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**U.S. Senate Committee on Environment
and Public Works
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by Addressing Toxic Chemical Threats.”
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I would like to thank the Committee for the opportunity to testify on S. 1009, the “Chemical Safety Improvement Act.” My name is Robin Greenwald. I have practiced in the field of environmental law most of my 30-year legal career. I spent nearly 20 years working for the federal government, as an Assistant United States Attorney in the Eastern District of New York, as an Assistant Chief in the Environmental Crimes Section of the U.S. Department of Justice and as General Counsel for the Department of the Interior, Office of Inspector General. In all of these positions I had the opportunity to work with scientists and attorneys at the Environmental Protection Agency. I also was the Executive Director of the Waterkeeper Alliance, an international organization dedicated to the protection of water bodies worldwide, and I was a Clinical Professor of Law at Rutgers College of Law, Newark. I am currently Of Counsel at the New York law firm Weitz and Luxenberg, where I head the Environmental and Toxic Tort Unit. In my various positions, I have worked with nearly every federal environmental statute and am familiar with principles of federal jurisprudence, including preemption, the Administrative Procedure Act and the Rules of Civil Procedure and Evidence. I am also a mother, and much of my work has been driven by the belief that we all have an obligation, regardless of our chosen profession, to protect public health for all segments of the population, to preserve our natural resources and to guarantee that future generations maintain their rights to challenge wrongdoing, both publicly and in the courts, and to be protected from industry irresponsibility that effects and compromises their health and life choices.

I wholeheartedly support efforts to reform the Toxic Substances Control Act and I thank this committee for taking steps towards this goal. I am also encouraged by the willingness to reopen the discussion on this issue as I believe Congress has a responsibility to take chemical safety reform seriously. I have witnessed first-hand how this country’s failure to effectively regulate toxic chemicals has negatively impacted the health and safety of American families.

While my support for TSCA reform is unwavering, my view is that S. 1009, the “Chemical Safety Improvement Act,” as it is currently written, contains critical and fundamental flaws which will take chemical safety reform in the U.S. a step backwards rather than a step forward. Theoretically designed “to improve the safety of consumers in the United States [and] ensure that risks from chemical substances are adequately understood and managed by modernizing Title I of the Toxic Substances and Control Act . . .,”¹ current provisions in the bill unfortunately render it neither protective of public health and welfare nor an improvement over

¹ S. 1009, 113th Cong. § 2(a)(2).

the Toxic Substances Control Act (“TSCA”). While the bill as currently drafted has numerous flaws, I intend to focus my testimony on the following infirmities:

- S. 1009 effectively precludes private parties from bringing actions against chemical manufacturers for injuries caused by their chemicals. It does so by wiping out state statutory and common law, and by declaring the EPA’s safety determination *per se* admissible in court and dispositive of the issue of the chemical’s safety, even when there is newly acquired safety information generated after EPA’s safety determination.
- S. 1009 takes the unprecedented step of preempting states from enforcing existing laws and/or promulgating new laws designed to supplement federal law regulating toxic chemicals. In most federal environmental statutes, the federal standard sets a floor rather than a ceiling; this bill is unprecedented in the environmental statutory world by setting a ceiling;
- S. 1009 does not improve on TSCA’s cost-benefit safety standard. To ban or limit a chemical’s use, EPA still has the heavy burden of performing a complex and difficult balancing of costs and benefits rather than using a health-based standard, which would be more appropriate when regulating toxic substances. This cost-benefit type standard has rendered EPA nearly powerless to ban toxic chemicals pursuant to TSCA; and
- S. 1009 effectively blocks a state from evaluating any chemical deemed by the EPA as a “Low-Priority Substance”.

I. History proves that S. 1009 removes critically important and necessary checks and balances on the chemical industry.

S. 1009 empowers the chemical manufacturers industry while compromising states’ and citizens’ power to protect themselves. The bill, like the Toxic Substances Control Act (TSCA), establishes a system for approving chemicals either already in the marketplace or in the development stage. First, it places trust in the chemical industry to submit complete and truthful information to the EPA in support of its application to market its chemicals. Based on that information, the EPA either approves or disapproves the chemical. A determination of approval by the EPA is *per se* dispositive of a chemical’s safety in a judicial proceeding. In legislating that standard, S. 1009 negates the check and balance that comes with states’ or citizens’ suits that challenge a chemical’s safety. Moreover, the proposed bill deprives states of their fundamental police power to promulgate more stringent testing before a chemical can be used and exposes a state’s own citizens. In doing so, the bill strips the country of yet another important check on dangerous decision-making.

The bill banks on the assumption that chemical manufacturers will always act in the interest of public safety, rather than in the name of profits, by being candid and forthright in disclosing ALL of the information they have amassed about their chemicals and the potential dangers of their use, especially if that disclosure risks their approval. History tells us that the industry cannot always be trusted to place public safety above their bottom line; and when the industry fails to do so, it puts the health of millions of Americans at risk. Yet S. 1009 proposes to shield the industry more than ever before by removing the threat of litigation for injuries caused by chemicals and by stripping states of their right to impose more stringent health and safety standards. A review of some examples shows the importance of protecting citizens' and states' ability to bring suit. The below examples may never have been brought to light if S. 1009 were law.

1. Industry deceit about vinyl chloride.

Consider those companies that manufactured vinyl chloride, for example. Chemical manufacturers, supported by the Chemical Manufacturers Association, engaged in a widespread cover-up of the evidence they had of vinyl chloride's health risks. When people increasingly became sick from exposure to vinyl chloride in the workplace, lawsuits were brought against PP&G, Dow Chemical, Ethyl Corporation, B.F. Goodrich and others. As explained below, those lawsuits, as well as other events, uncovered decades of deceit by the chemical industry about the dangers of vinyl chloride.

A brief history is instructive.² The first experimental evidence of vinyl chloride carcinogenicity was reported in 1969.³ Additional data were published in 1971,⁴ followed in 1974–1975 by disclosure of rare liver cancers in workers exposed to vinyl chloride.⁵ Upon release of these data, first disclosed through an anonymous source to the federal Occupational Safety and Health Association (OSHA), OSHA issued a notice effective April 1975 that vinyl chloride and polyvinyl chloride production plants must reduce Time-Weighted Average workplace exposure levels from 500 parts per million (ppm) to 1 ppm, to provide adequate

² A chilling, comprehensive rendition of the depth and breadth of the vinyl chloride cover up is produced by Chemical Industry Archives, a project of Environmental Working Group, together with links to the wealth of information withheld from the government and the public demonstrating the chemical industry's early knowledge of vinyl chloride's dangers, at

<http://www.chemicalindustryarchives.org/dirtysecrets/vinyl/1.asp>. See also <http://www.deceitanddenial.org/docs/timeline.pdf>.

³ Dr. P.L. Viola, Regimi Elana Institute for Cancer Research, Rome, Italy, unpublished data. See <http://www.chemicalindustryarchives.org/dirtysecrets/vinyl/1.asp>.

⁴ Viola *et al.* 1971 at <http://cancerres.aacrjournals.org/content/31/5/516.full.pdf>.

⁵ Creech and Johnson 1974; Creech and Makk 1975; Maltoni 1974, 1975; Maltoni *et al.* 1974. See http://www.medscape.com/viewarticle/508568_2.

worker protection. Litigation years later exposed the breadth of the industry's early knowledge about and its failure to disclose the dangers of vinyl chloride.⁶

When OSHA issued the new exposure limit of 1 ppm, industry spokespeople used the age-old intimidation tactic of predicting widespread job loss and plant closures. Fortunately, OSHA did not succumb to industry's veiled threat and, in less than two years following the regulations' effective date, virtually all chemical manufacturing plants in the United States had been able to meet the new standard while maintaining rapid growth of sales volume. All it took was a small expenditure of money – and I mean small – and these improved safety measures were easily accomplished.

Yet it is now well documented that industry leaders had learned and failed to disclose as early as the 1950s – long before the 1975 OSHA standard -- that the then-existing limit of 500 ppm was far beyond a level that assured worker safety and health. In 1959, for example, internal industry experiments revealed micropathology in rabbit livers after repeat exposures to 200 ppm vinyl chloride monomer,⁷ causing Dow Chemical toxicologist Dr. Rowe to admit privately to his counterpart at B.F. Goodrich – *“We feel quite confident ... that 500 ppm is going to produce rather appreciable injury when inhaled 7 hours a day, five days a week, for an extended period. As you can appreciate, this opinion is not ready for dissemination yet and I would appreciate it if you would hold it in confidence but use it as you see fit in your own operations.”*

Vinyl chloride and polyvinyl chloride manufacturers also delayed public release of findings of liver angiosarcoma in vinyl chloride-exposed rodents by Dr. Cesare Maltoni.⁸ In 1972, the industry was briefed on Dr. Maltoni's report of primary cancers of both liver and kidneys at exposure levels as low as 250 ppm, **half** the then 500 ppm allowable exposure limit for workers. Nevertheless, in a meeting with government officials -- eight months after receiving this information -- industry representatives failed to disclose Dr. Maltoni's findings. The public began to learn of the hazards of vinyl chloride only in early 1974 through newspaper reports of the deaths of three workers in a B.F. Goodrich vinyl chloride plant in Louisville, Kentucky.⁹ Consistent with Dr. Maltoni's studies, the workers suffered from liver angiosarcoma.

In addition to evidence of liver cancer, starting in the 1970s the industry's internal studies

⁶ See affidavit of Dr. Judith Schreiber, Senior Public Health Scientist, New York State Department of Law, in *In The Matter of the Application of Resilient Floor Covering Institute v. New York State Department of Environmental Conservation*, outlining early knowledge about vinyl chloride's harmful effects at http://www.healthybuilding.net/pvc/NYS_vinyl_affidavit_js.pdf.

⁷ Markowitz and Rosner, *Corporate Responsibility for Toxins*, *Annals of the American Academy of Political and Social Science*, 584, November 2002.

⁸ Markowitz and Tosner 2002.

⁹ Creech and Johnson 1974.

revealed excess cancers in non-liver sites, including the respiratory system and the brain. Industry suppressed this information also. Indeed, the International Agency for Research on Cancer (IARC), unaware of the industry's internal studies, reported at the time that "***there is no evidence that there is an exposure level below which no increased risk of cancer would occur in humans.***" The truth was not discovered until the late 1970s, when IARC discovered the existence of international studies that disclosed that vinyl chloride is a human carcinogen with target organs including the liver, brain, lung and haemo-lymphopoietic system. We now know that the evidence to support this finding had existed decades earlier but had been intentionally suppressed by the very industry this bill would shield from liability for such deceit.

It is critically important for this Committee to understand how this type of information comes to light: it is not through intensive investigative research of either the OSHA or the EPA – they do not have the funds or the human resources to dig into the closets of large corporations to find the suppressed health studies. Rather, it is largely disclosed through judicial proceedings – the judicial process upon which all citizens rely and that time and again allows victims of wrongdoing to unveil information that would otherwise never be seen.

Here is another disturbing aspect of this saga. EPA had the information about vinyl chloride's dangers in the 1970s. Nonetheless, EPA waited until the year 2000 to finalize an update of vinyl chloride's toxicological information, over two decades after the federal government had proof of the carcinogenic effects of vinyl chloride. EPA explains this delay by claiming it could not establish a numerical estimate of vinyl chloride's potency and therefore could not decide whether to classify vinyl chloride as a carcinogen. Regardless of the legitimacy of that rationale, a two-decade process to determine a chemical's safety is inexcusable, as during those years workers continued to be exposed to harmful levels of the chemicals.

Of course, during those two decades the chemical industry had been provided with ongoing opportunities to weigh in on EPA's review of vinyl chloride's toxicity. EPA's 2000 vinyl chloride assessment downplayed risks from all cancer sites other than the liver. Its assessment reduced the cancer risk 10-fold – a big industry victory as it reduced the extent and costs of pollution reduction and clean-up measures.

The vinyl chloride story is but one illustration of the chemical industry's deceit and how EPA all too often takes action that serves industry rather than the public. At least under the current legal regime, states are permitted to cure these deficiencies and protect their citizens. But if S. 1009 were passed in its current form, states would be left powerless to fill the gaps left by the federal government.

2. Industry deceit about asbestos.

The vinyl chloride story is not an outlier. Owens Corning, Johns Manville and other asbestos manufacturers had reliable, proven information from their own experts that asbestos was dangerous and could and would kill many of those exposed to it. But asbestos promised to earn chemical manufacturers billions in revenue. Disclosing internal information they had about the dangers of the chemical risked those billions of dollars; suppressing the evidence meant the product could enter the stream of commerce. So the chemical industry suppressed its knowledge of asbestos' toxicity, in utter disregard for the health and safety of its workforce and for human life generally. In the words of one of these manufacturers: "... if you have enjoyed a good life while working with asbestos products, why not die from it."¹⁰ Need this Committee be reminded of the consequences of this depraved perspective: hundreds of thousands, if not millions of people to date have died or become seriously ill from asbestos-related diseases, including mesothelioma. Perhaps before taking any further action on this proposed bill the Committee would consider inviting the surviving spouses and children who watched their loved ones, with no hope of recovery, die an incredibly painful death from mesothelioma, to tell their stories. Asbestos is still legal in this country today and thousands more continue to die every year due to exposure to Asbestos-containing products.

3. Industry deceit about polychlorinated biphenyls (PCBs).

Monsanto Corporation, the principal manufacturer of PCBs in the United States, knew as early as the 1930s that PCBs caused serious health problems in workers. But as the case with vinyl chloride, asbestos and many other chemicals, it was keenly aware that public disclosure of this information would jeopardize the product's sales and years later would subject them to considerable liability for making people ill and degrading numerous communities around the country with PCB waste, such as Anniston, Alabama; Schenectady, New York; and Pittsfield, Massachusetts, to name a few. Moreover, faced with the choice between protecting public health and making money, these companies chose money. As a result, and similar to the stories above, Monsanto suppressed information it had about PCB's harmful effects.¹¹

S. 1009, with its broad preemptive effect, would undoubtedly result in a replay of these and many other similar events. The story of the marketing, manufacture and use of just these three

¹⁰ 1966 Bendix Corporation Letter, www.ewg.org/research/asbestos-think-again/industry-hid-dangers.

¹¹ A summary of Monsanto's deceit about PCBs' dangers is at <http://www.chemicalindustryarchives.org/dirtysecrets/annistonindepth/toxicity.asp>.

chemicals illustrates why significant changes must be made to S. 1009 for the health and safety of the country. In its current form, S. 1009 renders citizens even more powerless to protect themselves in the face of this powerful chemical industry than during the decades of the vinyl chloride, asbestos and PCB cover-ups. No one questions that the current TSCA needs major modification, but S. 1009 in its current form is not the modification required for many reasons, and I address several of these below.

II. Overview of Toxic Substances Control Act: What it did and did not accomplish.

As a backdrop to a more detailed discussion of the proposed Chemical Safety Improvement Act, I provide a brief overview of what I believe TSCA accomplished and what it did not. I further outline several relevant TSCA provisions that illustrate why improvement is needed in specific areas that are mishandled or altogether ignored by the proposed bill. Finally, I address the manner in which the proposed bill increases the power of the chemical industry and relies upon the judgment and discretion of that industry to make decisions despite its history of abusing its responsibilities.

Congress passed TSCA to address, and theoretically to redress, the Executive Branch's lack of oversight of chemicals in commerce. Earlier clean water and clean air laws and regulations were focused primarily on the waste streams from manufacturing, not on the chemical themselves. These Acts generally relied on EPA to establish standards and demonstrate risks before taking enforcement actions. Through TSCA, the federal government was permitted exercise authority over production and use decisions, thereby regulating the type and nature of chemicals that could be manufactured and placing limitations on their use. TSCA permits the EPA to regulate toxic substances in several ways, from outright banning of chemical substances to testing and labeling requirements. These safeguards have had some important beneficial impacts for society (for example, the banning of PCBs), but these measures do not go far enough.

TSCA's provisions vary as applied to new versus existing chemicals. A "new chemical substance" is defined as "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA] section 8(b)." This list, called the "TSCA Inventory," is a list of all chemical substances in commerce prior to December 1979. All chemicals on the market prior to this date are considered existing chemical substances. This list represents 99% by volume of chemicals on the market today. Under TSCA, these existing chemical substances are considered *per se* safe unless EPA can demonstrate that they present an unreasonable risk to human health or the environment. This method of identifying *per se* "safe" substances, needless to say, was the result of significant industry lobbying and involvement.

Certain sections of the bill are worth specific mention. Section 5 prohibits the manufacturing, processing or importing of a “new chemical substance” or “significant new use” of an existing substance unless a Pre-Manufacture Notification (PMN) is submitted to EPA at least 90 days before the commencement of the proposed activity. The PMN identifies the chemical, its physical characteristics, processing and use, and provides available toxicity data. During the 90-day review period, EPA reviews the chemical’s human and environmental risks and exposures, examining the data submitted in addition to other information. EPA may request more data, prohibit or limit manufacture, or halt the review process. The pre-manufacture submission requirements only apply to chemicals and products of biotechnology for industrial use, while different laws apply to any chemical used as a drug, food additive or pesticide. In addition, certain types of chemicals and chemical uses are exempted from the review process, and EPA is authorized to make future exemptions.¹²

Section 6¹³ authorizes EPA to issue regulations to address the risks of existing substances if “there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment . . . using the least burdensome requirements” that are necessary to address that risk. Such regulations can be issued immediately when a threat of harm is imminent.

Section 4¹⁴ compels the EPA Administrator to require the testing of chemical substances or mixtures, new or existing, if (1) there are insufficient data to make an unreasonable risk determination and testing is necessary; and (2) the chemical substance or mixture (a) may present an unreasonable risk or (b) the chemical will be produced in substantial quantities and either (i) may enter the environment in substantial quantities or (ii) lead to significant or substantial human exposure.

Section 8¹⁵ authorizes EPA to promulgate rules that require chemical manufacturers, processors and distributors to maintain records and make reports on chemicals and mixtures. This includes requirements to submit health and safety studies, provide immediate notice of “substantial risks,” and maintain records of adverse health effects for 30 years. This Section allows EPA to issue rules to collect production and use information as well as information on disposal and byproducts, and includes the Inventory Update Rule, which generates an inventory every four years of all of the non-polymeric chemicals produced or imported into the United

¹² Ashford, N and C. Caldart. 1997, *Technology, Law and the Working Environment*, Washington, DC, Island Press.

¹³ TSCA, 15 U.S.C. § 2605.

¹⁴ TSCA, 15 U.S.C. § 2603.

¹⁵ TSCA, 15 U.S.C. § 2607.

States.

Section 9¹⁶ requires the EPA formally to refer regulation of an unreasonable risk to other agencies if that risk “may be prevented or reduced to a sufficient extent under a federal law not administered by the Administrator.” These “referral agencies” include OSHA and the Consumer Product Safety Commission.

I am informed by Dr. Nicholas Cheremisinoff, a renowned chemical engineer who has authored/co-authored more than 160 books on industry practices and worked extensively on developing environmental regulations in numerous countries under United States Agency for International Development funded programs, and with whom I recently consulted about TSCA and S. 1009, that despite the intent of these provisions to fill a substantial gap in the regulation of toxic substances, the implementation of TSCA has been largely unsuccessful, particularly for existing chemicals. In implementing restrictions on the manufacturing or use of toxic chemicals, the EPA has an extremely high burden before it can take action under TSCA. To restrict dangerous chemicals, EPA must prove that the chemical “will present an unreasonable risk,” that it is choosing the least burdensome regulation to reduce risks to a reasonable level, and that the **benefits of regulation outweigh the costs to industry**. EPA must do this on a chemical-by-chemical basis. As a result of this heavy burden, EPA has placed few restrictions on chemicals over the years.

Asbestos is one important example of TSCA’s shortcomings. EPA began regulating asbestos in the late 1980s. After ten years of research, public meetings and regulatory impact analyses, EPA issued a final rule under Section 6 of TSCA in 1989 to prohibit the future manufacture, importation, processing and distribution of asbestos in almost all products. The asbestos industry challenged EPA’s ban. In a landmark case,¹⁷ the court all but eliminated EPA’s ability to use Section 6 of TSCA to restrict dangerous chemicals. The court held that EPA had presented insufficient evidence, including risk information, to justify its asbestos ban. Specifically, the court found that EPA: (1) had not used the least burdensome regulation to achieve its goal of minimizing risk, (2) had not demonstrated a reasonable basis for the regulatory action, and (3) had not adequately balanced the benefits of the restriction against the costs to industry. The court further held that “EPA’s regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA” and that “EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA

¹⁶ TSCA, 15 U.S.C. § 2608.

¹⁷ *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

equation.”¹⁸ While S. 1009 does not have TSCA’s “least burdensome requirements” safety standard,¹⁹ it retains TSCA’s “unreasonable risk” language and is vulnerable to being interpreted as placing a similarly heavy burden on EPA to impose even the most modest restrictions on a chemical.

In sum, TSCA’s shortcomings are perhaps best illustrated by the fact that EPA’s success rate in restricting chemicals is poor. Since its passage in 1976, EPA has restricted only five chemicals -- PCBs, chlorofluorocarbons, dioxin, asbestos, and hexavalent chromium -- under TSCA. EPA has only referred risks to other agencies, as required under TSCA Section 9, on only four occasions in 37 years.²⁰

To make matters worse, TSCA has even hindered EPA’s ability to provide public information on chemical production and risk by creating broad confidential business information provisions. During TSCA’s early history, industry had to substantiate confidentiality claims; claiming confidential business information now requires little more than a routine check-off procedure. A 1998 EPA analysis found that 65 percent of the information in industry filings with the Agency under TSCA was submitted as confidential.²¹ About 40 percent of substantial risk notifications by industry claims confidentiality for the identification of the chemical, thus keeping from the public which chemicals are acknowledged to be dangerous to health and safety.²² S. 1009 permits the same *pro forma* claims of confidentiality.

III. S. 1009, rather than providing needed improvements to TSCA, presents new and greater risks to public health and safety.

1. Preemption and Effective Immunity for Private Actions.

Section 15 of the bill is broad in effect and raises serious concerns about its impact on state laws, including state common law. The section states that no state may create a new, or continue to enforce an existing restriction on the manufacture, processing, distribution, or use of a chemical after the EPA completes a safety determination for that chemical. Under this section, if the EPA takes *any* action on a chemical, state laws and state tort liability could be wiped out. This would have the effect of banning U.S. consumers from filing causes of action based on state tort law if they are harmed or killed by a toxic chemical. Further, states would be prohibited from

¹⁸ *Id.*

¹⁹ TSCA § 6, 15 U.S.C. § 2605(a).

²⁰ See www.chemicalspolicy.org/downloads/Chemicals_Policy_TSCA.doc.

²¹ *Id.*

²² *Id.*

creating new restrictions on such chemicals' manufacture, processing, or distribution for chemicals the EPA classifies as high- or low-priorities.

Further, S. 1009's preemption provisions effectively bar individuals from bringing private suits for injuries caused by exposure to approved chemicals. The bill provides that EPA's safety determination for a high-priority substance "shall be admissible as evidence in any public or private action in any court of the United States or State court for recovery of damages or for equitable relief relating to injury to human health or the environment from exposure to a chemical substance."²³ The bill moreover declares that the "safety determination **shall be determinative** of whether the substance meets the safety standard under the conditions of use addressed in the safety determination."²⁴ By dictating the admissibility and weight that an EPA "safety" finding must be given in a judicial proceeding, the proposed bill puts a further nail in the coffin of private actions by effectively shielding the chemical industry from lawsuits for injuries caused by their products. An attorney simply could not defeat summary judgment, even if he or she has abundant evidence of a chemical's danger and even if that evidence post-dates EPA's finding, because the court would be **bound** to make a finding that the subject chemical is safe based on EPA's determination and regardless of the evidence. This absolute barrier would be present regardless of whether an injured person files suit in federal or state court.

Based on my understanding and knowledge of the federal environmental laws, there is no other environmental law that declares the federal standard the ceiling, or declares that that ceiling is *per se* admissible in court and determinative of the issue of safety. Such a result would be counterproductive and potentially tragic for the health and safety of the populace. After all, it is important for the Committee to recall that the limitations on the use and/or outright ban of vinyl chloride, asbestos and PCBs, to name just a few, are largely the result of environmental groups and attorneys for private citizens who fought relentlessly to uncover the multiple layers of deceit perpetrated by the chemical industry.

2. Preemption of State Action.

Historically, TSCA's deficiencies have been addressed through individual state implementation programs. The proposed bill intends to preempt state regulations,²⁵ thereby potentially depriving the public of one of the most important – and perhaps the most efficient – safeguards in TSCA. Specifically, S. 1009 as currently drafted would preempt existing and

²³ S. 1009, 113th Cong. § 15(e)(1).

²⁴ S. 1009, 113th Cong. § 15(e)(2).

²⁵ S. 1009, 113th Cong. § 15.

future state regulations that, for example, require chemical companies to develop and provide test data and studies on chemicals.

The bill also would preclude states from imposing restrictions on the manufacturing, processing, distributing or use of a chemical that EPA has classified as a low-priority substance. This limitation on states' authority effectively means that no safety assessments will be performed on chemicals EPA declares to be low priority substances.²⁶ Furthermore, the bill would prohibit states from even challenging EPA's determination of whether a substance is high-priority or low-priority, because such a finding is not considered a 'final agency action' and thus is not subject to judicial review.²⁷ Finally, if the history of TSCA is a prologue for future EPA action, since the bill exempts low-priority substances from regulatory protections, and since EPA historically has classified the majority of chemicals as low-priority substances, states for the most part will be deprived of the ability to regulate the use of chemicals in their states and to require the manufacturer to provide information about a chemical's safety.²⁸

Such preemptive treatment in the environmental law arena is unprecedented, and there is a good reason why such sweeping preemption exists nowhere else.²⁹ The Tenth Amendment to the Constitution preserves states' exercise of police powers to protect the health and safety of their citizens. Courts have consistently recognized health and safety regulations to be at the heart of those constitutional police powers.³⁰

I am not aware of any other federal environmental law which blocks the states from regulating toxics more stringently than the federal government. Other than the proposed bill, federal environmental statutes quite properly set the floor for regulatory compliance.³¹ Section 15 of S. 1009, to the contrary, entitled "Preemption," strips the states of their police power to protect their citizenry. This provision is not only bad policy but may well not pass constitutional muster.

²⁶ This proposed bill would remove even those inherent police powers in instances in which the EPA has not yet undertaken regulation or will not be regulating a chemical substance (for example, a chemical it declares a low-priority substance: "The Administrator shall not perform safety assessments on low-priority substances, unless a low priority substance is redesignated [a high-priority substance]. S. 1009, 113th Cong. § 4(e)(3)(H)(ii)).

²⁷ S. 1009, 113th Cong. § 4(e)(5).

²⁸ See *supra* at page 8.

²⁹ For examples of the negative consequences of the preemption provision of S. 1009, see the Center for Environmental Health website at <http://www.ceh.org/making-news/press-releases/29-eliminating-toxics/656-center-for-environmental-health-opposes-the-chemical-safety-improvement-act-of-2013-lautenbergvitter-s1009-unless-substantial-changes-are-made-to-protect-the-health-of-american-families>.

³⁰ See Letter from Attorney General for the State of California for a discussion of the dangers of the bill's preemption provisions at <http://www.healthandenvironment.org/docs/CaliforniaAGMemoOnCSIAPreemption.pdf>.

³¹ See, e.g., 33 U.S.C. § 2718.

3. The Safety Standard and EPA's Burden to Uphold Action.

The proposed bill retains TSCA's onerous safety standard, defining "safety" as the lack of "unreasonable risk of harm to human health or the environment ... result[ing] from exposure to a chemical substance."³² A safety determination under the proposed bill requires the Administrator to determine "whether a chemical substance meets the safety standard under the intended conditions of use."³³ If the goal of S.1009 is truly as declared – "to improve the safety to consumers in the United States" – and in keeping with the bill's findings that "chemicals should be safe for the intended use of the chemicals" and "the unmanaged risks of chemical substances may pose a danger to human health and the environment" -- then this bill should include a strictly health-based standard requiring evidence of a "reasonable certainty of no harm." As now drafted, the standard based upon "unreasonable risk" requires EPA to engage in a complex balancing of costs and benefits rather than mandating a standard that forces the chemical manufacturers to carry the burden of proving that a proposed product does not present a threat to the public. As explained above, this standard functionally is the equivalent of the TSCA Section 6 standard that has hamstrung the agency from banning or limiting the use of chemicals.³⁴

Not only does EPA have a heavy burden before it can impose restrictions on a chemical, but those decisions are subject to a more onerous administrative standard than is generally required for the review of administrative actions. Under the Administrative Procedure Act, an agency's regulations will be upheld unless it is shown that the agency acted in an arbitrary or capricious manner.³⁵ The proposed bill abandons this well-established standard of agency action in place of a more onerous one that requires courts to set aside EPA rules requiring additional testing data, safety determinations and restrictions unless EPA can support its action with "substantial evidence." This standard functionally shifts the burden of proof to EPA to submit substantial evidence that a chemical is not safe for particular uses. EPA is not in the business of manufacturing chemicals and generally does not, and cannot financially afford to, commission studies about a chemical's safety or lack of safety. The contrast with the chemical industry's financial ability to present support for its product and attempt to carry a burden of proving a product's safety is stark.

³² S. 1009, 113th Cong. § 3 (16).

³³ S. 1009, 113th Cong. § 3 (15).

³⁴ See discussion *supra* at pages 10 and 11 and footnote 14.

³⁵ Administrative Procedure Act, 5 U.S.C. §706.

4. Low-Priority Substances Are Unchecked.

As explained above, judicial review of agency decisions made under this proposed bill is anemic. While the bill purports to permit judicial review of final agency action regarding approved uses for high-priority chemicals,³⁶ the bill precludes judicial review of agency of the threshold agency decision classifying a chemical as being a high-priority or low-priority substance.³⁷ The consequences of this are enormous because, once EPA decides that a chemical is a low-priority substance, [“t]he Administrator shall not perform safety assessments on [the chemical].”³⁸ That important determination, however, is based upon incomplete information. A low-priority substance identification is based on “available information” that the chemical “is likely to meet the safety standard under the intended conditions of use.”³⁹ The “information” that forms EPA’s low-priority finding is comprised of “information and data submitted to the Administrator by manufacturers and processors of the substance.”⁴⁰

The manufacturer and processor are allowed broad latitude to label the information presented to EPA as “confidential information,” thereby blocking the information’s availability from public review and comment. Further, the manufacturer and processor are not required to disclose to EPA the funding sources for the studies except to the “extent reasonably ascertainable.”⁴¹ Anyone who has made an effort to learn funding sources of industry-commissioned studies knows that industry sets up sufficient barriers between themselves and the institution performing the research to make it difficult at best to confirm the funding source. The “reasonably ascertainable” language allows industry to circumvent any requirement that it provide funding sources for the studies they submit.

One of the reasons the above provisions are so troublesome is that the structure of the bill favors a chemical being identified as a low-priority substance. In an instance, that chemical will be in the marketplace with no requirements and, indeed, no ability to provide additional or future assessment of the chemical’s safety and with no judicial review of the decision that has resulted in insulating the product from further review. While the bill permits judicial review of agency decisions regarding high-priority substances, there is hardly even the pretense of seeking real or ongoing evaluation of low-priority substances. The consequences are great: not only can the decision not be challenged by anyone, including a state, but a state also cannot, as explained

³⁶ S. 1009, 113th Cong. § (1).

³⁷ S. 1009, 113th Cong. § 4(e)(5).

³⁸ S. 1009, 113th Cong. § 4(e)(3)(H)(ii).

³⁹ S. 1009, 113th Cong. § 4(e)(3)(F).

⁴⁰ S. 1009, 113th Cong. § 4(c)(1)(A).

⁴¹ S. 1009, 113th Cong. § 4(b)(2).

above, require additional assessments for any substance the EPA identifies as low-priority. A misguided EPA decision effectively leaves the entire country powerless to defend itself against the placement of a dangerous chemical in commerce.

IV. Conclusion.

Fundamentally, S. 1009 suffers from multiple flaws, almost unprecedented in the world of environmental regulation to date. Under the bill, organizations and individuals who have fought so hard over the years to uncover the truth about chemicals would be barred from any meaningful participation in the assessment and accountability processes. Those guardians of our health and safety also would be effectively barred from bringing suit in the courts to challenge and expose wrongdoing by the chemical industry. States would not be permitted to fill the gaps left by the federal government and might be prevented from enforcing their current laws on toxic substances. And as a practical matter all interested parties, including the EPA, would be prevented from gaining full access to relevant company information about the chemical product. The bill puts the chemical manufacturing industry in charge of the health and welfare of our citizens and our environment. History proves that to be an unwise decision.

Consider this scenario: Chemical Company A develops Chemical X and submits an application to EPA for permission to sell Chemical X for Y uses. Company A has been developing Chemical X for years and has commissioned and funded studies during that time to support the application. Company A has shielded disclosure of that funding by filtering the funding through other entities in such a way so as to avoid the “reasonably ascertainable” standard for disclosure. Neither the public nor EPA know pre-application that Chemical X is being developed or that Company A intends to seek approval to market Chemical X for Y uses in the United States. The application is submitted and the states and the public, while given an opportunity for comment, must amass information and fight the uphill battle of challenging industry-controlled (and most likely funded) studies during the public comment time frame. It is a battle that rarely, if ever, can be won.

Assume a slightly different scenario. Company A submits information to EPA that Chemical X should be identified as a low-priority substance. The states and the public amass a body of peer-reviewed studies by top-notch scientists from around the world that show that Chemical X has the potential for high hazard and high exposure and, therefore, should be identified as a high-priority substance. Company A submits a fraction of the information submitted by the states and the public, and either does or does not disclose that it paid for each study it submitted in support of the low-priority substance determination.

Despite the fact that the evidence is overwhelming in favor of identifying the chemical as high-priority which, in turn, would trigger the assessment process established by the bill, EPA nevertheless issues a notice of its determination that Chemical X is a low-priority substance. That decision is not subject to judicial review. It is final. End of story. Company A is now permitted to market Chemical X for Y uses in the United States, without any further assessment, despite the overwhelming evidence that X is not safe. Citizens are not able to hold the manufacturers accountable in a court of law and states are left powerless to exercise their police power to impose additional assessments before the product is marketed to their citizens.

The bill in several ways steps back in time to an era where industry safety claims about their products went unchallenged. The public health and welfare should not only be entrusted to chemical manufacturers and a federal agency with limited powers and resources. Enforcement of state law, both by private citizen suits and state enforcement actions, are essential components to fully protecting human health and safety. This multi-layered approach to protecting public health has been in operation for decades, and while TSCA reform is sorely needed, such reform need not disrupt or eviscerate this comprehensive system of checks and balances.

I am honored by the opportunity to provide this commentary and I look forward to doing anything I can to aid this Committee in its efforts to achieve meaningful TSCA reform.