Case No. 17-72260
Consolidated with Docket Nos. 17-72501, 17-72968, 17-73290, 17-73383, 17-73390

In the United States Court of Appeals for the Ninth Circuit

SAFER CHEMICALS, HEALTHY FAMILIES *et al.*,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY *et al.*,

Respondents.

IPC INTERNATIONAL, INC. *et al.*,

Respondents-Intervenors.

On Petition for Review of Final Rules of the U.S. Environmental Protection Agency

BRIEF OF *AMICI* THE AMERICAN ACADEMY OF PEDIATRICS, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AND THE AMERICAN PUBLIC HEALTH ASSOCIATION IN SUPPORT OF PETITIONERS

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CORPORATE DISCLOSURE STATEMENT

Amici do not issue stock and have no parent corporations.

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I. STATEMENTS OF INTEREST[1]

Amici are organizations of health professionals that collectively represent more than 124,000 health care providers who have expertise in the health and wellbeing of pregnant women, infants, and children. Pregnant women, infants, and children are disproportionately exposed to and impacted by the toxins regulated under the Toxic Substances Control Act ("TSCA"). As a result, *amici* have a strong interest in Petitioners' challenges to the final TSCA rules because those rules, if not vacated, empower the United States Environmental Protection Agency ("EPA") to ignore significant health risks posed by TSCA-covered chemicals, especially those affecting pregnant women, infants, and children.

Amicus the American Academy of Pediatrics ("AAP"), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of AAP has grown from the original group of 60 physicians specializing in children's health to 66,000 pediatricians. Over the past 88 years, AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the well-

[1] No party's counsel authored this brief in whole or in part nor did a party, its counsel, or any other person contribute money to fund preparing or submitting this brief. *See* Fed. R. App. P. 29(a)(4). All parties have consented to the filing of this *amicus* brief.

being of America's children. AAP has engaged in broad and continuous efforts to prevent harm to the health of infants, children, adolescents, and young adults caused by exposure to chemicals. This work has included the issuance of an evidence-based policy statement on chemical management and commenting on and offering testimony regarding the implementation of TSCA.

Amicus the American College of Obstetricians and Gynecologists ("ACOG") is a national, non-profit educational and professional organization that works to promote the advancement of women's health through continuing medical education, practice, research, and advocacy. With more than 58,000 members, ACOG is the leading organization of women's health care providers. ACOG is dedicated to preserving and improving women and children's health by reducing prepregnancy and prenatal exposure to environmental toxins. ACOG's work in this regard has included developing clinical guidance on exposure to toxic environmental agents and commenting and offering testimony regarding amendments to TSCA and those amendments' implementation.

Amicus the American Public Health Association ("APHA") champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices, and advocates for public health policies grounded in research. APHA represents over 20,000 individual members and is the only organization that combines a nearly

150-year perspective and a broad-based member community with an interest in improving the public's health. APHA has long advocated in support of protecting pregnant woman, infants, children, and others from harmful chemical exposures. This work has included commenting and offering recommendations regarding amendments to TSCA and those amendments' implementation.

II. INTRODUCTION

Although exposure to toxic chemicals can have negative consequences for all people, the risk is especially pronounced for vulnerable populations such as pregnant women, infants, and children. Robust scientific evidence demonstrates that exposures to toxic chemicals in prepregnancy and prenatal stages of human development as well as in childhood can have profound and lasting impacts on health across the life course. Moreover, as infants and children grow and mature, their unique physiologic, developmental, and behavioral differences make them especially vulnerable to chemical exposures during critical windows of development. Women who are pregnant also have a unique risk of harm from exposures because physical changes to a woman's body during pregnancy make women more susceptible to toxic chemicals.

To protect the public from the dangers that toxic substances cause, in 1976 Congress passed TSCA, which directed EPA to oversee reporting, record-keeping, and testing requirements, as well as restrictions relating to chemical substances.

Although TSCA was a significant step in protecting the public from toxic exposures, medical experts, scientists, and the public health community, including *amici*, expressed significant concerns that TSCA as implemented did not adequately protect the public from toxic exposures and particularly fell short in protecting vulnerable patient populations such as pregnant women, infants, and children.

To address these and other concerns, in 2016, Congress amended TSCA to increase the statute's protections of public health. To this end, Congress added two requirements: (1) that EPA determine whether a chemical presents an unreasonable risk to human health or the environment—and thus requires regulatory management—*without* considering the costs of regulation, and *solely* based on a comprehensive assessment of the harms the chemical could cause; and (2) that EPA pay particular attention to the risks a chemical listed on the TSCA Chemical Substance Inventory ("TSCA chemical") poses to vulnerable subpopulations, including pregnant women, infants, and children.

Yet, in 2017, EPA finalized rules—EPA's so-called "Framework Rules"—that undermine both statutory commands. The Framework Rules consist of (1) the "Procedures for Chemical Risk Evaluation" rule, which concerns how EPA will analyze the risks TSCA chemicals pose; and (2) the "Procedures for Prioritization of Chemicals for Risk Evaluation" rule, which concerns which TSCA chemicals

EPA will evaluate for risks. These Rules provide the agency will *not* be driven by health and environmental concerns, but instead by other policy considerations. In issuing these Rules, EPA declared it is empowered to select which exposures it considers in its analysis. The agency further stated it need not consider *any* exposure unless it results from the *current sales* of a chemical—EPA stated it can exclude from its analysis risks from ongoing and prior uses of a chemical, if the chemical is no longer sold for those purposes.

Unsurprisingly, by drastically narrowing the risks EPA will consider in deciding whether and how it should regulate chemicals, the Framework Rules endanger everyone, but especially vulnerable subpopulations like pregnant women, infants, and children. If not enjoined, EPA's approach will enable it to ignore numerous types of exposures, which is particularly dangerous for subpopulations whose size, metabolism, and developmental stage mean chemicals are more likely to accumulate in their body, so any additional exposure presents a special risk. Moreover, EPA's analysis is designed to exclude from consideration the precise type of exposures—those that come from chemicals lingering in the environment—to which pregnant women, infants, and children are uniquely susceptible.

The likelihood for under-regulation due to EPA's Framework Rules is easily seen by applying the agency's approach to two well-studied chemicals with

established detrimental health effects that disproportionately harm pregnant women, infants, and children: lead and polybrominated diphenyl ethers ("PBDEs"). Yet, in both instances, the Rules single out for exclusion from EPA's analysis the precise types of exposures that have been demonstrated to cause lifelong disabilities, starting from pregnancy.

Rather than enhance protections, EPA's Rules create the guise of review and regulation while allowing known harms to linger. This endangers the very populations that Congress sought to protect; it is bad policy, and it is unlawful.

III. ARGUMENT

A. EPA's Framework Rules Undermine the 2016 TSCA Amendments and Endanger the Public Health.

Congress's 2016 TSCA amendments directed EPA to evaluate covered chemicals solely based on the risks each chemical presents—Congress expressly precluded EPA from taking cost and other factors into consideration when deciding whether a TSCA chemical presents an unreasonable risk requiring regulation. Moreover, Congress required that EPA's regulation result from a comprehensive review of the chemicals' dangers, especially considering how the chemicals could differently impact distinct subpopulations—such as pregnant women, infants, and children. According to the amendments, if EPA determines a chemical poses an unreasonable risk, EPA *must* act to restrict the chemical's use.

Yet, EPA's Framework Rules—laying out how EPA will conduct its unreasonable-risk assessments and identify which chemicals it will subject to that analysis—insist the agency can exercise discretion in deciding what exposures it considers, undermining the statutory mandates. EPA's Rules state the exposures it chooses to evaluate will be informed by non-risk-based "policy" considerations, akin to economic considerations, *and* declare that EPA will typically decline to consider certain pathways to exposure. EPA's approach will enhance the risks from exposures for all and will particularly put subpopulations like pregnant women, infants, and children—who are more at risk from every exposure—in harm's way.

i. The pre-amendment TSCA standards failed to sufficiently capture risks to pregnant women, infants, and children presented by chemicals.

TSCA's amendments resulted, in part, from the recognition that EPA's determination whether to regulate chemicals based on non-risk-based factors was inconsistent with statute's purpose "to take action with respect to chemical substances and mixtures which are imminent hazards" to public health and the environment. 15 U.S.C. § 2601(b)(2). The pre-amendment standard "require[d] a balancing of health and economic factors *before* the agency [could] act." Letter from Health Organizations to Members of Congress 1 (Feb. 12, 2016) (emphasis

added).[2] During the amendment process, *amici* joined with numerous other health organizations to explain that such an approach failed to protect the public. *Id*. It empowered EPA to disregard certain harms and thus weaken protections, particularly the risks presented by "aggregate" exposures, where each individual exposure might seem insignificant as compared to the cost of regulation, but the exposures accumulate to compound one another, collectively producing additional harms. Letter from AAP & APHA to Senate Leadership 2 (Mar. 20, 2015).[3]

As a result, prior to the 2016 amendments, EPA's approach to TSCA chemical regulation was under-protective for some of the most at-risk populations: pregnant women, infants, and children. These populations are at vulnerable developmental stages where *any* exposure is more likely to have substantial, irreversible negative impacts. *Id.* at 1-2. *See also* Muhammad Akmal Siddiqi, PhD, et al., *Polybrominated Diphenyl Ethers (PBDEs): New Pollutants-Old Diseases*, 1 Clinical Medicine & Research No. 4, 2003 at 284-85. Thus, an assessment that allows EPA to disregard exposures necessarily puts these groups in danger.

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[2] *Available at* https://www.apha.org/-/media/files/pdf/advocacy/letters/2016/160212_tsca_signon_epw_ec.ashx.
[3] *Available at* https://www.scribd.com/document/261725447/American-Academy-of-Pediatrics-American-Public-Health-Assoc.

Physiologically, these subpopulations are less able to withstand seemingly "minor" exposures that a cost-benefit analysis might allow to continue. Throughout development, humans undergo dramatic changes in their ability to metabolize and excrete chemicals, meaning the consequence of any, even seemingly insignificant, exposure can be much more impactful *in utero* and during early development. *See, e.g.*, Hong Lu and Sara Rosenbaum, *Developmental Pharmacokinetics in Pediatric Populations*, 19 J. Pediatr. Pharmacol. Ther. No. 4, 2014 at 262. In addition, children's surface area to body mass ratio is greater than adults, so children more readily absorb toxic substances that turn into high concentrations in their bodies. Letter from American Academy of Pediatrics to Jim Jones, Assistant Administrator, U.S. EPA, Docket No. EPA-HQ-OPPT-2016-0399, at 1 (Aug. 24, 2016) ("First Letter from AAP to Jim Jones"). Further, each exposure is relatively greater for children because, "Pound for pound, children also breathe more air, eat more food, and drink more water than do adults and therefore have greater exposure than adults to toxic chemicals in air, food, and water." *Id*.

Children are also more likely to suffer from indirect and environmental exposures that tend to go unregulated if EPA focuses on the cost or effeciency of regulation. For instance, TSCA chemicals—as discussed below, including PBDEs and lead—can permeate the ground on which children play, be brought home on family members' clothing, and accumulate in household dust. *Id.* at 2-3. These

pathways create only "minor" additional exposures for adults, but are major sources of exposure for children and difficult to protect against. This is particularly the case because of the developmentally appropriate hand-to-mouth behaviors of infants and small children and the fact that they play on the floor where dust and dirt settles. *See id.* at 2. Put simply, children are much more likely to be impacted by toxins present in the environment via exposure mechanisms that are not equally significant for adults. World Health Organization, *Lead Poisoning and Health* (last visited Apr. 20, 2018).[4]

During pregnancy, changes in a woman's physiology—such as increases in the volume of air inhaled/exhaled and increases in cardiac output—make pregnant women more susceptible to toxic chemicals. UCSF, *Pregnant Women + Chemicals Don't Mix* (Apr. 2018).[5] As a result, levels of toxins that might not affect a non-pregnant adult present risk and danger to a pregnant one.

In short, pregnant women, infants, and children are at risk from exposures that tend to be pushed to the side by a non-risk-based analysis, as they are subject to the sorts of exposures that could be labeled as minimal, difficult to quantify, or economically inefficient to regulate.

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[4] *Available at* http://www.who.int/mediacentre/factsheets/fs379/en/.
[5] *Available at* https://ucsf.app.box.com/s/hznrlz3tislhyr9u25ghsg2di0kozqxy.

ii. Congress directly responded to these concerns in the 2016 amendments.

The 2016 amendments directly addressed the concerns of *amici* that the prior TSCA regime was under-protective. Congress established a new risk assessment paradigm, requiring EPA to determine whether chemicals require regulation "without consideration of costs or other nonrisk factors." 15 U.S.C. § 2604(a)(3)(A); *see also, e.g.*, § 2605(b)(4)(A)(i) (making clear that prioritization determinations must be made "without consideration of costs or other nonrisk factors"); § 2606(b)(1) (authorizing judicial relief to protect "health or the environment from unreasonable risk … without consideration of costs or other nonrisk factors").

Congress coupled this instruction with the directive that EPA's risk-based-analysis should consider all "conditions of use," including those that might not be considered risky based on their impact to the population as a whole, but could be found to create "an unreasonable risk to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(a)(3)(A); *see also, e.g.*, § 2605(b)(4)(A) (providing that prioritization determinations must be made based on all "conditions of use"). A risk that was unreasonable for some, but not all, is a risk EPA must now consider.

Seeking to ensure EPA would not narrow its consideration of the dangers chemicals pose, the amendments make clear "conditions of use" has its natural, broad meaning: It includes all foreseeable ways in which a chemical is or would be employed. Congress provided that "conditions of use" means "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or [ ] any combination of such activities." 15 U.S.C. § 2605(a); *see also* § 2602(4) (defining "conditions of use" to "mean[] the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of").

Congress also removed any doubt that EPA should consider the potential for harms caused by indirect exposures, including exposures that may only cause damage through the chemical accumulating in the body from multiple exposures. EPA must "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance." 15 U.S.C. § 2605(b)(4)(F). Each risk evaluation should account for the ways in which the chemical "persist[s]" in the environment, creating multiple pathways for exposure and resulting in "bioaccumulation." 15 U.S.C. § 2605(b)(1)(A) (stating these are factors that should be included in EPA's prioritization of risk evaluations). Where EPA understands that multiple exposures

could occur and compound one another, it must consider how those multiple exposures interrelate and the unique harms this could produce.

Relatedly, the amendments explained, the potentially susceptible subpopulations EPA must consider include any population that "due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, [and] pregnant women." 15 U.S.C. § 2602(12). That is, EPA must pay specific attention to the "greater risk[s]" chemicals pose to subpopulations like pregnant women, infants, children, whose greater susceptibility results, at least in part, from the risks caused by *cumulative* exposures.

In short, Congress directed EPA to determine the nature and extent of its TSCA chemical regulations based on a comprehensive and complete understanding of the human health harms the chemical could produce, including the risks those chemicals pose by accumulating in the body.

iii. EPA's Framework Rules are contrary to and undermine the statute's text and objectives and endanger the public health.

In contrast to the Congressional directive that EPA act based on all foreseeable chemical exposures, EPA's Framework Rules narrow what exposures the agency will consider based on non-risk-based considerations, which EPA acknowledges will cause it to disregard the types of exposures most likely to harm

pregnant women, infants, and children, and particularly the risks from cumulative exposures. *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33730 (July 20, 2017) (acknowledging its non-risk-based considerations will cause the agency to exclude exposures that are naturally part of an "aggregate exposure" analysis).

Although Congress directed that EPA's risk-based-analysis should consider all "conditions of use," including those that could be found to create "an unreasonable risk to a potentially exposed or susceptible subpopulation," EPA has interpreted the "conditions of use" it must consider to provide it "discretion" to decide what it "will address in its evaluation" of chemicals. *Id.* at 33728. That is, EPA claims it can decide whether a chemical poses an unreasonable risk by cherry-picking what exposures it will consider—rather than obtaining a complete understanding of the risks—skewing its analysis and conclusion. This claim turns Congress's directive that all conditions of use be considered on its head.

EPA's claim of discretion is also inconsistent with how the agency previously interpreted TSCA's amendments. Following the amendments, EPA initially proposed a rule wherein, "it interpreted TSCA to *require* that risk evaluations encompass *all* manufacture, processing, distribution in commerce, use, and disposal activities." *Id*. (emphasis added). However, in its final Rule, it "reevaluated its proposal" and instead asserted that the agency need not consider

"every activity relating to the chemical substance," as certain exposures should take a back seat to those EPA selects. *Id.*

Directly contrary to the intent of the amendments, EPA's newly claimed discretion is *broader* and more unfettered than EPA's prior (and now removed) authority that existed under the pre-amendment TSCA to factor cost into its analysis. EPA stated its new risk evaluation methodology will be determined "on a case-by-case basis," "focus[ing] its analytical efforts on those exposures that are likely to present the greatest concern," which will be determined by what EPA believes is "manageable" and other "policy considerations." *Id.* at 33728-29. EPA insists its evaluations will "always include … the conditions of use that raise the greatest potential for risk." *Id.* at 33728. However, the agency will twist how it determines the "greatest" risks, as well as what other risks it considers, based on an open-ended list of other factors that can be economic or political. *Id*.

Risks that come from indirect exposures or that affect just a subset of the population because of that subpopulation's unique physiology—*e.g.*, the exposures most likely to impact pregnant women, infants, and children—are likely to be excluded. These are the exposures that are most difficult to classify as clearly "rais[ing] the greatest potential for risk" and thus will likely fall outside EPA's focus if its Framework Rules are permitted to stand. *See id.*

Although the Framework Rules ultimately empower EPA personnel to exercise discretion independently for each chemical, EPA states that, as a default, "legacy uses, associated disposal, and legacy disposal" will *not* be considered "conditions of use" it will assess in its risk analysis. *Id.* at 33730. By this EPA means that even if a chemical remains in use, if it is no longer sold for the purpose, EPA will *not* consider the risks posed by exposures stemming from the chemical's prior sales, nor the disposals of chemicals resulting from those prior sales. *Id.* at 33729-30.

EPA claims its peculiar construction—which would exempt legacy uses from regulation—of "conditions of use" is acceptable because, while Congress instructed EPA to consider disposals of chemicals, Congress did not spell out this meant all disposals. *Id.* at 33729-30. Of course, in construing "conditions of use" and "disposal" to be ambiguous, so that the agency can rewrite the terms to exclude "legacy uses," EPA undermines Congress's plain objectives. For instance, EPA purports to be able to ignore ways in which chemicals persist in homes, workplaces, and the environment, freeing itself from engaging in a comprehensive assessment of a chemicals' risks, particularly those of susceptible subpopulations. Indeed, EPA acknowledges "an assessment of aggregate exposure" would include "legacy use, associated disposal, and legacy disposal." *Id.* 33730. Yet, EPA states

it is empowered to construe TSCA to remove exposures from "legacy uses" from the agency's consideration.[6]

EPA's recent proposal for evaluating asbestos illustrates the extreme, counterintuitive implications of EPA's rewriting "conditions of use" to allow the agency to exclude "legacy uses." EPA stated it worked to "align[]" its approach to evaluating asbestos "with the approach set forth in the risk evaluation process rule." U.S. EPA, Scope of the Risk Evaluation for Asbestos (Doc. # EPA-740-R1-7008) 12 (2017). As a result, EPA would not consider the risks posed by "asbestos-containing materials that remain in older buildings or are part of older products," or how those products are disposed. *Id.* at 8.

EPA acted in this way notwithstanding its acknowledgement that "[m]ost of the reported asbestos releases were to landfills," *id.* at 9, and that those landfill deposits likely resulted from "materials [that] were installed in the past, and there is no current manufacturing, processing or distribution," *id.* at 24. The agency also

[6] Further confirming that EPA plans to overlook exposures that may individually appear insignificant, but collectively present a danger to pregnant women, infants, children, or the population as a whole, EPA states that it will only conclude an exposure presents an "unreasonable risk" if the exposure is unreasonable under "*each* condition of use[]." 40 C.F.R. § 702.47 (emphasis added). That is, it will *not* regulate a chemical if the chemical's pathways collectively present an unreasonable risk, only if particular pathways on their own present an unreasonable risk. EPA's Rule offers no justification for this approach, but it is plainly an effort to narrow what it considers, and will produce similar dangers to those from EPA's claims of discretion and refusal to consider "legacy uses."

ignored the recommendation of the National Institute of Occupational Safety and Health at the CDC that, "EPA should make an exception to the legacy exclusion because of the extreme persistence of asbestos in the human environment." Petitioners' Motion to Amend 34 (EPA Response to Interagency Comments on TSCA risk evaluation rule).

Instead, EPA said the *only* risks from asbestos it will consider are those posed by "[a]sbestos diaphragms" and "sheet gaskets," as these are the only asbestos products currently sold in the United States. U.S. EPA, Scope of the Risk Evaluation for Asbestos, *supra*, at 23. The continuing risk from asbestos shingles, roofing, pipes, and tile that are no longer sold is well-known and significant. As aging structures deteriorate or are remodeled, demolished, or disposed of, asbestos exposures are likely to occur from those "legacy uses" unless precautions are taken. But, based on its claimed discretion and narrow construction of "conditions of use," those are not risks EPA's TSCA analysis will consider. *Id.* at 25.

EPA's attempts to undermine the TSCA amendments did not stop with its risk evaluation rule. EPA expanded the impact of its claimed discretion by incorporating it into EPA's "prioritization rule." Although EPA stated the need to make TSCA "manageable" and "efficient" justified its asserted discretion over the risk evaluation analysis, TSCA does not actually require the agency to undertake analyses for every covered chemical. Before a risk analysis is performed, the

agency must determine that the chemical is a "high priority." Low priority substances are not subject to *any* risk evaluation, let alone regulation. Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33753, 33754 (July 20, 2017) (citing 15 U.S.C. § 2605(b)(1)(A)). Nonetheless, the agency incorporated its definition of "conditions of use" into determining what priority designation a chemical will receive. *Id.* at 33755. In other words, EPA stated it will exercise "discretion" to determine what risks it assesses to decide whether to conduct a fuller risk assessment, which will also be conducted based on the agency's exercise of discretion. *Id.* EPA has instituted not just one, but two filters that prevent full consideration of the risks posed by TSCA chemicals.

* * *

Because the original TSCA framework failed to protect the public, particularly pregnant women, infants, and children, in 2016, Congress instructed EPA to discard the prior cost-benefit approach and focus first on identifying the risks from TSCA chemicals and then on regulating accordingly. Instead, in the Framework Rules, EPA developed methodologies to determine the risks chemicals pose that are infected with the same non-risk-based considerations Congress rejected. EPA's new risk assessment approach empowers the agency to ignore the

precise types of exposures that are uniquely problematic for pregnant women, infants, and children. These Rules cannot be reconciled with Congress's intent.

B. Applying EPA's Framework Rules Demonstrates They Will Enable EPA to Disregard Substantial Health Risks to Pregnant Women, Infants, and Children.

To appreciate the impropriety of EPA's TSCA Rules and their likelihood to harm pregnant women, infants, and children, one only needs to apply the Rules to representative chemicals—PBDEs, which are used as flame retardants, and lead—known to have negative health impacts for these subpopulations. EPA itself recognizes these chemicals present unique risks to pregnant women, infants, and children. *See* U.S. EPA, *Polybrominated Diphenyl Ethers* (last visited Apr. 10, 2018) ("EPA is concerned that certain PBDE congeners are persistent, bioaccumulative, and toxic to both humans and the environment. The critical endpoint of concern for human health is neurobehavioral effects" that will impact the developing brain.)[7]; U.S. EPA, *Learn About Lead* (last visited Apr. 10, 2018) ("Lead is particularly dangerous to children because their growing bodies absorb more lead than adults do and their brains and nervous systems are more sensitive to the damaging effects of lead.").[8]

[7] *Available at* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/polybrominated-diphenyl-ethers-pbdes.
[8] *Available at* https://www.epa.gov/lead/learn-about-lead#exposed.

As with the discussion above concerning asbestos, applying EPA's Framework Rules to PBDEs and lead demonstrates that EPA's approach will increase the risks to pregnant women, infants, and children. These substances are representative of the need for EPA to engage in a comprehensive and complete review because both chemicals pose significant developmental risks at low levels and can be present in the environment for long periods. Nonetheless, the agency's Framework Rules are designed to exclude large numbers of exposures to these chemicals, including some of the most toxic exposures, vastly underestimating and thereby under-regulating the risks they present.

i. PBDEs

PBDEs are added to products to slow the spread of fire. National Ocean Service, *What are PDBEs?* (last visited Apr. 10, 2018).[9] They are included in everything "from TVs and toasters to mattresses and drapes." *Id.* They have also been added to paints, plastics, rugs, building materials, and automobiles. Siddiqi et al., *supra*, at 282. They can "constitute 5% to 30% of some of these products by weight." *Id.* Indeed, PBDEs are so prevalent in United States consumer goods that the domestic population has anywhere between 10 and 100 times higher levels of

[9] *Available at* https://oceanservice.noaa.gov/facts/pbde.html.

PBDEs in their bodies than equivalent populations in Europe or Asia. National Ocean Service, *supra*.

PDBEs are known to be both "endocrine disrupters and neurotoxins." Siddiqi et al., *supra*, at 284, 286. Thus, they are associated with a wide variety of harms, including lymphoma, breast cancer, and thyroid disruption. *Id.* at 285-86. Because of their impacts on neurology and hormones (produced by the thyroid) they are particularly associated with negative effects on fetal development and children, including "decrements in motor development, cognitive development, and attention-related behaviors." Juleen Lam et al., *Development PBDE Exposure and IQ/ADHD in Childhood*, 125 Environ. Health Perpect., Aug. 2017 at 086001-2.[10]

These developmental impacts can be substantial, rapid, and irreversible. Exposure to PBDEs *in utero* has been reported to lead to "significant decrements in motor and mental development at ages 1-6 years." Brenda Eskenazi et al., *In Utero and Childhood Polybrominate Diphenyl Ether (PBDE) Exposures and Neurodevelopment in the CHAMACOS Study*, 121 Environ. Health Perspect., Feb. 2018 at 257[11]; *see also* Julie Herbstman et al., *Prenatal Exposure to PBDEs and*

[10] *Available at* https://ehp.niehs.nih.gov/wp-content/uploads/2017/08/EHP1632.alt_.pdf.
[11] *Available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3569691/.

Neurodevelopment, 118 Environ. Health Perspect., May 2010 at 712 (finding an association between concentrations of PBDE in "cord blood" and lower scores on "mental and physical development" through 72 months).[12] A study in mice indicated exposure to a single dose of PBDEs within ten days of birth "permanently impaired spontaneous motor behavior, affected learning and memory, and had permanent behavioral effects." Siddiqi et al., *supra*, at 288. A human population study "found a positive association between breast milk levels" of PBDEs and "impulsivity" in 30-month olds. Eskenazi et al., *supra*, at 257-62. The first comprehensive analysis of studies considering PBDEs' effect on humans, known as a meta-analysis, concluded the research collectively supports finding exposure to PBDEs is associated with lifelong "diminished intelligence" and that there is an association between "increased exposures" to PBDEs and an individual's diminished capabilities. Lam et al., *supra*, at 186001-15.

Exposure to PBDEs is virtually impossible to avoid. Not only are PBDEs added to many common home products in high volumes, but they do not bind with the other chemicals in the goods, meaning that PBDEs are likely to migrate out of the products over time. Siddiqi et al., *supra*, at 283; *see also* U.S. EPA,

[12] *Available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866690/.

Polybrominated Diphenyl Ethers (PBDEs), *supra*. As a result, "there is a higher potential for leaching [or] volatilization." Lam et al., *supra*, at 086001-1.

Free PBDEs remain in the environment "for years" without being broken down into non-PBDE material. Siddiqi et al., *supra*, at 283; *see also* U.S. EPA, *Technical Fact Sheet-Polybrominated Diphenyl Ethers* 2 (Nov. 2017) (stating that studies, while limited, indicate "biodegradation does not appear to be significant").[13] From there, they can be taken up by fish and other animals and retained in their tissue to be transmitted to humans through food consumption. Siddiqi et al., *supra*, at 283. Exposure can also occur through inhalation or skin contact. U.S. EPA, National Center for Environmental Assessment, Office of Research and Development, *An Exposure Assessment of Polybrominated Diphenyl Ethers* 5-42 (May 2010).

Pregnant women, infants, and children cannot be protected by limiting their contact with contaminated places or food. "Human exposures are ubiquitous beginning *in utero*." Lam et al., *supra*, at 086001-1. And because PBDEs are common in household goods—such as furniture cushions, crib mattresses, and electronics—meaningful levels are found in everyday "house dust." Ami R. Zota et al., *Elevated House Dust and Serum Concentrations of PBDEs in California:*

[13] *Available at* https://www.epa.gov/sites/production/files/2014-03/documents/ffrrofactsheet_contaminant_perchlorate_january2014_final_0.pdf.

Unintended Consequences of Furniture Flammability Standards?, 42 Environ. Sci. Technol., Nov. 2008 at 8158.[14] Indeed, "[h]ouse dust has been identified as the primary route of exposure," because even vacuuming PBDE laden material can release PBDE into the room. *Id*. Exposure to PBDEs is virtually unavoidable, especially for infants and children—who may be consuming PBDE-laden breast milk or crawling or playing on the floor while engaging in hand-to-mouth behaviors.

These same qualities that make exposure to PBDEs highly likely also increase the potential for each exposure to combine with additional exposures. PBDEs have been shown to be "bioaccumulative," meaning that they are absorbed at a faster rate than they can be expelled. While this is unsurprising given the number of pathways for exposure, it means people typically suffer from a higher dosage than would be suggested by an analysis of any individual pathway, and that even seemingly minor exposures can quickly accumulate to create a larger danger. Siddiqi et al., *supra*, at 283

Despite these well established and meaningful risks, EPA's Rules are designed to overlook key aspects of PBDE exposure. PBDEs exist in three commercial forms, penta, octa, and deca—which refer to differences in the

[14] *Available at* https://escholarship.org/uc/item/8mn1t1hz.

chemical structure. While deca PBDE production continues, penta and octa PBDE have been phased out of production. *Technical Fact Sheet-Polybrominated Diphenyl Ethers*, *supra*, 1. However, tens of millions of pounds of PBDEs were added into U.S. products annually into the early 2000s, when penta and octa PBDE goods were still sold. Marla Cone, *Cause for Alarm Over Chemicals*, L.A. Times (Apr. 20, 2003).[15] As a result, substantial amounts of penta and octa PBDEs remain in homes and offices, from which they will eventually make their way into landfills and the environment.

However, EPA will not consider the risks posed by penta and octa PBDEs under its default rule because those exposures will be considered "legacy uses." 82 Fed. Reg. at 33730. Because EPA has declared its analysis can focus exclusively on risks from current commercial sales, it has stated it will not consider exposures from chemicals like penta and octa PBDEs that remain in *use* and will linger in the environment as the products that contain them degrade.

If EPA's approach to asbestos leaves any doubt that it will exclude the risks from penta and octa PBDE in its analysis, EPA's Rule hypothesizes facts nearly identical to those presented by penta and octa PBDEs and states these are the precise circumstances where EPA believes it *should* narrow its analysis, limiting it

[15] *Available at* http://articles.latimes.com/2003/apr/20/local/me-chemicals20.

to the risks presented by current sales and excluding continuing risks from prior sales. EPA stated that where a chemical is present in "insulation," as are PBDEs,[16] its analysis "w[ill] not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or ongoing." 82 Fed. Reg. at 33730. According to EPA, that a chemical, like penta or octa PBDE, remains in the insulation to eventually be removed, disposed of, and allowed to degrade and shed into the air, soil, and environment is insufficient to justify "reaching back" to consider such "legacy uses." *Id.* As a result, EPA's risk analysis will not take into account the potential harms caused by PBDEs that it knows can continue to impede human development.

EPA's approach to "legacy uses" also means that even the analysis the agency does perform on currently marketed PBDEs will not properly account for the risks from *those* PBDEs. Because of the prevalence of all forms of PBDEs, the deca PBDE exposures that EPA will consider—because products containing deca PBDE are still sold—are likely to overlap with exposures to penta or octa PBDE that EPA will label "legacy uses." Thus, if EPA's risk assessment excludes penta and octa PBDE, it cannot possibly consider the full impact from deca PBDE

[16] U.S. EPA, *Polybrominated Diphenyl Ethers*, *supra* (PBDE present in insulation).

exposure. EPA will be artificially assuming deca PDBE exposures occur in a vacuum, and not alongside other PBDE exposures that magnify one another. Thereby, EPA will underreport the consequences from deca PBDE exposures, regardless of whether the agency should also separately evaluate the risks of penta and octa PBDE.[17]

The case of PBDEs not only illustrates the harms from EPA's refusal to consider "legacy uses," but also reveal how the agency's claim of discretion undermines the value of its risk analysis. Deca PBDE has been shown to break down into penta and octa PBDE. Thomas A. McDonald, *Polybrominated Diphenylether Levels among United States Residents: Daily Intake and Risk of Harm to the Developing Brain and Reproductive Organs*, 1 Integr. Environ. Assess. Manag., May 2005 at 344.[18] One might think this makes the concerns above overstated, because EPA will consider the risks from penta and octa PBDE to the extent those exposures result from deca PBDE uses. However, EPA's final rule states "EPA intends to exercise discretion" to exclude risks from chemicals based on "various policy considerations." 82 Fed. Reg. at 33730. While EPA

[17] As noted above, EPA's insistence that it will decide whether a chemical presents an "unreasonable risk" based exclusively on the risks from each isolated "condition of use," 40 C.F.R. § 702.47, will also lead to this same illogical and dangerous result.

[18] *Available at* https://setac.onlinelibrary.wiley.com/doi/pdf/10.1002/ieam.5630010404.

refuses to commit to what "policy considerations" will narrow its analysis, it suggests it is likely to exclude risks if they are "unintentionally" present or result from non-labeled uses of a product or chemical. *Id.* Penta and octa are "unintentionally" present in deca PBDE-containing products because such products are marketed solely as deca PBDE-containing goods. Penta and octa PBDE are unwanted side-effects. *Id.* Therefore, EPA's claim of "discretion" will likely result in it failing to account for the true range of impacts from the *present* uses of deca PBDE.

PBDEs demonstrate how EPA's discretion to limit its risk analysis would undermine the public health and the objectives of the TSCA amendments.[19]

ii. Lead

Applying EPA's Framework Rules to lead further demonstrates just how unreasonable the agency's approach would be. In 1992, Congress passed an entire

[19] TSCA allows EPA to choose not to assess the risks of deca PBDE and move immediately to restricting deca PBDE's uses—although EPA has not stated how it will proceed. *See* 15 U.S.C. § 2605(h) (exempting certain types of chemicals from a "risk evaluation"); U.S. EPA, EPA-HQ-OPPT-2016-0724-0001, Memorandum (2016), *available at* https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0724 (stating that deca PBDE is one such chemical). However, ironically, this is because Congress recognized EPA needs to act swiftly with regard to deca PBDE and similar chemicals, as they "persist[]" in the environment and "bioaccumulat[e]." 15 U.S.C. § 2605(h). It remains unclear how EPA will regulate deca PBDE; but, regardless of how EPA approaches deca, without this Court's intervention, EPA's faulty risk evaluation scheme will be applied elsewhere and the dangers PBDE demonstrates will arise with other chemicals.

statute focused on the risks of "low-level lead poisoning … among American children." 42 U.S.C. § 4851(1). It explained that even "at low levels, lead poisoning in children causes intelligence quotient deficiencies, reading and learning disabilities, impaired hearing, reduced attention span, hyperactivity, and behavior problems." 42 U.S.C. § 4851(2). Moreover, Congress acknowledged that most of these risks to children are produced by what EPA would deem "legacy uses," such as "lead-based paint" that is no longer produced but remains in "pre-1980 American housing stock … with the vast majority of homes built before 1950 containing substantial amounts of lead-based paint." 42 U.S.C. § 4851(3).

Those harms continue today, and not just from paint. One need look no further than Flint, Michigan to see how outmoded lead products continue to harm pregnant women, infants, and children—decaying lead pipes caused damaging lead consumption across an entire city. Further, lead-contaminated soil, including soil contamination resulting from leaded gasoline and exhaust, former industrial uses, and pre-1950 homes, "is an important source of lead intake for children." American Academy of Pediatrics, *Prevention of Childhood Lead Toxicity,* 6 (last visited Apr. 10, 2018).[20] Those same sources also cause lead to be present in household dust, which, as described above, is a particularly meaningful pathway to

[20] *Available at* http://pediatrics.aappublications.org/content/early/2016/06/16/peds.2016-1493.

exposure for children. Petitioners' Appendix 437-38 (Declaration of Dr. David Bellinger).

These pathways are established to have significant impacts. "From 2007 to 2010, approximately 2.6% of preschool children in the United States had a blood lead concentration ≥5 μg/dL (≥50 ppb), which represents about 535,000 U.S. children 1 to 5 years of age." First Letter from AAP to Jim Jones, *supra*, at 4. Developing scientific evidence indicates that exposures at levels lower than 5 μg/dL are sufficient to "impair cognition," *id.*, "reduce[] academic achievement, and [cause] behavioral problems," Petitioners' Appendix 441 (Declaration of Dr. David Bellinger). Likewise, lead exposure during pregnancy has "known adverse effects on maternal health and infant outcomes across a wide range of maternal blood lead levels." AAP & ACOG, *Guidelines for perinatal care* 195 (8th ed. 2017). Consistent with this, current scientific consensus establishes there is "*no* 'safe' level of lead exposure, i.e., no threshold below which exposure is harmless." Petitioners' Appendix 440 (Declaration of Dr. David Bellinger) (emphasis added). As a result, CDC has "eliminated its 'action level' for lead," because any level is excessive. *Id.* at 442.

However, EPA's Framework Rules would exclude from the agency's risk analysis most, if not all, of these exposures. If EPA is excluding from its consideration the degradation and disposal of existing asbestos installation on the

basis that those are "legacy uses," the same logic dictates that it would exclude from its analysis exposures to lead paint, lead-contaminated soil, and lead in drinking water from corroded lead pipes that are no longer manufactured for sale.

Further still, the Rules will also cause it to discount the risks posed by lead's current uses. Parents can continue to be exposed to lead at "battery manufacturing and recycling" plants, as well as working with "smelting, car repair, [or] welding." ACOG, *Exposures to Toxic Environmental Agents* Table 2.[21] Through dust on their clothes or shoes, parents' exposure can result in "'take home' exposure [that] can cause poisoning of children." Letter from American Academy of Pediatrics to Jim Jones, Assistant Administrator, U.S. EPA, Docket No. EPA-HQ-OPPT-2016-0400, at 3 (Aug. 24, 2016).

However, because these "current" exposures are secondary exposures—resulting from detritus from an initial exposure being carried home—EPA indicates it will exercise its discretion to exclude these exposures from its analysis, claiming that they do not "raise the greatest potential for risk." 82 Fed. Reg. at 33728. Indeed, these take-home exposures are the types of exposures that will be challenging to quantify and regulate. Thus, they are likely to be pushed aside

[21] *Available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/ExposuretoToxic.pdf.

based on EPA's contention that it can ignore risks that are purportedly insufficiently quantifiable to warrant the burden of analysis. *Id.*

As a result, under its Framework Rules, EPA is prepared to ignore some of the most substantial risks from a chemical that is established, *in any amount*, to cause lifelong, untreatable impairments to pregnant women, infants, and children. Explaining EPA's position demonstrates it is untenable.

IV. CONCLUSION

For the reasons stated above and those given in Petitioners' brief, *amici* support Petitioners' request for relief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the April 23, 2018, the foregoing document was served on all parties or their counsel of record through CM/ECF system.

DATED this April 23, 2018.

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