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TESTIMONY

before

**The Subcommittee on Energy and the Economy
Committee on Energy and Commerce**

of the

U.S. House of Representatives

on the

Chemicals in Commerce Act

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Presented by

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Good morning,

Mr. Chairmen, Mr. Ranking Member and Members of the Subcommittee on Energy and the Economy, I thank you for having invited me to appear before you.

My name is Philip J. Landrigan, MD, MSc. I am pediatrician. I serve as Dean for Global Health, Professor and Chairman of the Department of Preventive Medicine, Professor of Pediatrics and Director of the Children's Environmental Health Center (CEHC) in the Icahn School of Medicine at Mount Sinai.

I come before you today to testify in support of the need for strong chemical safety legislation in the United States and to offer my views on the discussion draft of the "Chemicals in Commerce Act".

Strong chemical safety legislation that mandates the safety testing of new chemicals before they come to market as well as safety testing of existing chemicals will improve the health of America's children. It will reduce the prevalence of such dread diseases as autism, attention deficit/hyperactivity disorder, certain congenital malformations and childhood cancer. It will reduce health care costs. It will make the United States of America more economically productive. It will pay for itself many times over.

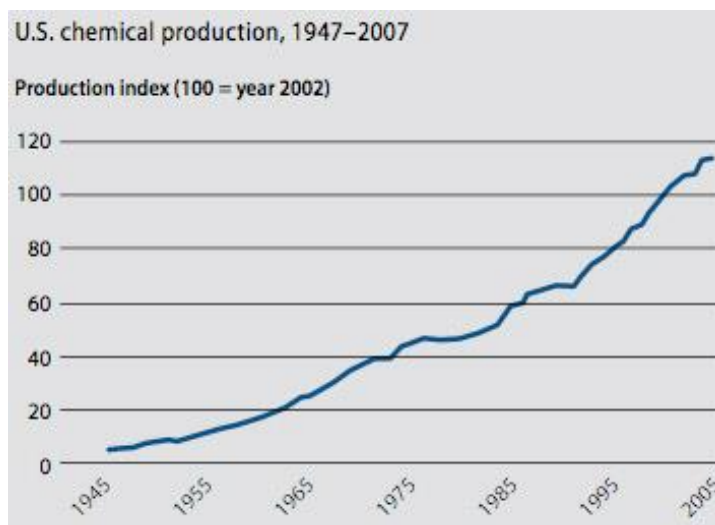
But chemical safety legislation will be of little value, and it will not accomplish these goals unless it contains certain vital provisions:

- It must contain explicit protections for infants and children, including unborn children in the womb, because infants, children and human fetuses are the most vulnerable among us to toxic chemicals.
- It must impose meaningful deadlines on EPA.
- It must permit the states to act to protect their citizens against toxic chemicals when the federal government fails to act.
- It must prioritize those chemicals that are found through biomonitoring to be most widespread in the American population, those for which there is evidence of toxicity, and those that are persistent and bioaccumulative.
- It must be based on a safety standard of "reasonable certainty of no harm". Steps to mitigate risks to children's health should not be subject to cost-benefit analyses in which children's health and well-being are weighed against costs to the chemical manufacturing industry.
- It must require chemical manufacturers to provide a minimum set of data to EPA on all chemicals proposed for commercial introduction just as companies must now provide safety data on pharmaceutical chemicals to the Food and Drug Administration, data on pesticide chemicals to EPA, and data on industrial and consumer chemicals to the European Chemical Agency under the European REACH legislation.
- It must require important data and information to be publicly available and not allow chemical manufacturers to hide behind overly broad and unsubstantiated claims of trade secrecy.
- It must allow for new science to be taken into account when prioritizing and reviewing chemicals.
- It must provide sufficient funding for EPA to effectively carry out the law.

Strong chemical safety legislation will improve the health of America’s children and reduce the prevalence of disease, especially developmental disabilities of the brain and nervous system.

Asthma, autism, attention deficit/hyperactivity disorder (ADHD), cancer, congenital malformations, obesity and diabetes are the principal causes of disease, disability, and death in American children today. Rates of many of these diseases are high and rising (1). The Centers for Disease Control and Prevention (the CDC) finds, for example, that autism spectrum disorder now affects 1 child in 88 (2) and that ADHD is diagnosed in 1 child out of every 7 (3).

At the same time, children’s environments are changing rapidly. More than 80,000 new synthetic chemicals have been invented over the past 50 years, and 1,000 new chemicals come to market every year (**Figure below**) (4). These chemicals are used today in millions of products that range from foods and food packaging to clothing, building materials, cleaning products, cosmetics, toys, and baby bottles. Synthetic chemicals have become widely disseminated in children’s environments and in the bodies of all Americans. In national surveys conducted by CDC, measurable levels of several hundred synthetic chemicals are found in the blood and urine of virtually all Americans (5). Detectable levels are seen in the breast milk of nursing mothers and the cord blood of newborn infants (6).



Most chemicals in commerce have never been tested for their possible toxicity. Of very great concern to me as a pediatrician, parent and grandparent is that most of the new chemicals introduced to the American market over the past two generations have never been subjected to even minimal safety testing (4).

An especially disturbing fact is that only about 20 percent of the chemicals in widest use have been screened for their potential to disrupt early human development or to cause disease in infants and children.(4)

My colleague, pediatrician Herbert Needleman, pioneer in the prevention of childhood lead poisoning has described this situation as follows: “We are conducting a vast toxicological experiment in the United States, and our children and our children’s children are the unwitting and unconsenting subjects.”

America's failure to require safety testing of chemicals carries grave risks. And these risks are not merely hypothetical. Time and time again, toxic chemicals that were not properly tested before they came to market in the United States have been proven to cause injury to unborn children in the womb, to young infants and to growing children.

Examples of chemicals that were brought to market with much fanfare and initially hailed as beneficial, but later found to cause great harm include:

- Lead added to paint and gasoline – caused widespread lead poisoning and brain injury (7,8)
- Asbestos – caused a global epidemic of cancer (9)
- Thalidomide – caused over 10,000 cases of birth defects of the limbs in newborn infants (10)
- Polychlorinated biphenyls (PCBs) – prenatal exposure causes loss of IQ (11)
- Di-ethylstilbestrol (DES) – caused cancer of the vagina in girls exposed *in utero* (12)
- Chlorofluorocarbons (CFCs) – destroyed the stratospheric ozone layer (13)
- Organophosphate pesticides – prenatal exposure causes brain injury with loss of IQ and behavioral problems (14)
- Brominated flame retardants – prenatal exposure causes brain injury with loss of IQ and behavioral problems (15)
- Phthalates – prenatal exposure causes brain injury with loss of IQ and behavioral problems resembling autistic behaviors and also causes anomalies of the amle reproductive organs.(16, 17)

Infants and children, and most especially unborn children in the womb, are exquisitely sensitive to toxic chemicals. We now know that infants and children are very sensitive to chemical exposures, much more so than adults. A landmark report issued 20 years ago by the National Academy of Sciences documented that infants and children have exposures to toxic chemicals that are much greater pound-for-pound than the those of adults and that children are much more vulnerable to toxic injury caused by chemicals. (18)

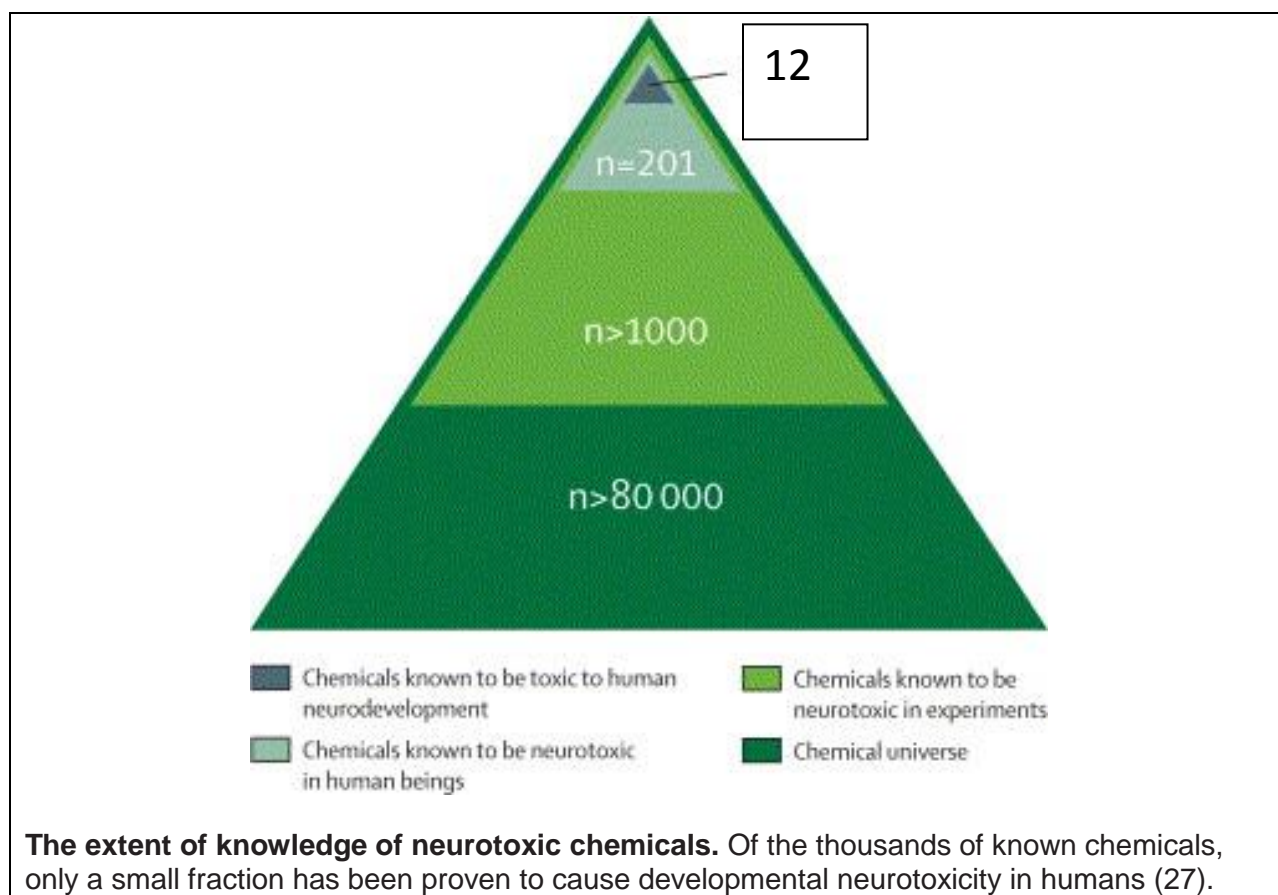
New research has identified "critical windows of vulnerability" in fetal life and early childhood when exposures of the unborn baby or the young infant to even minutely low levels of chemicals can cause devastating injury to the developing organs (18). Children's developing brains, because they are so incredibly complex, are at particularly high risk of chemical injury during the nine months of pregnancy and in the first months and years after birth. A number of chemicals have now been strongly linked to brain injury in human infants:

- Lead (7, 8)
- Methyl Mercury (19)
- Polychlorinated Biphenyls (PCBs) (11)
- Organophosphate pesticides (14)
- Arsenic (20)
- Manganese (21)
- Organochlorine pesticides (22)
- Brominated flame retardants (Polybrominated diphenyl ethers) (15)
- Phthalates (16)
- Bisphenol A (23)
- Polycyclic aromatic hydrocarbons (24)
- Perfluorinated compounds (25).

Suspicion is high that, beyond these few well established chemical causes of developmental disabilities in children, there may be other widely used chemicals that also are toxic to the developing human brain, but that have never been properly tested (26).

A recent systematic review of the world's literature produced a list of approximately 200 industrial chemicals that are documented to be neurotoxic in adult humans (27). These are primarily acutely toxic chemicals that have caused serious, clinically obvious, acute effects at high levels of exposure. None of these chemicals, even those in wide use, have been tested to determine whether they are safe for infants and children. Additionally, this search produced a second list of approximately 1,000 chemicals that have been found to be neurotoxic in animal species, principally in acute, high-dose exposure scenarios. None of these chemicals have been examined in humans, let alone in human infants (27).

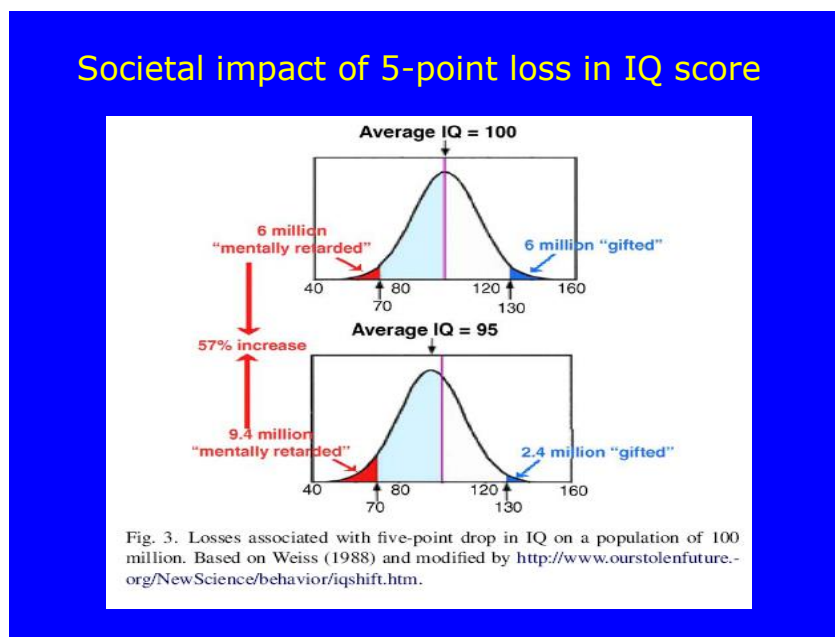
The relatively small number of chemicals that have been identified as proven causes of brain injury in children is likely the tip of an iceberg that could be very large (**See Figure below**). But we do not how large might be this iceberg because testing data on chemicals in wide use have never been required.



Widespread exposure to untested neurotoxic chemicals can reduce the intelligence, creativity and economic productivity of entire societies. Beyond obvious developmental disabilities such as autism, ADHD and learning disabilities, current research has shown that exposures to toxic chemicals at levels too low to cause obvious symptoms can still cause real, but less obvious brain injury in children. This is termed “subclinical” brain injury (7, 8).

Subclinical brain injury results in decreased intelligence, impaired cognitive skills, shortening of attention span and disruption of behavior (7, 8). Because the human brain has only very limited capacity for regeneration or repair, most cases of subclinical brain injury result in permanent and irreversible damage and thus produce lifelong reduction in children's ability to function.

When subclinical brain injury is widespread in a society, it can reduce intelligence and diminish economic productivity across an entire nation (28). An example is the downward shift in population IQ that occurred in the United States between the 1930s and mid-1970s when virtually all of our children were exposed to substantial amounts of lead emitted into the environment by the combustion of leaded gasoline. It is estimated that this widespread exposure to lead, which reduced the average IQ of all American children by 2-5 points, reduced the number of children with truly superior intelligence (IQ scores above 130 points) by over 50% and at the same time doubled the number with IQ scores below 70 (**Figure below**).



The consequence of widespread subclinical neurotoxicity is decimation of a country's future capacity for leadership. Widespread exposures to neurotoxic chemicals threaten societal sustainability. Widespread exposures to neurotoxic chemicals undermine national security. There is speculation that exposure of the ruling classes to lead with subsequent widespread brain injury and reduced fertility accelerated the fall of Rome.

Strong chemical safety legislation will reduce health care costs and make the United States of America more economically productive.

Disease caused by toxic chemicals in the environment is very expensive and contributes to health care costs in the United States. The costs associated with disease in children caused by environmental exposures include direct medical costs as well as indirect or non-medical costs. These indirect costs include the cost of a child's time lost from school; the cost of a parent's time lost from work while caring for a sick child; the costs of special education; the costs of rehabilitation; the costs of lifelong reduction in economic productivity in damaged children; and the costs of lost productivity from premature death

A 2011 estimate of the costs of environmental disease in the United States examined the annual medical and non-medical costs of lead poisoning, methyl mercury exposure, childhood cancer, asthma, intellectual disability, autism, and attention deficit hyperactivity disorder in US children. The analysis concluded that these costs currently amount to \$76.6 billion per year (29) (See Table).

	<u>Best estimate</u>	<u>Low-end estimate</u>	<u>High-end estimate</u>
Lead poisoning	\$50.9 billion	\$44.8 billion	\$60.6 billion
Methylmercury toxicity	\$5.1 billion	\$3.2 billion	\$8.4 billion
Asthma	\$2.2 billion	\$728.0 million	\$2.5 billion
Intellectual Disability	\$5.4 billion	\$2.7 billion	\$10.9 billion
Autism	\$7.9 billion	\$4.0 billion	\$15.8 billion
AD/HD	\$5.0 billion	\$4.4 billion	\$7.4 billion
Childhood cancer	\$95.0 million	\$38.2 million	\$190.8 million
Total	\$76.6 billion	\$59.8 billion	\$105.8 billion

(From Trasande and Liu, 2011 [29])

Neurodevelopmental disorders are especially costly because they last lifelong. The direct medical costs of caring for children with neurodevelopmental disabilities fall on families, school districts, employers, insurers and government. The annual per capita cost of caring for a person with autism in the United States is estimated to be \$3.2 million. The annual cost for providing medical care to the entire population of children who develop autism in the United States in any given year is estimated to be \$35 billion. In addition, people with autism spend twice as much on health care than the typical American over their lifetimes and spend 60% of those incremental direct medical costs after age 21 years (30).

In addition to direct medical costs, neurodevelopmental disabilities have substantial indirect costs such as costs of special education, legal costs, costs of institutionalization and incarceration, costs of alternative therapies, and the costs associated with lifelong reductions in economic and social productivity (31).

Special education services for students with developmental disabilities including ASD and PDD cost over \$77 billion per year (32).

Current Chemical Safety Legislation in the United States Does not Protect Children's Health.

At the present time, chemicals that are intended for industrial or consumer use, chemicals that are found in products as diverse as foods and food packaging, clothing, building materials, cleaning products, cosmetics, furniture, toys, and baby bottles, are virtually unregulated in the United States. These chemicals are subjected to little or no safety testing before they come to market. Unlike pharmaceutical chemicals, they are not monitored for safety after they come to market even though they may result in exposures to millions of Americans of all ages.

This failure to test chemicals for safety reflects failure of the Toxic Substances Control Act of 1976 (4)

At the time of its passage, the Toxic Substances Control Act was intended to be pioneering legislation that would require safety testing of chemicals already in commerce and would also require premarket evaluation of all new chemicals. The Act never fulfilled those noble intentions. A particularly egregious lapse was a decision soon after passage of the Act to "grandfather in" the 62,000 chemicals that were then already on the market without any toxicity testing requirement. These chemicals were simply presumed to be safe and allowed to remain in commerce, unless and until the Environmental Protection Agency made a finding that they posed an "unreasonable risk." (4)

This "unreasonable risk" standard in the Toxic Substances Control Act has created a substantial barrier to the regulation of industrial and consumer chemicals. This standard has been so burdensome that EPA has not been able to remove chemicals from the market even when there is overwhelming evidence of potential harm. The result is that only five chemicals have been controlled under the act in the thirty-five years since its passage. (4)

Further barriers to enforcement of the Toxic Substances Control Act have resulted from the federal courts' interpretation of the "unreasonable risk" standard. Thus, in a 1991 opinion on the asbestos ban in *Corrosion Proof Fittings v. EPA*, the Fifth Circuit found that the Environmental Protection Agency had failed to show that it was taking the "least burdensome" approach required under the Act in formulating its final rule banning asbestos. The court thus overturned the agency's rule banning asbestos.

This interpretation has made it virtually impossible since 1991 for the Environmental Protection Agency to regulate dangerous chemicals under the Act.

Strong Chemical Safety Legislation Protects Children's Health

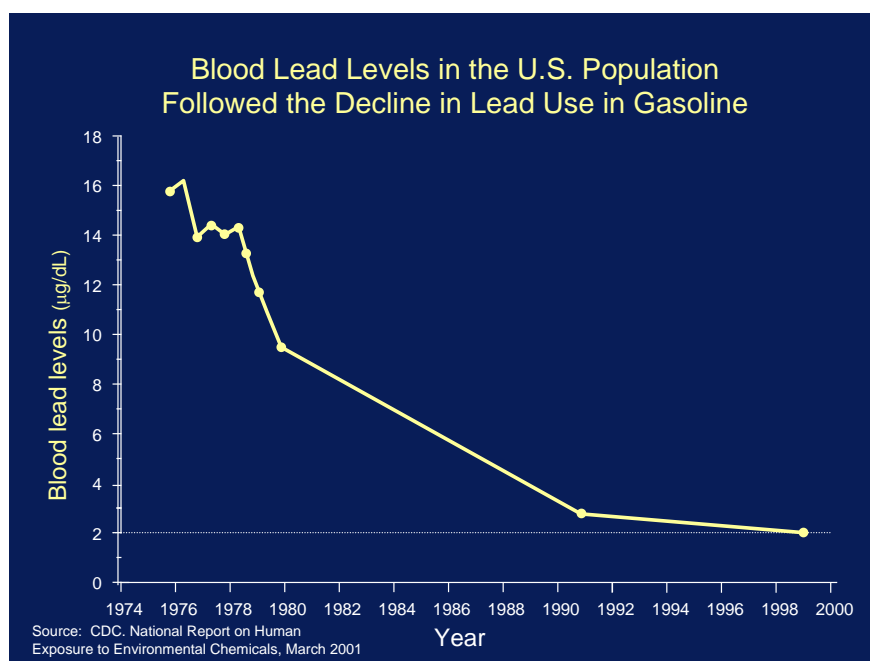
Diseases caused in American children by toxic chemical exposures can be prevented. They can be prevented when research identifies links between the chemicals and disease and when that research is translated in to policy and regulation that protects infants, children and all Americans against toxic chemicals

The removal of lead from gasoline, which began in the United States in 1976, is a classic example of the successful removal of a toxic chemical from commerce (**See Figure below**) (33). The action by EPA to remove lead from gasoline was triggered by research findings showing that exposure of American children to lead was eroding intelligence and disrupting behavior (7, 8). This action was taken in the face of strong opposition from the chemical industry which claimed that removal of lead from gasoline would cost jobs and cripple the American economy.

In fact, the removal of lead from gasoline produced a series of benefits, all of them much greater than had been anticipated (34):

- It resulted in a more than 90% reduction in blood lead levels in American children.
- It produced a 90% reduction in incidence of childhood lead poisoning.
- It raised the average IQ of all American children by 2 -5 points.
- It has produced an economic benefit estimated to be approximately \$200 billion in each US birth cohort born since the 1980s (50). This economic benefit resulted largely from increases in productivity that followed population-wide increases in intelligence.

This success has now been replicated in countries around the world.



The Urgent Need for a New US Chemical Policy that Protects Children's Health.

To better defend America's children against the unforeseen consequences of industrial and consumer chemicals and to avoid the repetition of past tragedies, the United States needs to adopt a new national paradigm for chemical safety and to pass new legislation that will enable EPA to exercise responsible stewardship over industrial and consumer chemicals (4).

This new paradigm must be designed explicitly to protect children's health and the environment. It must overturn the dangerous and outdated assumption that chemicals are "innocent" until proven "guilty". This hallowed principle of American jurisprudence has no place in the regulation of consumer chemicals.

One critical component of a new, health-based chemical policy in the United States must be a legally enforced requirement that chemicals already on the market be systematically examined for potential toxicity beginning with those chemicals that are found through biomonitoring to be most widespread in the American population, those for which there is evidence of toxicity, and those that are persistent and bioaccumulative.

A second critical component of a health-based chemical policy would be a legally mandated, strictly enforced requirement that all new chemicals be assessed for potential toxicity before they enter the market.

A third pillar of a health-based chemical policy would be continued research to examine the impact of chemicals on children's health. Such research is an essential complement to toxicity testing. It provides direct evidence of the effects of chemicals on human health. It also provides an evidentiary basis for assessing the impact on children's health of policy interventions.

Conclusion.

The discussion draft of the "Chemicals in Commerce Act" that is currently before us is not satisfactory. It will not protect the health of America's children – born and unborn. It will not protect America's environment. It will not reduce health care costs. It will not benefit the United States of America. It will perpetuate the mistakes of the past and jeopardize the health and well-being of America's children today and in the future.

Nonetheless, I applaud the United States Congress for seriously considering chemical safety legislation and for recognizing that the Toxic Substances Control Act of 1976 is outmoded, ineffective and failed legislation that needs to be replaced. I salute the legacy of the late Senator Frank Lautenberg of New Jersey who for so many years pioneered the reform of chemical safety legislation in the United States. I stand ready to assist you in your continuing deliberations.

Thank you.

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