.