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February 4, 2014

Testimony of
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On behalf of the
American Academy of Pediatrics

Before the
House Energy and Commerce Subcommittee on the Environment and the Economy

"Testing of Chemicals and Data Reporting of Information Under Toxic Substances Control Act (TSCA) Sections 4 and 8."

Good morning Chairman Shimkus, Ranking Member Tonko, and other members of the Subcommittee on Environment and the Economy, and thank you for the opportunity to testify today about the testing and data collection requirements under the Toxic Substances Control Act of 1976 (TSCA) under Sections 4 and 8.

My name is Dr. Jerome Paulson; I am here representing the American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. I currently serve as chair of the AAP's Council on Environmental Health.

In addition to my role within the AAP, I also serve as Director of the Mid-Atlantic Center for Children's Health and the Environment, this region's Pediatric Environmental Health Specialty Unit (PEHSU), housed at Children's National Medical Center. I am also a professor of pediatrics and of environmental and occupational health at George Washington University.

Chemical Management Reform Is an Important Child Health Policy Priority

Chemical management reform is an important policy that uniquely impacts child health. Children are not little adults. They have unique physiologic, behavioral, and developmental differences that amplify their exposure to environmental chemicals. Because children are smaller than adults, their surface area–to–body mass ratio is greater. Children eat more food and drink more water per unit of body weight than do adults. The respiratory minute ventilation—inspired air per unit time adjusting for weight—is greater in young children than in adults[i].

As children grow and mature, their bodies may be especially vulnerable to certain chemical exposures during critical windows of development. For example, infants may be exposed to contaminants in water used in formula preparation and chemicals that may leech from bottles used during feeding. Toddlers engage in normal mouthing behaviors where they put foreign objects into their mouths that may expose them to dangerous toxins. Children of all ages spend more time on the floor or ground than do adults and come into more contact with contaminants on these surfaces[ii].

Not only do children have more opportunities to be exposed to environmental chemicals, extensive evidence supports a causal relationship between prenatal and childhood exposure to environmental chemicals and a variety of health effects in the fetus and the child.

A substantial proportion of chemicals are known to have a wide range of adverse – and mostly irreversible -- effects on child health. Metals such as lead, mercury, and arsenic can have negative developmental and behavioral effects at very low levels of exposure. Polychlorinated biphenyls exposure is associated with reduced intelligence. Prenatal exposures to phthalates and bisphenol A (BPA), used in plastics, cosmetics, and other household products, are associated with behavioral abnormalities. Prenatal exposure to brominated flame retardants can be linked to cognitive impairments, and prenatal exposure to perfluorinated chemicals used for nonstick pans has been linked to decreased infant birth weight and head circumference. U.S. Centers for Disease Control and Prevention (CDC) researchers have found measurable levels of over 200 common industrial chemicals in body tissues and fluids of children of all ages, including in cord blood. A number of hazardous chemicals also appear in breast milk[iii].

Understanding children's unique susceptibility to chemical exposure and the lifelong health impacts, the AAP published a 2011 policy statement titled, *Chemical-Management Policy: Prioritizing Children's Health,* which calls for reform of TSCA, the primary federal law that governs chemical management in the United States. In addition, the American College of Obstetricians and Gynecologists, American Medical Association, American Public Health Association and American Nursing Association have endorsed the need for changes to TSCA.

Unfortunately, the law as written is not protective of the health of children and pregnant women and has not undergone any meaningful revision since its passage. Within nearly four decades, TSCA has been used to regulate only 5 chemicals or chemical classes: polychlorinated biphenyls; fully halogenated chloroflouroalkanes, dioxin, asbestos, and hexavalent chromium.

Each time one of these chemicals or classes of chemicals was regulated, it required Congress to specifically amend the legislation. The law as currently written does not allow the U.S. Environmental Protection Agency (EPA) to collect adequate data on safety to make regulatory decisions. As a result, there are tens of thousands of other chemicals in commerce where adequate information about health and safety is lacking.

The AAP's policy statement outlines an extensive set of concerns but consistent with the scope of today's hearing, my testimony will primarily focus on testing requirements and data collection and reporting.

Toxic Substances Control Act Section 4 Testing Requirements Are Inadequate.

The safety testing requirements under Section 4 of TSCA are inadequate to protect child health and place too great of a burden for safety testing on the public sector. Chemicals introduced into commerce when the law was enacted have little oversight because TSCA distinguished between chemicals in existence in 1976 and those introduced after the passage of the law. Those on the market decades ago were assumed to be relatively safe and in need of less testing than "new" chemicals. To pursue regulation of these "existing" chemicals, the EPA must demonstrate that a chemical has a high likelihood of causing harm before it can order testing to determine if there is a health risk. Between 1979 and 2005, the EPA has used its authority to require testing on fewer than 200 chemicals in commerce.[iv]

The reason for this dearth of testing data from chemical companies to EPA on existing chemicals is directly tied to the inadequacies of Section 4 of TSCA. Section 4 directs the EPA to require chemical manufacturers and processors to conduct testing on existing chemicals under certain circumstances. EPA has the authority to do so when the manufacture, distribution, processing, use, or disposal of those chemicals may present an unreasonable risk of injury to health or the environment, or when those chemicals are produced in substantial quantities and there is a significant or substantial potential for environmental release or human exposure. Additionally, EPA must determine that existing data on the chemical are insufficient to predict the effects of human exposure and environmental releases, and that testing is necessary to develop such data[v].

This structure of Section 4 is fundamentally flawed because it significantly burdens EPA with requirements to adequately demonstrate the potential danger of a chemical to human health or the environment before it may move forward with compelling companies to conduct testing on these chemicals. In doing so, TSCA places the majority of the burden of obtaining information about the potential toxicity of a chemical on the public rather than the manufacturer. This limits EPA's ability to protect the most vulnerable, including children and pregnant women, because they face substantial barriers to obtaining the information they need to make effective risk management decisions.

An additional flaw that compounds these issues within Section 4 is that TSCA does not allow review of chemicals by group, instead requiring regulation on a chemical-by-chemical basis. With tens of thousands of chemicals in need of review and the multiyear process for each such undertaking, it would require many decades to review just the high-production chemicals. This compounds the inefficiencies of Section 4 and prevents the timely analysis of the safety of thousands of chemicals[vi].

Toxic Substances Control Act Data Gathering and Reporting Standards Under Section 8 Need Reform.

Under TSCA Section 8, companies are required to keep a file of allegations of significant adverse reactions (to human health or the environment) of any chemical they manufacture, import, process or distribute. Companies must also provide this information to EPA upon request. Companies may be required to submit to EPA a list and/or copies of unpublished studies that address the health or safety issues of certain listed chemicals[vii].

Companies are under a duty to report to EPA within 30 days any new information they have which reasonably supports the conclusions that a substance or mixture they manufacture, import, process or distribute presents a substantial risk of injury to health or the environment. The law also requires that notices be submitted within 30 calendar days after obtaining information that a substance or mixture presents a substantial risk[viii].

TSCA has created a non-evidence-based system for chemical management. As a pediatrician, I can attest that parallels currently exist, such as within prescription drug regulation, which could provide guidance as to how EPA's authority could be strengthened with regard to data gathering and reporting.

Under current law, concerns about chemicals are permitted to be kept from the public. In their notifications to the EPA, chemical companies may declare large amounts of information to be confidential business information (CBI). This broad exemption has effectively prevented the EPA from sharing information about potentially hazardous chemicals with community groups, local and state governments and foreign governments or international organizations[ix].

Certainly, an effective management system must include greater transparency than what is currently in existence. There are many important regulatory practices that protect public health while supporting innovation, which could be incorporated into TSCA reform efforts.

Recommendations for TSCA Reform.

Given the urgent and ongoing threat to child health posed by chemical exposures, the AAP respectfully submits the following key recommendations for reforming TSCA:

1) **Under Section 4, manufacturers should be required to provide minimum data sets that provide information that is relevant to the special needs of pregnant women and children and provide data on reproductive, developmental, neurodevelopmental toxicity and endocrine disruption. Furthermore, EPA needs the flexibility to change data collection processes as new methodologies for testing become available.**

2) **Under Section 4, the EPA should have a simple process to require additional testing when information suggests the need for such testing.**

3) **Federal biomonitoring programs such as the CDC's National Biomonitoring Program must be expanded. It is well recognized that this program provides secondary prevention, but it may serve as an early warning system. Stored samples may allow look-backs when new problems develop in the future.**

4) **When appropriate for hazard determination, there must be consideration of aggregate and cumulative exposure concepts similar to those of the Food Quality Protection Act (FQPA). For example, the law standardized and mandated a health-based standard for pesticides used in foods. It also provided special protections for babies and infants, streamlined the approval of safe pesticides, established incentives for the creation of safer pesticides, and required that pesticide registrations remain current.**

5) **Companies must develop a public information document for each new chemical marketed. This document should be in lay language and approved by EPA before the chemical is marketed. A companion document should be updated with each new formulation every three years.**

Conclusion.

In conclusion, strong chemical management policy must integrate evidence-based decision making for chemical use to adequately protect children and other vulnerable populations from harm.

There have been a number of legislative proposals introduced to revise federal chemical management policy. It is important to note that while the AAP strongly supports bipartisan engagement within Congress to enact TSCA reform; the organization has not supported or endorsed the Chemical Safety Improvement Act of 2013.

The AAP looks forward to working with you to advance sound and protective chemical management policy during the 113th Congress. I welcome the opportunity to answer your questions.

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[i] American Academy of Pediatrics, Council on Environmental Health. Pediatric Environmental Health, 3rd Edition. 2012.
[ii] American Academy of Pediatrics, Council on Environmental Health. Policy Statement: Chemical-Management Policy: Prioritizing Children's Health. *Pediatrics*. 2011; 127(5): 983-990.
[iii] American Academy of Pediatrics. Toxic Chemicals: An Untested Threat to Child Health. Policy Brief. October 2013.
[iv] American Academy of Pediatrics, *Pediatrics*. 2011; 127(5): 983-990.
[v] Schierow, Linda-Jo. Congressional Research Service. The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements. February 23, 2011.
[vi] American Academy of Pediatrics, *Pediatrics*. 2011; 127(5): 983-990.
[vii] Schierow, Linda-Jo. Congressional Research Service. The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements. February 23, 2011.
[viii] Ibid
[ix] Gomeze, Alfredo. Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation. Testimony before the Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives. June 13, 2013.