S. HRG. 111–1218

OVERSIGHT HEARING ON THE FEDERAL TOXIC SUBSTANCES CONTROL ACT

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH

AND THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

DECEMBER 2, 2009

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ONE HUNDRED ELEVENTH CONGRESS
FIRST SESSION

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C O N T E N T S

OVERSIGHT HEARING ON THE FEDERAL TOXIC SUBSTANCES CONTROL ACT

WEDNESDAY, DECEMBER 2, 2009

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON SUPERFUND, TOXICS,
AND ENVIRONMENTAL HEALTH,
Washington, DC.

The committee and subcommittee met, pursuant to notice, at 2:40 p.m. in room 406, Dirksen Senate Office Building, Hon. Frank R. Lautenberg (chairman of the subcommittee) presiding.

Present: Senators Lautenberg, Boxer, Inhofe, Barrasso, Bond, Cardin, Klobuchar, Merkley, Udall, and Whitehouse.

OPENING STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. I am a little alarmed because I am put to the right of the Chairman, and that is not where I intend to be.

[Laughter.]

Senator LAUTENBERG. But so I want to thank everyone for being here. I thought you would be the left of me, but that is so ordinary.

[Laughter.]

Senator LAUTENBERG. Anyway, despite evidence to the contrary, Senator Inhofe and I are good friends, and the evidence is not real. Oh, I don't want to get into that.

[Laughter.]

Senator LAUTENBERG. Now for the serious part.

I want to thank everyone for being here as we focus on better protecting the health of our families by updating our chemical safety laws.

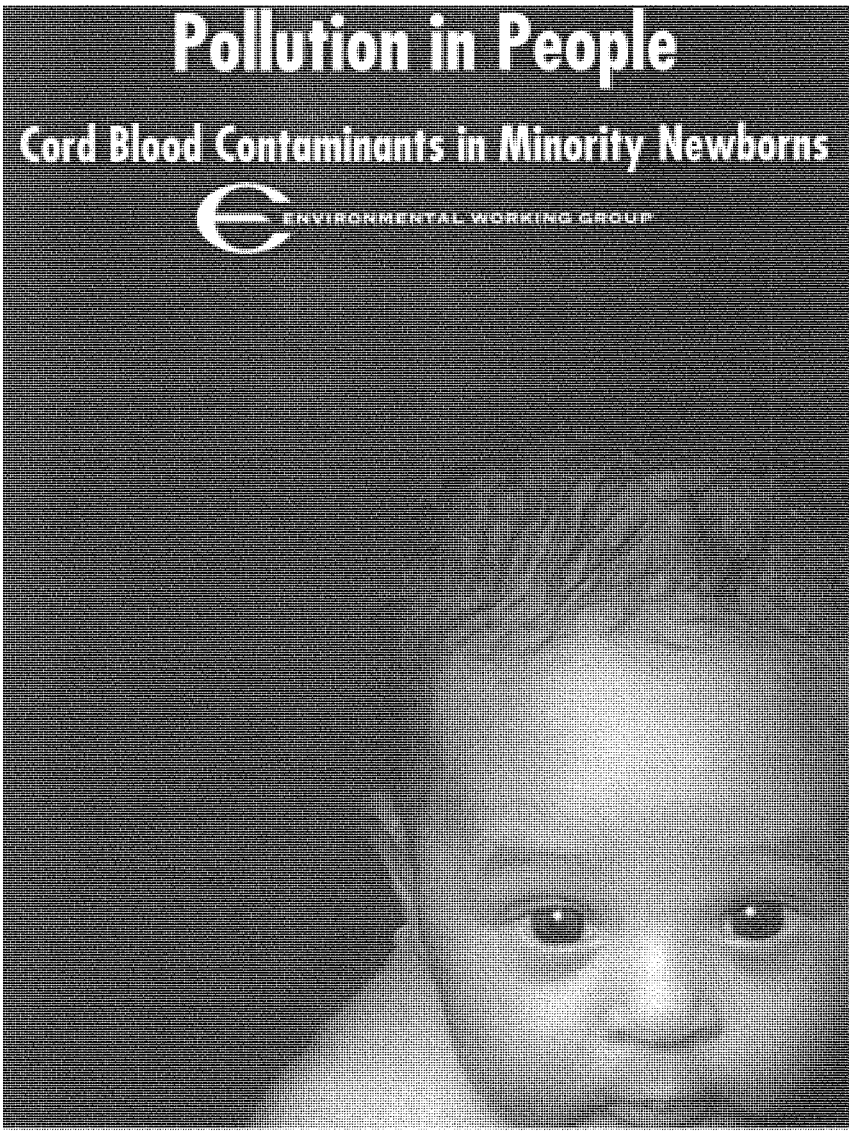
This is a joint hearing of my Subcommittee on Superfund, Toxics, and Environmental Health and the full committee, which Senator Boxer chairs ably, and the two are going to—Senator Boxer asked, because I had such an active interest for such a long time in the subject at hand, that she agreed to hold this hearing and to permit me, again, the leadership of the hearing, at the hearing.

Right now, there are hundreds of industrial chemicals in our bodies. That goes for nearly everyone in America. In fact, just this morning, the Environmental Working Group released the results of a 2-year study that found nearly 250 different industrial chemicals in the blood of 10 babies who were exposed to the substances while still in the womb.

While some of these chemicals might not be harmful, others clearly are. And that means that these children face the possibility

of chronic, life long health problems from the day they are born. And I ask unanimous consent to enter the Environmental Working Group study into the record.

[The referenced information follows:]


Pollution in People
Cord Blood Contaminants in Minority Newborns
ENVIRONMENTAL WORKING GROUP

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Executive Summary

A two-year study involving five independent research laboratories in the United States, Canada and the Netherlands has found up to 232 toxic chemicals in the umbilical cord blood of 10 babies from racial and ethnic minority groups. The findings constitute hard evidence that each child was exposed to a host of dangerous substances while still in its mother's womb.

The research, commissioned by the Environmental Working Group in partnership with Rachel's Network, marks the most extensive investigation of the particular environmental health risks faced by children of African American, Hispanic and Asian heritage.

The laboratory analyses represent the first reported detections in American newborns for 21 contaminants. Among them:

- **Bisphenol A (BPA)**, a derivative of the petrochemical benzene essential to the manufacture of tough polycarbonate plastic and epoxy resins that are fabricated into a wide variety of modern products, including metal food cans, hard plastic infant formula bottles, water bottles, safety helmets and glasses, television, computer and cell phone housings, compact discs and high performance coatings. BPA is a synthetic estrogen that researchers have found to disrupt the endocrine system, disrupt normal reproductive system development and diminish test animals' intellectual and behavioral capacity.
- **Tetrabromobisphenol A (TBBPA)**, a fire retardant for circuit boards that interferes with thyroid function and may inhibit the production of T cells the body uses to fight disease, undermining immune defenses against bacteria, viruses and cancer. TBBPA can break down to BPA, and when incinerated it creates brominated dioxins, which are considered likely human carcinogens.
- **Galaxolide and Tonalide,** polycyclic musks that are synthetic fragrances in cosmetics, laundry detergent and other scented products and that have been detected in numerous biomonitoring studies of pollution in people and in the aquatic environment.
- **Perfluorobutanoic acid (PFBA, or C4)**, a member of the perfluorocarbon (PFC) chemical family used to make non-stick, grease-, stain- and water-resistant coatings for consumer products, including brands Teflon, Scotchgard and Goretex. The most studied PFCs, the Teflon chemical PFOA and the Scotchgard chemical PFOS, are linked to cancer, birth defects and infertility. PFCs are extremely persistent in the environment. There is almost no toxicological data for PFBA in the public domain.
- **8 Previously Undetected Polychlorinated biphenyls** (PCBs). Developed as industrial lubricants, coolants and insulating materials, also used in caulk, PCBs were effectively banned in the late 1970s but are long-lasting in the environment. The U.S. government lists PCBs as probable human carcinogens. According to government and academic scientists, PCBs have been shown to disrupt the endocrine system and damage the immune system, and are toxic to the developing brain.

Pollution in People - Cord Blood Contaminants in Minority Newborns

Some racial and ethnic minority communities in the U.S. experience disproportionate exposures to environmental pollution (Brulle and Pellow 2006). Whether through poverty or historical patterns of discrimination, some are more likely to live near busy roads, industrial sites and in older housing. These factors, combined with workplace exposures, diet and use of certain consumer products, may lead to greater contamination with chemicals. When combined with poor nutrition and health, the adverse effects of having a greater chemical body burden can be aggravated.

In spite of the acute need to understand prenatal exposures in all segments of American society, EWG could find no studies that examined the chemical body burden in the womb for minority children. This study is a first attempt to fill that void.

The 10 children in this study were born between December 2007 and June 2008 in Michigan, Florida, Massachusetts, California and Wisconsin. They are otherwise anonymous.

We have no way of knowing anything about the homes and neighborhoods into which they were born. This study tested for chemicals that can be found in virtually every American household. We did not test for chemicals, such as the byproducts of smoking or alcohol consumption, that would indicate behaviors by the mother that could in any way jeopardize the health of the child. We also did not test for chemicals from local pollution sources.

We cannot determine how chemical exposures in utero may vary from one community to another, but our results strongly suggest that the health of all children is threatened by trace amounts of hundreds of synthetic chemicals coursing through their bodies from the earliest stages of life.

What's Unique About EWG's Biomonitoring Research?

This study is EWG's eleventh biomonitoring investigation. To date, EWG studies have found 414 industrial chemicals, pollutants and pesticides in 186 people, from newborns to grandparents. Our goal is to quantify the pollution in people, or what we call the "human toxome," and to drive science and policy changes to protect public health.

The Centers for Disease Control and Prevention (CDC) has published biomonitoring study results involving thousands of people nationwide over the past decade. Its next report, the fourth in a series, is expected to list detections of more than 200 pollutants found in representative samples of the U.S. population.

EWG's biomonitoring program complements the CDC in three key respects:

1. **More chemicals:** CDC looks for fewer chemicals, but in larger, statistically representative samples of the U.S.population. EWG studies typically look for more chemicals than the CDC, but in smaller sample cohorts. EWG has detected more than 414 chemicals in people, compared to 203 reported by the CDC. EWG relies on specialized laboratories around the world to maximize the scope of its analyses.
2. **Mixtures in each person:** CDC reports its results chemical by chemical, estimating how many Americans are exposed to each chemical under investigation. EWG publishes the full list of chemicals found in each person tested to convey the scope and complexity of each person's body burden.
3. **Early life exposures:** CDC tests adults and children age 6 and up. The agency rarely tests cord blood or infants. EWG studies include cord blood, infants and toddlers to help document exposures during the most vulnerable periods of development.

The contaminants found in these children are from unintended exposures to some of the most problematic consumer product and commercial chemicals ever put on the market. Their presence in fetal cord blood represents a significant failure on the part of the Congress and government agencies charged with protecting human health.

Scientists know far too little about the health threats posed by exposure to toxic chemicals in the womb. There is broad agreement, however, that the dangers are greater when exposure occurs before birth. Just how much more dangerous is not known.

Brominated flame retardants, PCBs, the Teflon chemical PFOA and the Scotchgard chemical PFOS, BPA, lead, mercury, perchlorate, dioxins and furans are all considered either likely human carcinogens, serious neurotoxins or well-established hormone disrupters, according to government health authorities. Many are strongly linked to more than one of these effects.

Recommendations

Government, academic and independent biomonitoring studies, including those by EWG, have detected up to 358 industrial chemicals, pesticides and pollutants in the cord blood of American infants. Exploring the so-called "additive" effects of possible carcinogens, hormone disrupters and neurotoxins is a new and urgent priority for environmental health scientists. EWG supports this very important work.

But as this science moves forward, we need to act now to reduce exposures that present the greatest health threats based on what we know today, even as scientists struggle to understand how the cocktail of chemicals in the womb could harm current and future generations.

Many of the up to 232 compounds detected in this study have been the target of regulatory action and government controls. As a rule, however, these actions came far too late, well after the environment and the human race were polluted to a degree that has raised serious health concerns. Our failure to act quickly has ensured that these chemicals will continue to pollute future generations for decades, even centuries to come.

EPA Administrator Lisa Jackson has identified several of the substances found in this study as priority chemicals of concern. These include BPA, brominated flame retardants and the entire class of perfluorinated (Teflon and Scotchgard) chemicals.

In our view, any chemical found in cord blood should be a top candidate for tough regulatory action to protect public health.

To ensure a full accounting of chemical exposure before birth, we recommend that the CDC initiate a comprehensive cord blood-testing program. This work should be coordinated with ongoing biomonitoring in the National Children's Study but should seek to identify and quantify the full extent of chemical exposures in the womb over time. The complete costs of this work must be borne by industry.

Findings

The Environmental Working Group, in partnership with Rachel's Network, commissioned five laboratories in the U.S., Canada, and Europe to analyze umbilical cord blood collected from 10 minority infants born in 2007 and 2008. Collectively, the laboratories identified up to 232 industrial compounds and pollutants in these babies, finding complex mixtures of compounds in each infant.

This research demonstrates that industrial chemicals cross the placenta in large numbers to contaminate a baby before the moment of birth. Test results are shown below.

Chemicals Detected in Umbilical Cord Blood from 10 Minority Newborns

Chemical or chemical family	Geometric Mean (of the detections)	Range	Number of newborn umbilical blood samples with detections	Number of chemicals detected within chemical family
Metals [µg/dL (wet weight) in whole blood] - 3 of 3 found				
Lead [pollutant from lead-based paint in older homes, household dust, vinyl products; harms brain development and function]	0.348 µg/dL	(0.222 - 0.549)	10 of 10	NA
Mercury [pollutant from coal-fired power plants, mercury-containing products, and certain industrial processes; accumulates in seafood; harms brain development and function]	0.64 µg/dL	(0.09 - 3.91)	10 of 10	NA
Methylmercury [organic form of mercury typically found in contaminated fish and seafood]	0.513 µg/dL	(0.08 - 3.28)	10 of 10	NA

Chemical or chemical family	Geometric Mean (of the detections)	Range	Number of newborn umbilical blood samples with detections	Number of chemicals detected within chemical family
Polybrominated dibenzodioxins and furans (PBDD/F) [pg/g (lipid weight) in blood serum] - contaminants in brominated flame retardants; pollutants and byproducts from plastic production and incineration; accumulate in food chain; toxic to developing endocrine (hormone) system				
Brominated dioxin	34.57 pg/g	(0 - 41.8)	2 of 10	Tested for: 6 Found: 1
Brominated furan	292 pg/g	(0 - 1440)	4 of 10	Tested for: 6 Found: 5
Perfluorinated chemicals (PFCs) [ng/g (wet weight) in whole blood] - active ingredients or breakdown products of Teflon, Scotchgard, fabric and carpet protectors, food wrap coatings; global contaminants; accumulate in the environment and the food chain; linked to cancer, birth defects and more				
Perfluorochemicals (PFCs)	2.38 ng/g	(0.736 - 7.08)	10 of 10	Tested for: 13 Found: 6
Polybrominated diphenyl ethers (PBDEs) [ng/g (lipid weight) in blood serum] - flame retardant in furniture foam, computers and televisions; accumulates in the food chain and human tissues; adversely affects brain development and the thyroid				
Polybrominated diphenyl ethers (PBDEs)	7.28 ng/g	(3.05 - 15.1)	10 of 10	Tested for: 46 Found: 26 to 29[1]
Polychlorinated naphthalenes (PCNs) [ng/g (lipid weight) in blood serum] - wood preservatives, varnishes, machine lubricating oils, waste incineration; common PCB contaminant; contaminate the food chain; cause liver and kidney damage				
Polychlorinated naphthalenes (PCNs)	0.64 ng/g	(0.0743 - 3.43)	10 of 10	Tested for: 70 Found: 17 to 24[2]
Polychlorinated biphenyls (PCBs) [ng/g (lipid weight) in blood serum] - industrial insulators and lubricants; banned in the U.S. in 1976; persist for decades in the environment; accumulate up the food chain to humans; cause cancer and nervous system problems				
Polychlorinated biphenyls (PCBs)	22.1 ng/g	(0.66 - 39.7)	10 of 10	Tested for: 209 Found: 98 to 147[3]

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Chemical or chemical family	Geometric Mean (of the detections)	Range	Number of newborn umbilical blood samples with detections	Number of chemicals detected within chemical family
Polychlorinated dibenzodioxins and furans (PCDD/F) [pg/g (lipid weight) in blood serum] – pollutants, by-products of PVC production, industrial bleaching and incineration; cause cancer in humans, persist for decades in the environment; very toxic to developing endocrine (hormone) system.				
Chlorinated dioxin	52.6 pg/g	(5 - 383)	10 of 10	Tested for: 7 Found: 6
Chlorinated furan	16.3 pg/g	(0 - 278)	6 of 10	Tested for: 10 Found: 9
Bisphenol A (BPA) [ng/mL (wet weight) in blood serum] – building block of polycarbonate plastics and epoxy resins for thousands of consumer products, including baby bottles, drinking water containers, metal food and beverage can liners and dental sealants; linked to hormone disruption, birth defects and cancer				
Bisphenol A	2.8 ng/mL	(0 – 8.61)	9 of 10	NA
Brominated fire retardant [ng/g (lipid weight) in blood serum] - 1 of 1 found				
Brominated Fire Retardant	2966 ng/g	(0 - 3210)	3 of 10	NA
Perchlorate [µg/L (wet weight) in whole blood] - 1 of 1 found				
Perchlorate	0.231 µg/L	(0 - 0.6)	9 of 10	NA
Polycyclic musks [ng/g (wet weight) in whole blood] – heavily used synthetic fragrances that mimic natural musk				
Polycyclic musks	0.835 ng/g	(0 - 2.74)	7 of 10	Tested for: 6 Found: 2

Notes:

1.) Numbers are expressed as a range because several PBDEs are tested for in pairs; a positive result may mean one or both are present. The range reflects the minimum and maximum number of possible positive results.

2.) Numbers are expressed as a range because many PCNs are tested for in groups of two or three chemicals; a positive result may mean that one, some, or all are present. The range reflects the minimum and maximum number of possible positive results.

3.) Numbers are expressed as a range because many PCBs are tested for in groups up to six at a time: a positive result may mean that one, some, or all are present. The range reflects the minimum and maximum number of possible positive results.

BPA – plastics chemical

Key findings:
- First ever detection of BPA in U.S. cord blood. Found in 9 of 10 cord blood samples tested.

What is it? - BPA is a petrochemical derivative used to toughen polycarbonate plastic and epoxy resin.

How does it contaminate cord blood? – BPA is found in food, beverages and infant formula sold in metal cans (lined with BPA-based epoxy resin), drinks in polycarbonate plastic containers (made from BPA). Because epoxy resin and polycarbonates are unstable, BPA in food packaging leaches readily into any food or liquids the packaging touches.

Health risks - BPA acts as a synthetic estrogen that disrupts the endocrine system and causes other harmful effects, even at very low doses. In test animals, BPA induces abnormal reproductive system development, diminishes intellectual capacity, causes behavioral problems and has induced reproductive system cancer, obesity, diabetes, early puberty, resistance to chemotherapy, asthma, cardiovascular system problems and other chronic ailments.

Regulatory status – The FDA is considering whether to regulate BPA in food packaging. Minnesota and Connecticut, Chicago, Suffolk County, N.Y., and Schenectady County, N.Y., have banned BPA in baby bottles and other children's food containers and utensils, and Massachusetts has issued a strong warning against them. In 2009, bills to ban or restrict BPA were introduced in the U.S. Congress and 21 states. Major baby bottle and sports bottle makers have voluntarily switched to non-BPA plastics, but the food canning industry has not developed non-BPA linings for metal cans.

Discussion:
Tests performed by the Division of Biological Sciences at the University of Missouri-Columbia identified BPA in cord blood from 9 of 10 minority newborns. Cord blood studies in Asia and Europe have found traces of BPA in cord blood, but until now, scientists have not reported finding the chemical in cord blood of American infants.

The impact on human health of BPA, a ubiquitous plastic component detected by CDC researchers in 93 percent of Americans over age 6 (Calafat 2008), is a major research priority for federal scientific institutions and major independent research laboratories around the world.

Scientists discovered that BPA was a synthetic estrogen as early as 1936, but exposure to traces of the chemical was thought to be harmless until 1997, when a team led by Missouri biologist Frederick Vom Saal demonstrated that very low doses of BPA caused irreversible damage to the prostates of fetal male mice. Since then, scores of animal studies have produced substantial evidence that BPA disrupts the endocrine system, even at the very small concentrations to which people are typically exposed, and may cause a lengthening list of serious disorders.

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Among them are:

- Endocrine system disruption
- Cancer
- Impaired brain function and behavioral abnormalities
- Cardiovascular disease
- Infertility and miscarriage
- Obesity and diabetes
- Asthma
- Resistance to chemotherapy
- Epigenetic and transgenerational effects

A rare human epidemiological study, published in November 2009 in the journal Human Reproduction, offers what its authors called "the first evidence that exposure to BPA in the workplace could have an adverse effect on male sexual dysfunction."

In 2008, the National Toxicology Program, an authoritative interagency science panel housed at the National Institute for Environmental Health Sciences, concluded that BPA may harm the brain, behavior and prostate gland of fetuses, infants and children, even at the low doses to which people are currently exposed. (NTP 2008). NTP officials called for more intensive research on BPA on the grounds that "the possibility that BPA may affect human development cannot be dismissed."

In response, in October 2009, NIEHS Director Linda Birnbaum targeted $30 million in federal stimulus funds to basic research on BPA and human health.

Children, African Americans and the poor may face heightened health threats from bisphenol A. The CDC has found average BPA levels 80 percent higher in children ages 6-11 than in adults over 20 (Calafat 2008). These surveys have also detected BPA levels 24 percent higher in people from households with annual incomes under $20,000 versus $45,000 or more, and 11 percent higher among non-Hispanic blacks than whites.

In 2008, citing two industry-sponsored studies, the FDA deemed low-dose BPA exposure safe, even for pregnant women and infants. At the urging of its Science Board and 33 university scientists and independent experts, the agency is now reassessing the safety of BPA in food packaging.

Perchlorate (rocket fuel oxidizer)

Key Findings:

- Found in 9 of 10 cord blood samples. This is just the second study to find perchlorate in American babies; the first was published in September 2009 and reported results from children born in New Jersey.

What is it? – Perchlorate is a rocket fuel oxidizer that powers missiles, the space shuttle, fireworks, road flares, automobile airbags and more.

How does it contaminate cord blood? – It seeps into soil and groundwater because of improper storage and disposal at defense and aerospace facilities and chemical plants. Water utilities in 35 states and territories have found perchlorate in drinking water. The FDA detected perchlorate in 74 percent of 285 popular foods and beverages tested, including baby food.

Health risks – Perchlorate can block the formation of thyroid hormones critical to brain development and growth in the fetus, infants, and children. Inadequate iodine intake increases the risk of perchlorate-related compromise of thyroid hormone production.

Regulatory status – EPA is re-evaluating the need for a national drinking water standard. Massachusetts and California have set standards for maximum perchlorate pollution in drinking water. The FDA has taken no action to address perchlorate contamination of food.

Discussion:

Nine of 10 cord blood samples in the current study tested positive for perchlorate. This is the second study to test U.S. cord blood for perchlorate. In the first, published in September 2009, CDC researchers reported the compound in 67 percent of cord blood samples from 126 babies born in New Jersey (Blount et al 2009).

Perchlorate, a component of rocket fuel integral to the firing systems of missiles and some military explosives, has been found to contaminate drinking water in 28 states and territories. The chemical has seeped into groundwater and soil at military and aerospace sites and chemical plants and has entered the food supply through polluted irrigation water, certain naturally contaminated fertilizers, and other routes not yet identified.

In a national biomonitoring study, CDC detected perchlorate in the urine of all 3,000 people tested (Blount et al 2006a), indicating widespread exposure in the U.S. population. FDA testing has found perchlorate contamination in 74 percent of 285 commonly consumed foods and beverages, including baby food (Murray et al 2008). CDC scientists have found widespread perchlorate contamination of powdered infant formula, especially brands derived from cow's milk (Schier et al 2009).

Adequate levels of thyroid hormone are critical to brain development and growth of the fetus. A recent large-scale epidemiological study by the CDC found that among women, current perchlorate exposures are associated with significant effects on thyroid hormone levels, especially in those with lower iodine levels (Blount et al 2006b). This is of special concern in women of childbearing age, who may experience perchlorate-associated fluctuations in thyroid hormone levels during pregnancy (EWG 2006).

Perfluorochemicals (PFCs) - Teflon and Scotchgard chemicals

Key findings:
- First test in the world for PFBA (C4 or perfluorobutanoic acid) in cord blood; found in 1 of 10 infants.
- PFOA (perfluorooctanoic acid) and PFOS (perfluorooctanesulfonate) found in 10 of 10 infants.

What are they? – PFCs are stain- and grease-proofing chemicals

How do they contaminate cord blood? – used in a variety of consumer products, such as carpets and furniture, as stain and grease repellents, in Teflon cookware, food packaging and clothing. PFCs have also been found in drinking water and certain food groups such as fruits and vegetables.

Health risks – PFCs are linked in human studies to a broad range of health risks, including decreased birth weight, reproductive problems, and elevated cholesterol. In animal studies, PFC exposure has been associated with immune suppression and liver, pancreatic and breast cancers.

Regulatory status – In 2002, 3M Corporation, the world's major manufacturer of PFOS, completed its voluntary phase-out of the chemical's production after the EPA raised concerns about its toxicity and widespread detection in human biomonitoring surveys. The EPA is currently developing drinking water standards for both chemicals.

Discussion:
One cord blood sample contained the first-ever finding in cord blood of PFBA, a PFC that appears to be a legacy pollutant. According to the CDC and the EPA, PFBA was last produced in the US in 1998.

This child, the first baby in the world found to be contaminated with this stain- and grease-proofing compound, joins 13 other Americans with PFBA in their blood, according to tests of 75 children and adults sponsored by EWG. Scientists know very little about its possible toxicity.

All 10 cord blood samples in this study tested positive for two members of the PFC family, PFOA and PFOS, confirming CDC studies that found widespread exposure to these chemicals throughout the U.S. population.

PFCs contaminate food, water, wildlife and consumer products and have been detected in every corner of the globe. In the human body, these chemicals are persistent and bioaccumulative and have been found in breast milk.

Researchers at the Johns Hopkins Bloomberg School of Public Health tested PFOA and PFOS levels in nearly 300 mother/infant pairs and found that women with elevated blood levels of these chemicals gave birth to infants with reduced birth weight and head circumference (Apelberg 2007). Low birth weight is a predictor of potentially serious medical problems later in life (Lau and Rogers 2004). Other human studies have linked PFC exposure to difficulty conceiving, lower sperm quality and elevated cholesterol (Fei et al 2009, Joensen et al 2009, Steenland et al 2009).

Concerns about PFOS have prompted an end to U.S. production. Manufacturers have agreed to phase out PFOA. EPA administrator Lisa Jackson recently announced that PFCs are one of six chemicals or chemical classes being considered for priority action (EPA 2009). EPA is developing drinking water standards for both chemicals.

Lead

Key findings:
- Lead was found in cord blood of 10 of 10 newborns tested.

What is it? – Lead is a neurotoxic metal that concentrates in the brain.

How does it contaminate cord blood? – Lead contamination occurs primarily as a result of mothers ingesting or breathing dust from chipped lead paint in older homes or drinking tap water containing lead that leaches from old water pipes, lead solder and brass plumbing fixtures.

Health risks – It is a known human neurotoxin believed unsafe in any amount. More than 30 years of studies have demonstrated lead's dangers to children at lower and lower doses.

Regulatory status – Lead was banned in gasoline and paint decades ago, but many other uses remain. Some states are moving to eliminate lead from consumer goods ranging from wheel weights to cosmetics to children's products.

Discussion:
All 10 newborns in this study had measurable amounts of lead in their cord blood, consistent with previous studies that have found that babies are often contaminated with this neurotoxic metal before birth.

Lead is one of only a handful of substances whose effects in people have been well studied. The EPA lists a litany of health problems linked to lead, including brain and nervous system damage, behavior and learning problems, hyperactivity, slowed growth, hearing problems, reproductive problems and nerve disorders (EPA 2009a).

Three decades of research have shown clearly that lead damages the human brain. Advances in cognitive and behavioral testing have allowed researchers to discern harm at lower and lower exposures. There is no known safe threshold for exposure.

In February, 2009, researchers at Jagiellonian University in Krakow, Poland, published a study in the journal Neuroepidemiology demonstrating damage to cognitive function in newborns exposed to amounts of lead lower than in any previous study – and lower than the amounts found in several newborns in EWG's study. The Polish researchers found a strong correlation between lead levels in cord blood at birth and deficits in cognitive performance in 12-, 24- and 36-month-old children. The median level they detected in cord blood was one-tenth of the current U.S. exposure standard for young children (Jedrychowski 2009). The lead levels EWG measured in minority newborns were about half the typical level in the Polish children.

Despite lead's hazards, a wide range of industries still use it. It is manufactured, imported, processed or used in at least 8,200 facilities in all 50 states, according to company reporting of lead use and emissions in EPA's 2007 Toxics Release Inventory. Lead-acid batteries -- used in cars, trucks and power supplies for computers, telecommunication networks and hospitals -- account for 88 percent of current lead use, but it also shows up in products such as crystal chandeliers and radiation shields.

For most Americans, lead exposure comes from contaminated drinking water (lead leaches from lead pipes, solder and brass plumbing fixtures) or from dust from chipping paint in older homes. Children living near industrial facilities may face higher exposures.

Americans' exposures were far higher until the EPA took steps 30 years ago to restrict lead in gasoline and house paint. Subsequently, the number of children exposed to lead above the government's action level (10 micrograms per deciliter of blood) fell from 87.4 percent to 3.1 percent as of 2001. Public health advocates declared the results a great victory.

Today, some children remain highly exposed, particularly among non-Hispanic blacks and Mexican Americans, children from lower socioeconomic groups and immigrants (CDC 2005). A range of consumer products, including many marketed for children, still contain lead. In recent years, lead has been reported in lunch boxes, lipstick, jewelry, window blinds and imported candy.

Mercury

Key findings:
- Total mercury and methylmercury found in 10 of 10 newborns tested.

What is it? – Mercury is a pollutant from coal-fired power plants and other industrial sources, also used in consumer products such as fluorescent light bulbs and thermometers. Mercury in elemental form pollutes waterways. It is readily converted to the organic compound methylmercury, which accumulates in the food chain, especially seafood.

How does it contaminate cord blood? – Eating methylmercury-tainted seafood is typically the primary source of contamination. Mercury dental fillings are a lesser source of contamination.

Health risks - Mercury is a neurotoxin that interferes with brain and nervous system development and is particularly harmful to the fetus, infants and children.

Regulatory status – EPA has set a reference dose (RfD) of 5.8 ppb for mercury levels in the blood of pregnant women. FDA has issued a health advisory urging pregnant women and young children to limit canned tuna consumption and avoid heavily contaminated fish.

Discussion:
Mercury is a naturally occurring element that can be found in some consumer products, notably thermometers, fluorescent lamps and electrodes, and in dental fillings. Coal-fired power plants pollute the air with mercury emissions that enter oceans and rivers, where they are converted to methylmercury and accumulate in fish and wildlife. Fish consumption is the primary route by which the U.S. population is exposed to mercury.

Mercury is a neurotoxin that interferes with brain and nervous system development and is particularly harmful to developing fetuses, infants and children. A growing body of research links consumption of mercury-contaminated fish during pregnancy to abnormal neuro-development in offspring. A European study of 800 mother/child pairs correlated elevated mercury exposure during pregnancy with lower scores on tests that assessed motor function, attention and verbal acuity in offspring (Debes et al 2006).

The U.S. safety standard for methylmercury is 5.8 ppb in blood during pregnancy. This level was established to protect the fetus from mercury's adverse effects on the brain and nervous system. Although the government has not yet set a safe level to protect non-pregnant adults, the National Academy of Sciences has found that mercury-driven risks for immune disorders and cardiovascular disease may occur at even lower levels than those associated with brain impairment (National Academies Press 2000).

Dioxins and furans (chlorinated and brominated)

Key findings:
- Chlorinated dioxins and furans found in 10 of 10 cord blood samples.
- Brominated dioxins and furans found in 4 of 10 samples.
- First reported detection of hexachlorodibenzodioxin (1,2,3,7,8,9-HxCDD), octabromodibenzofuran (1,2,3,4,6,7,8,9-OBDF) and pentabromodibenzodioxin (1,2,3,7,8-PBDF)

What are they? – Dioxins and furans are contaminants in brominated flame retardants used in foam, pads, furniture, and other products. They also occur as byproducts of incineration of plastics treated with brominated flame retardants.

How do they contaminate cord blood? – Dioxins and furans enter the body from contaminated air, food and water.

Health risks – The state of California considers chlorinated dioxins and furans to be known human carcinogens. Animal studies suggest other health risks, including endocrine disruption and immune suppression.

Regulatory status - Most dioxins and furans enter the environment as byproducts of industrial activities. EPA restricts industrial emissions of dioxins and furans. The agency reports that these restrictions have reduced emissions by 90 percent since the 1980's.

Discussion:
Chlorinated and brominated dioxins and furans pollute the environment as byproducts of incineration and other industrial processes. They have been found in air, soil, food and drinking water. They accumulate in fish and fatty foods such as milk, meats and dairy products. Contaminated food is thought to be the primary route of exposure among Americans.

Animal studies have linked some dioxins and furans to developmental and reproductive toxicity (FDA 2002). German scientists studying 104 mother/child pairs correlated maternal concentrations of chlorinated dioxins and furans with cord blood levels of testosterone and estradiol (Cao 2008) and found that infants born to mothers with elevated blood levels of chlorinated dioxins and furans in breast milk had lower cord blood levels of estradiol and testosterone. Fetuses and infants need adequate levels of testosterone and estradiol for normal reproductive system development.

Polybrominated diphenyl ether (PBDEs) brominated fire retardants

Key findings:
- First detection of PBDE-75 and PBDE 181 in cord blood.

What are they? – PBDEs are flame retardants in electronics, fabric, foam, furniture and plastics.

How do they contaminate cord blood? – PBDEs gradually migrate out of consumer products, contaminating house dust. Meat, poultry, dairy products and fish are sometimes contaminated by processing and packaging.

Health risks – Animal studies have associated PBDEs with disruption of thyroid hormone balance and behavioral changes. PBDEs are considered developmental neurotoxins and can interfere with formation of thyroid hormones critical to fetal and infant brain development.

Regulatory status – Two types of PBDEs, octa and penta, have been phased out of use due to toxicity concerns. Another type, deca, is still widely used, but several states are considering restricting its use.

Discussion:
Although octa and penta-PBDEs have been phased out, all 10 cord blood samples in this study tested positive for penta and six of 10 for octa.

The sources of this contamination may be older foam furniture and plastic components of electronics such as televisions and computers manufactured before the phase-out but still in use in many American homes. Some imported products still contain PBDEs.

These chemicals interfere with the thyroid gland, which controls metabolism and growth. Because thyroid hormones control brain development, PBDEs may affect children's cognitive abilities and behavior. They may also contribute to thyroid disease in adults.

PBDEs accumulate in fatty tissues and can remain in the body for years. They have been found in breast milk. An EWG study tested the blood of 20 mother/child pairs for PBDE and found that on average, each toddler had three times the PBDE levels of his or her mother. Investigators theorize that the children ingested more PBDE-tainted house dust as they played on the floor and placed their hands and toys into their mouths (EWG 2008).

In 2003, European authorities banned two of the most toxic PBDE commercial mixtures because of concerns over their ubiquity in human blood and breast milk: penta (predominantly containing chemicals called PBDE-99 and PBDE-47) and octa (predominantly comprising PBDE-183). In 2005, U.S. manufacturers stopped selling penta and octa, but furniture and other goods permeated with these substances can still be found in many U.S. homes.

Deca-PBDE continues to be in widespread use in the U.S. Deca shares some toxicity characteristics of penta and octa and can break down into those chemicals. Maine and Washington have restricted deca use, and similar bills have been introduced in several other state legislatures.

PCBs (polychlorinated biphenyl ethers)

Key findings:

- PCBs found in all 10 newborns tested
- First reported detection in U.S. newborns of five PCBs - PCB-7, PCB-43, PCB-55, PCB-144, PCB-181. Testing also detected three PCB mixtures: PCB-134/143, PCB-107-124, PCB-139-140.

What are they? – There are more than 200 PCB chemicals. Some are thin, light-colored liquids, others are yellow or black waxy solids. PCBs have been used in many industrial applications, including as transformer insulators and fire retardants, and in pesticides, paints, plastics and caulk. Manufacturers made more than 1 billion pounds between 1929 and 1976, when Congress passed legislation effectively banning PCBs. EPA classifies PCBs as probable human carcinogens, and many studies have shown that they damage the developing brain.

How do PCBs contaminate cord blood? – primarily through food. PCBs enter the food chain in various ways, including migration from packaging, contamination of animal feed and accumulation in fatty tissues of animals.

Health risks – PCBs have been classified as probable carcinogens and are known to be toxic to the immune, nervous and endocrine systems.

Regulatory status – Although Congress voted to ban PCB's in 1976, they are still found in older electrical equipment, in soil, air and water, in toxic waste sites and in some meat.

Discussion:

The United States banned the manufacture of polychlorinated biphenyl ethers (PCBs) in 1979, but these once-widely used, man-made and highly persistent organic chemicals continue to be found in the environment worldwide. EWG's cord blood study found PCBs in all 10 minority newborns tested.

PCBs are synthetic chemicals formerly used in electrical, heat transfer and hydraulic equipment; as plasticizers in paints, plastics, and rubber products; and in many other industrial products (EPA 2009b). In the United States, more than 1 billion pounds of PCBs were produced from 1929 until they were banned under the Toxic Substances Control Act in 1976.

Due to their extensive use and uncontrolled disposal, PCBs still contaminate waterways and soils, the food supply and people's bodies. They are found in older electrical transformers, capacitors and coolers (EPA 2009c). The EPA is struggling to deal with PCB-containing equipment and multiple hazardous waste sites that leach PCBs. The chemicals have been found in at least 500 of the 1,598 hazardous waste sites identified by the EPA (ATSDR 2000).

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Since the 1970s, scientists have been aware of PCB toxicity to the immune, nervous, and endocrine systems. Animals exposed to PCBs develop liver cancer. In occupational studies, workers exposed to PCBs had increased mortality from several kinds of cancer, including of the liver and biliary tract. The EPA and the International Agency for Research on Cancer (IARC) have declared that PCBs are probably carcinogenic to humans (ATSDR 2000). In recently published human studies, PCBs have been also associated with an elevated risk of breast (Brody 2007) and prostate cancer (Prins 2008), possibly due to effects on the hormonal system and interference with estrogen signaling (Wolff 2008). Three animal studies published this year indicated that low levels of PCB exposure may have greater health effects than higher exposures. Those studies found that low doses hampered animals' ability to swim a maze (Lein et al 2007) and that exposures increased the "excitability" of neurons (Pessah 2009) and interfered with cell-to-cell signaling in the brain (Yang et al 2009).

Food is the main source of exposure for the general population. PCBs enter the food chain by migrating from packaging materials, by contaminating animal feed, by accumulating in the fatty tissues of animals and by other means. Mothers can transfer PCBs to their infants via breast milk (CDC 2005).

PCB levels in human serum (blood) have been declining since the 1970s, according to studies by the Centers for Disease Control and Prevention (Sjodin 2004), but the majority of Americans are still contaminated (CDC 2005; Herbstman 2007) at levels that can have subtle and insidious long-term effects on health, especially for newborns and developing fetuses.

EWG's tests of umbilical cord blood samples found PCB concentrations of 6.2 ng/g on a lipid basis. Scientists from the Harvard School of Public Health and Harvard Medical School have reported that at these concentrations, PCBs are associated with decreased alertness, responsiveness and other attention-associated behavioral measures in infants, including effects on self-quieting and motor control (Sagiv 2009).

Other major epidemiology studies have consistently found that infants and children with higher PCB exposures score lower on numerous measures of neurological function.

Tetrabromobisphenol A (TBBPA), brominated fire retardant

Key findings:
- Found in 3 of 10 cord blood samples

What is it? – TBBPA is a fire retardant found in electronics, carpet padding and plastic casings for televisions and computers. TBBPA can break down into the plastics chemical bisphenol A (BPA), a synthetic estrogen.

How does it contaminate cord blood? – TBBPA is released from electronics and plastics over time. Consumption of contaminated food and, to a lesser extent, house dust contribute to human exposure.

Health risks – can disrupt thyroid hormone balance. Preliminary studies suggest that it may disrupt the immune system.

Regulatory status – TBBPA use is unrestricted in the U.S.

Discussion:
Three of 10 cord blood samples in the current study had measurable amounts of the fire retardant tetrabromobisphenol A (TBBPA) in cord blood, the first report of the chemical in American newborns. More than 70 percent of electrical and electronic appliances worldwide contain TBBPA bonded to circuit boards or impregnated in plastic (BSEF 2008).

Because of the chemical's prevalence in consumer products, it is implicated in widespread pollution of people and the environment. Scientists have detected it in sewage sludge in Sweden, human fat in New York City residents, breast milk and cord blood in France, in North Sea sediments and in dolphins and sharks from Florida's coastal waters (Cariou et al 2008, Talsness et al 2009).

Little is known about the dangers of TBBPA. In a 2009 review, scientists noted, "There are only a few published studies regarding the toxicology of TBBPA (Talsness et al 2009).

The most consistent toxicity data links TBBPA exposure to thyroid disruption (NIEHS 2009). Some animal studies link TBBPA to adverse effects on the immune and reproductive systems, but the implications for human health are unclear (Birnbaum 2006, Van der Ven 2008). TBBPA can degrade into BPA, an endocrine-disrupting chemical considered a major priority for U.S. researchers.

Tonalide and Galaxolide Musk Fragrances

Key findings:
- Tonalide and/or Galaxolide found in 7 of 10 cord blood samples tested.

What are they? – Tonalide and Galaxolide are synthetic fragrances that mimic musk odor from endangered Asian musk deer. They are members of a large family of natural and synthetic compounds.

How do musks contaminate blood? – Industry uses 9,000 tons of synthetic musks annually worldwide. People absorb musks through the skin, from soap, cosmetics and clothes washed with scented detergent, and by inhalation from perfumes and cologne sprays. Musks contaminate rivers, pollute fish, concentrate in body fat and persist in tissues long after exposure.

Health risks – unknown. Safety in people has never been studied. A few lab studies, which require confirmation, suggest Tonalide and Galaxolide disrupt hormones and damage organisms' defenses, allowing more toxins to seep into body cells. Musks cling to fat in human blood and breast milk (Washam 2005).

Regulatory status – The industry is in rapid transition, perhaps responding to growing evidence of environmental and health risks from older musks. Tonalide is still in widespread use, but Galaxolide is in decline. At least two new musks, Habanolide and Helvetolide, appeared on the market around 2005. Habanolide is now among at least seven widely used musks never tested in people.

Discussion:
EWG's minority cord blood study produced the first documentation of Tonalide and Galaxolide, synthetic musk fragrances, in American babies. Cord blood from 7 of 10 infants tested positive for at least one synthetic musk. Six of 10 samples contained Galaxolide, 4 of 10 contained Tonalide, and three contained both.

Natural and synthetic musk fragrances have a characteristic animal-like scent originally taken from the glands of the Asian musk deer. Many synthetic musks are used to "fix" scented products, slowing down the release of fragrance molecules and extending product life. Some cling to fabric and are used in laundry detergent.

Galaxolide and Tonalide were invented in the 1950s. They became popular in the 1980s when older musks fell out of use because of questions about their toxicity and persistence in the environment. Galaxolide has been produced or imported in quantities of between 1 million and 10 million pounds annually for the past decade. Tonalide was produced or imported in amounts of up to 10 million pounds in 1997, but industry has not reported manufacturing or importing it since then (EPA 2006).

Little is known about the safety of Tonalide and Galaxolide, particularly for exposures in the womb. Recent research has raised environmental concerns. Both are ubiquitous in wastewater and rivers and are toxic to aquatic life. Scientists from the Technical University of Denmark placed small crustaceans called copepods in water contaminated with tiny amounts of Tonalide, Galaxolide and other musks and reported that, "Since the synthetic musks strongly inhibited larval development... at low nominal concentrations, they should be considered as very toxic" (Wollenberger 2003). Their findings and others have overturned presumptions of safety for synthetic musks.

Because of growing concerns over polycyclic musks like Tonalide and Galaxolide, the market is shifting and macrocyclic musks like helvetolide and habanolide are coming into widespread use. Some are now used in amounts exceeding 1 million pounds annually (EPA 2006). They are poorly tested and have never been monitored in human tissues.

Polychlorinated naphthalenes (PCNs)

Key findings:
- Found in 10 of 10 cord blood samples tested
- First detection of PCNs 9, 13, 63

What are they? – found in wood preservatives, varnishes and industrial lubricants and as a byproduct of waste incineration.

How do they contaminate cord blood? – PCNs pollute the environment and have been found in air, sewage sludge, soil, wildlife and fish.

Health risks – Occupational exposure to PCNs has been associated with liver cirrhosis. Animal studies suggest that PCNs may disrupt hormone systems.

Regulatory status – PCNs were phased out of production starting in the late 1970's due to toxicity concerns but still enter the environment as a byproduct of waste incineration.

Discussion:
Polychlorinated naphthalenes were found in all 10 cord blood samples in this study. Structurally similar to dioxins, they accumulate in fatty tissue. They have been found to contaminate breast milk. A study of workers subjected to high concentrations of PCNs found higher risk of liver disease, especially cirrhosis, after just two years of exposure (Ward 1994). No studies have been conducted of health effects of long term, low level PCN exposure in humans.

Although PCNs were phased out of major production more than 30 years ago, small amounts are still produced for specific industrial applications. Many PCNs persist in the environment for years. The major source of ongoing environmental contamination is waste incineration.

Chemical Mixtures

Biomonitoring research such as EWG's minority cord blood study show that real world exposures do not occur chemical by chemical. Rather, each of us encounters complex mixtures of chemicals. Many of these compounds are associated with a myriad of toxicities. There are little or no data on how chemical mixtures may affect human health.

For example, EWG found 191 individual chemicals in cord blood from Anonymous Newborn #1. Testing each possible combination of these chemicals at a single dose -- first testing them singly and then in pairs, triplets, quadruplets, all the way up to 191 -- would entail a number of tests equal to 649 times 10 to the 30th power. This is nearly a billion times more than the estimated number of stars in the universe (ESA 2009).

It's no wonder, then, that science has yet to understand how chemical mixtures affect our health. New paradigms for studying mixture toxicity may hold greater promise.

THE MIXING BOWL: Newborns are contaminated with an average of more than 100 chemicals known or suspected to cause cancer, birth defects or other health problems

Health Effect	Average no. of chemicals found in 10 minority newborns (range)	Chemical or chemical class	Hazard classification
Neurotoxicity	103 (71-128)	Lead	Known to be neurotoxic to humans (Grandjean and Landrigan 2006)
		Mercury & methylmercury	Known to be neurotoxic to humans (Grandjean and Landrigan 2006)
		Polychlorinated biphenyls (PCBs)	Known to be neurotoxic to humans (Grandjean and Landrigan 2006)
Developmental toxicity	104 (71-129)	Lead	Known to cause developmental toxicity - California Proposition 65
		Mercury & Methylmercury	Known to cause developmental toxicity - California Proposition 65
		Polychlorinated biphenyls (PCBs)	Known to cause developmental toxicity - California Proposition 65

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Health Effect	Average no. of chemicals found in 10 minority newborns (range)	Chemical or chemical class	Hazard classification
Cancer	105 (70-130)	Chlorinated dioxins	Known to cause cancer - California Proposition 65
		Chlorinated furans	Known to cause cancer - California Proposition 65
		Hexadioxin (1,2,3,6,7,8-HxCDD)	Probable human carcinogen class B2 - based on sufficient evidence of carcinogenicity in animals - EPA
		Hexafuran (1,2,3,4,7,8-HxBDF)	Known to cause cancer - California Proposition 65
		Hexafuran (1,2,3,6,7,8-HxCDF)	Probable human carcinogen class B2 - based on sufficient evidence of carcinogenicity in animals - EPA
		Lead	Probable human carcinogen class B2 - based on sufficient evidence of carcinogenicity in animals - EPA
		Methylmercury	Known to cause cancer - California Proposition 65
		Perfluorooctanoic acid (PFOA)	Likely human carcinogen - EPA Science Advisory Board
		Polychlorinated biphenyls (PCBs)	Probably carcinogenic to humans group 2A - IARC; Probable human carcinogenic class B2 - EPA; known to cause cancer - California Proposition 65

Source: EWG compilation of chemical classifications published by U.S. Environmental Protection Agency, California Environmental Protection Agency, the European Union Consumer Products Safety and Quality Unit, the International Agency for Research on Carcinogens (IARC) and neurotoxin listings from academic review published in the journal Lancet (references).

Traditional toxicology testing has involved evaluating one chemical at a time at various concentrations to determine its effects on various biological endpoints. Although toxicologists have been aware for decades of the risks posed by exposure to mixtures of chemicals, a 1992 literature review of 151 toxicology papers calculated that 95 percent focused on single chemicals.

Since then, interest in chemical mixtures has grown. Government agencies such as the Agency for Toxic Substances and Disease Registry (ATSDR), the Centers for Disease Control and Prevention (CDC), and the National Institute of Environmental Health Sciences (NIEHS) have convened programs and conferences on this topic. Federal agencies have also started to develop initiatives to help guide researchers studying health effects of chemical exposures (Monosson 2005).

Linda Birnbaum Ph.D., Director of the NIEHS, has called for more research into the impact on human health of mixtures of environmental chemicals. "Some chemicals may act in an additive fashion," she told a Columbia University audience in March 2009. "When we look one compound at a time, we may miss the boat."

In all, EWG's biomonitoring studies have tested 186 individuals (cord blood from newborns and blood and urine samples from older children and adults) for 552 chemicals and have detected more than 414. (The number ranged from 414 to 493 because laboratories could not distinguish between some congeners.)

EWG's new cord blood study amplifies our understanding that the developing fetus is exposed to complex mixtures of potential neurotoxins, endocrine disruptors and carcinogens. Among the chemicals found by EWG are known neurotoxins such as lead and methylmercury, probable endocrine disruptors such as bisphenol A and perchlorate and suspected carcinogens such as PFOA and deca PBDE.

Recent animal studies support the theory that exposures to mixtures of chemicals often result in more significant adverse effects than single chemical exposures. For example, researchers from the Technical University of Denmark and University of London looked at the effects of four hormone disruptors, individually and in combination, on the reproductive systems of male rats. They found that "the effect of combined exposure to the selected chemicals on malformations of external sex organs was synergistic, and the observed responses were greater than would be predicted from the toxicities of the individual chemicals" (Christiansen et al 2009). Researchers at the University of California found that exposure to combinations of pesticides resulted in higher mortality rates among tadpoles than occurred with individual pesticide exposures (Hayes et al).

Physicians know they should scrutinize potential drug interactions closely before starting patients on new medications. Medications in combination can interact with one another, resulting in toxicities that might not occur if they were administered individually. Similarly, environmentally-acquired chemicals may interact to produce toxicities. In addition, exposure to mixtures of chemicals that have similar biological effects or mechanisms of action may result in cumulative or synergistic toxicity.

Epigenetics

Research teams around the world are exploring the mechanisms by which environmental pollutants may trigger genetic changes that can affect a person's health and that, in some cases, may be passed on to future generations.

EWG intends to share its biomonitoring findings with researchers funded by the National Institutes of Health, including projects under the aegis of the NIH Roadmap Epigenomics Program, which plans to distribute $62 million over the next five years for basic research on "epigenetic changes," meaning "chemical modifications to genes that result from diet, aging, stress, or environmental exposures [that] define and contribute to specific human diseases and biological processes."

In September, NIH awarded 22 grants to researchers exploring epigenetic aspects of glaucoma, Alzheimer's disease, hypertension, autism, mental illness, breast cancer, lupus and other serious conditions. Some research under this initiative is investigating how BPA alters body chemistry at the genetic level.

The National Institute for Environmental Health Sciences, meanwhile, has designated BPA a top research priority and has announced plans to spend $30 million over the next two years to study the chemical's impact on human health and the environment. The BPA program is part of a larger NIEHS-backed effort to broaden and deepen scientific understanding of what scientists call the "developmental basis of disease."

Another promising line of research is focusing on environmental factors behind the epidemic of childhood asthma. An April 2009 study by researchers at the Columbia Center for Children's Environmental Health and University of Cincinnati produced evidence that New York City children exposed in utero to high levels of polycyclic aromatic hydrocarbons (PAHs) from vehicular emissions were more likely to develop asthma than other children. The study involved 700 children born to mothers living in traffic-congested New York neighborhoods. By monitoring prenatal air pollution exposures and collecting cord blood and fetal placental tissue, researchers reported a "positive and significant association" among children with asthma between their mothers' high PAH exposures during pregnancy and structural changes called "methylation" in a particular gene under investigation as an epigenetic marker for asthma.

Ultimately, EWG believes that by directing research toward causes and prevention, instead of focusing solely on treatment, scientists may someday be able to avert incalculable human suffering.

Proving Harm at Low Doses

Confronted with studies documenting that hundreds of industrial chemicals are present in the human body, chemical manufacturers and their leading trade association, the American Chemistry Council, resort to the blanket qualifier: the "mere presence of a chemical" does not prove harm. The U.S. Centers for Disease Control and Prevention uses similar language in reporting its own biomonitoring data.

Mere presence does not prove harm, but studies often do. EWG reviewed the published scientific literature relating to cord blood contaminants detected in the current study. Seven relevant studies published between 1997 and 2009 tested 2,151 newborns for six chemicals or chemical families also detected in the current study: mercury, lead, PBDEs, PCBs, PFOS and PFOA. All these studies found that babies with higher exposures were more likely to experience health problems at birth or later in childhood, including low birth weight, damaged hearing or intelligence deficits.

Three animal studies published in 2009 indicated that low levels of PCB exposure may have greater health effects than larger exposures. The studies produced evidence that low doses hampered animals' ability to swim a maze (Lein 2009), increased the "excitability" of neurons (Pessah 2009) and interfered with cell-to-cell signaling in the brain (Pessah 2009).

In a scientific statement on endocrine disrupting chemicals (EDCs) issued in 2009, The Endocrine Society said: "There are several properties of EDCs that have caused controversy. First, even infinitesimally low levels of exposure — indeed, any level of exposure at all — may cause endocrine or reproductive abnormalities, particularly if exposure occurs during a critical developmental window. Surprisingly, low doses may even exert more potent effects than higher doses. Second, EDCs may exert non-traditional dose-response curves, such as inverted-U or U-shaped curves. Both of these concepts have been known for hormone and neurotransmitter actions, but only in the past decade have they begun to be appreciated for EDCs" (Endocrine Society 2009).

Pollution in People - Cord Blood Contaminants in Minority Newborns

Studies find trace chemical exposure in cord blood associated with mental and physical effects at birth and later in childhood.

Cord Blood Contamination and Associated Health Effects

Chemical	Newborns in the study	Amount in cord blood found harmful	Health effect at birth or later in childhood
Scotchgard (PFOS, or perfluorooctane sulfonate)	293 babies born in Baltimore, Md. 2004-2005 (Apelberg 2007)	**> 7.8 ppb** [nanograms per gram (wet weight) in serum]	Reduced birth weight and head circumference, factors associated with effects on intelligence and greater susceptibility to chronic diseases later in life
Teflon (PFOA, or perchlorooctanoic acid)	293 babies born in Baltimore, Md. during 2004-2005 (Apelberg 2007)	**> 2.1 ppb** [nanograms per gram (wet weight) in serum]	Reduced birth weight and head circumference, factors associated with effects on intelligence and greater susceptibility to chronic diseases later in life
Lead	444 babies born 2001-2004 in Krakow, Poland (Jedrychowski 2009)	**>1.81 µg/dL** [micrograms per deciliter (wet weight) in whole blood]	2.3-3.3% reduction in cognitive test scores at age 1 compared to children with cord blood levels <0.91 µg/dL (depending on mother's education level). Deficit in cognitive function was also observed at ages 2 and 3 for these groups of children.
Mercury	Birth cohort study of 1022 babies born 1986-1987, Faroe Is., Denmark, tested at age 7 (Grandjean 1997)	**>13.1-40.8** ppb [micrograms per liter (wet weight) in whole blood], interquartile range for the entire cohort	Children with higher cord blood levels of mercury had lower scores on neurobehavioral tests of attention, memory, and language skills at age 7 than children with lower cord blood mercury levels.
Mercury	Birth cohort study of 1022 babies born 1986-1987, Faroe Is., Denmark, followed up at age 14 (Debes 2006 1997)	**>16.7 ppb** [nanograms per gram (lipid weight) in serum), median level for four PCB congeners: PCB 118, 138/158, 153, and 180]	Children with higher cord blood levels of mercury had lower scores on neurobehavioral tests of motor function, attention and verbal acuity at age 14 than children with lower cord blood mercury levels.

Chemical	Newborns in the study	Amount in cord blood found harmful	Health effect at birth or later in childhood
PCBs (Polychlorinated biphenyls)	297 babies born in Baltimore, Md. in 2004-2005 (Herbstman 2008)	**>16.7 ppb** [nanograms per gram (lipid weight) in serum), median level for four PCB congeners: PCB 118, 138/158, 153, and 180]	Decreased levels of thyroid hormone, necessary for normal brain development, found in newborn infants with higher levels of four PCB congeners (PCB 118, 138/158, 153, and 180).
PBDEs (polybrominated biphenyl ethers)	297 babies born in Baltimore, Md. in 2004-2005 (Herbstman 2008)	**>18.7 ppb** [nanograms per gram (lipid weight) in serum], median level for three PBDE congeners (BDE-47, BDE-100, and BDE-153).	Decreased levels of thyroid hormone, necessary for normal brain development, found in newborn infants with higher levels of three PBDE congeners (BDE-47, BDE-100, and BDE-153).
PCBs (polychlorinated biphenyls)	542 babies in New Bedford, Mass., born 1993-1998 (Sagiv 2008)	**>0.3 ppb** [nanograms per gram (lipid weight) in serum]	Decreased alertness, responsiveness, and other attention-associated behavioral measures in infants with overall levels of four PCB congeners (PCBs 118, 138, 153, and 180) above 0.3 ppb

Descriptions of Studies Showing Health Harm Related to Cord Blood Pollutants

Scotchgard (PFOS, or perfluorooctane sulfonate) – Apelberg (2007)
Scientists at Johns Hopkins University studied the relationship between cord blood concentration of Teflon (PFOA) and Scotchgard (PFOS) and birth weight, head circumference and gestational age in 293 infants born in Baltimore, Md. They found that newborns with higher exposures to PFOA and PFOS had statistically significant decreases in head circumference and birth weight compared to those who had lower cord blood concentrations of the chemicals (Apelberg 2007). Compared to newborns with 3.4 ppb of PFOS (the 25th percentile) in their cord blood, infants with 7.9 ppb of PFOS (the 75th percentile) had a 0.27 cm (0.8 percent) decrease from mean head circumference, a 58 g (1.8 %) decrease from mean body weight and 0.062 (2.4%) decrease from mean Ponderal Index (a measure of body size, expressed in g/cm3 x 100). Lower birth weight and smaller head circumference at birth are associated with greater susceptibility to chronic diseases later in life and effects on intelligence (Lau 2004; Schlotz 2009). [Full ref. Lau C, Rogers JM. 2004. Embryonic and fetal programming of physiological disorders in adulthood. Birth Defects Res C Embryo Today 72(4): 300-12. Schlotz W, Phillips DI. 2009. Fetal origins of mental health: evidence and mechanisms. Brain Behav Immun 23(7): 905-16.]

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Teflon (PFOA, or Perfluorooctanoic acid) – Apelberg (2007)
This study by scientists at Johns Hopkins University is described above (Abelberg 2007). Compared to infants with up to 1.2 ppb (the 25th percentile) PFOA in their cord blood, newborns with 2.1 ppb of PFOA (the 75th percentile) had a 0.23 cm (0.6%) decrease from mean head circumference, a 58 g (1.8%) decrease from mean body weight and a 0.039 (1.5%) decrease from mean Ponderal Index (a measure of body size, expressed in g/cm3 x 100).

Lead (Jedrychowski 2009)
Lead is an extensively studied neurotoxicant whose adverse effects on cognitive performance are well established. A new study published this year found that extremely low levels of lead in cord blood are associated with impaired cognition in young children (Jedrychowski 2009). Polish researchers found a strong connection between levels of lead in cord blood at birth in 444 children and cognitive performance when they reached 12, 24 and 36 months of age. The researchers used the standard Bayley Scales of Infant Development MDI test, which measures habituation, problem solving, early number concepts, generalization, classification, memory, vocalization, language and social skills. The median level in cord blood was one-tenth the current U.S. standard for young children. The lead levels we measure in minority newborns were about half of the typical level in the Polish children. Researchers found a decline in cognitive function of about 6 points on the Bayley Mental Development Index for every 10-fold increase in cord blood level concentrations.

Methylmercury (Debes 2006)
Researchers at Harvard University and the Faroese Hospital System, Faroe Islands, Denmark, measured mercury concentrations in cord blood, cord tissue and maternal hair in 878 mother-child pairs at birth and correlated prenatal mercury exposure with performance on neurobehavioral tests at ages seven and 14. The researchers found that infants with higher exposure to mercury during the prenatal period had lower scores on the tests, which assessed motor function, attention and verbal acuity compared with newborns who had lower exposures (Debes 2006). Mercury has long been established as a neurotoxin, especially when exposure occurs during pregnancy. In the U.S., exposure to mercury occurs primarily through consumption of contaminated seafood.

Mercury (Grandjean 1997)
Scientists at Odense University, Denmark studied a group of 917 seven-year-old children in the Faroe Islands The study found that mercury concentrations of 46-79 ppb in maternal blood were associated with doubling of the number of children who perform below the 5th percentile for neruropsychological effects (Grandjean 1997).

PCBs (Herbstman 2008)
Scientists at Columbia and Johns Hopkins universities measured levels of cord blood thyroid hormone at birth relative to levels of PCBs and PBDEs in 297 newborns delivered at the Johns Hopkins Hospital (Baltimore). Researchers found that infants with higher cord blood concentrations of PCBs and PBDEs had statistically significant decreases in thyroid hormone levels compared with newborns who had lower levels of these two classes of chemical pollutants (Herbstman 2008). Adequate thyroid hormone levels during pregnancy and infancy are necessary for normal brain development; research has shown that even minor decreases in thyroid hormone levels during these critical periods can have long-term ill effects (Zoeller 2002, Ginsberg 2007).

PBDEs (Herbstman 2008)
This study by scientists at Johns Hopkins University and Columbia University is described above (Herbstman 2008). Researchers found that newborns with higher cord blood concentrations of PBDEs and PCBs had statistically significant decreases in thyroid hormone levels compared with those who had lower levels of these two classes of chemical pollutants. These associations occurred only in infants born by spontaneous vaginal delivery; other birth modes result in stress-induced changes in thyroid hormone levels, thereby potentially masking effects associated with PBDEs. Adequate thyroid hormone levels during pregnancy and infancy are necessary for normal brain development; research has shown that even minor decreases in thyroid hormone levels during these critical periods can have long-term ill effects (Zoeller 2002, Ginsberg 2007). The newborns in EWG's cord blood study had slightly lower PBDE levels than infants in the Baltimore study. PBDEs were widely used as flame retardants in consumer products. The two most commonly used forms, Octa and Penta, are now banned in the U.S., but Deca PBDE is still in widespread use. PCBs were banned in the 1970's due to their toxicity and persistence in organisms and the environment.

PCBs (Sagiv 2008)
A study by scientists at the Harvard School of Public Health has strengthened the link between fetal exposure to PCBs and behavioral effects in childhood, such as inattention. Study participants were 542 infants from a birth cohort whose mothers resided adjacent to a PCB-contaminated harbor in New Bedford, Mass. between 1993 and 1998. Researchers found that serum PCB levels above the median of 0.3 ppb (on a total serum basis) were associated with decreased alertness, responsiveness and other attention-associated behavioral measures, including self-quieting and motor control in infants tested two weeks after birth. The authors stated that this observation was "particularly notable given ... the low-level PCB exposure in [the] study population" (Sagiv 2008).

Vulnerability Early in Life

During pregnancy, the placenta transfers nutrients from the mother's circulation to the fetus and returns waste products from the fetus to the mother to be excreted. Numerous studies have shown that the placenta does not, as once thought, shield the fetus from chemicals and pesticides carried in the mother's body (Barr 2007, EWG 2005, Bearer 1995, Guvenius 2003, Tittlemier 2004, Sandau 2002).

In utero exposures are particularly worrisome because of the unique vulnerabilities of the fetus (Grandjean and Landrigan 2006). Studies have shown that exposure to toxic chemicals during critical windows of development can result in permanent and irreversible brain and organ damage (Barr 2007).

There are several reasons for the greater vulnerability of the developing fetus:

- A developing child's chemical exposures are greater pound-for-pound than those of adults.
- The blood-brain barrier, which prevents many harmful substances from entering the brain, is not fully developed until after birth (Rodier 1995).
- The fetus cannot detoxify and excrete many chemicals as completely as an adult (Birnbaum 2003).
- Fetal blood contains lower levels of some proteins that bind to harmful chemicals and neutralize them. As a result, fetal blood can contain higher levels of unbound, biologically active chemicals than the mother's blood (Koren 1990).
- The fetus undergoes rapid cell division, proliferation and differentiation in utero, making its developing cells particularly sensitive to chemical exposures (Birnbaum 2003).

Fetal exposures to industrial chemicals can result in immediate harm to the developing brain and other organ systems, but some adverse effects may not manifest themselves for years or decades. Scientists refer to this phenomenon as the "fetal basis of adult disease," a term coined by British researcher David Barker. He found that newborns malnourished during pregnancy had higher rates of heart disease and diabetes later in life than well-fed infants(NIEHS 2008).

This phenomenon has also been seen as a result of chemical exposures, including to mercury (NIEHS 2008). Scientists now consider it prudent to assume that the environment in which the fetus develops has long-term health repercussions and that harmful exposures during pregnancy can increase the later incidence of certain diseases or medical conditions (Basha 2005, Anway 2005).

Minority Children and Chemical Risks

Minority communities often experience high exposures to toxic chemicals

The newborns in the current study are anonymous, and we have no evidence that they were born into homes and neighborhoods with unique amounts of contaminants. But a large body of research has found that certain minority groups are at particular risk from chemical exposures, simply because of where they live or work.

A number of body burden studies have identified "hot spots" -- polluted communities -- where residents have elevated levels of industrial chemicals. CDC's massive NHANES (National Health and Nutrition Examination Survey) survey series, which examines pollution exposures in the general population, has identified some general differences in pollution exposures for racial and ethnic groups. Academic studies have also investigated this issue.

Some notable trends:

- African American children ages one to five have 64 percent higher geometric mean levels of lead exposure than white children. They were also 2.8 times more likely to have elevated blood lead levels than white or Mexican American children (3.4 percent vs. 1.2 percent) (Jones 2009).
- Mercury levels in women of childbearing age are highest for Asian American, Native American, Pacific Islander, and Caribbean (Hispanic Black) populations, with many more women of childbearing age exceeding health-based levels (Mahaffey 2009).

Farmers and farm workers, who in the U.S. are often Latino, have higher exposures to a variety of pesticides, including some that can impair brain development. Children born to women in agricultural communities have high levels of pesticide exposures in utero. (Eskenazi 2008).

African Americans and Mexican Americans have higher levels of two phthalates than non-Hispanic whites. Phthalates are widely used in consumer and personal care products.

Mexican Americans have higher levels of PBDE-47, a fire retardant (Sjodin 2008).

There are several important reasons why minority populations, especially those living in poorer communities, experience higher exposures to environmental pollutants. For one thing, hazardous waste sites and other polluting facilities are more likely to be deliberately placed near communities of color and low-income communities than near more affluent neighborhoods (Brulle and Pellow 2006).

The sociologist Robert Bullard noted in his watershed book *Dumping in Dixie* that communities of color are deliberately and consistently sought out for toxic dumping. The proximity of these toxic facilities can result in heavily polluted local environments. Residents of "fenceline" communities, so-called because they border toxic industrial facilities, are often exposed to outsized concentrations of pollutants.

Pollution in People - Cord Blood Contaminants in Minority Newborns

Some minority populations reside in poorer urban neighborhoods that are congested and close to busy roads. Their homes may be older and deteriorating and have pest infestations. Exposure to lead, indoor and outdoor air pollutants and soil pollutants have all been found to be higher in minority populations who live in congested urban neighborhoods (Frumkin 2005).

Some minority groups are also exposed to toxic chemicals through employment in hazardous industries. The National Institute of Occupational Safety and Health (NIOSH) reports that 84 percent of the 2 million U.S. farm workers are of Latino heritage. Many of these workers are Spanish speakers and cannot understand English instructions on the proper use and disposal of chemicals. Others lack protective gear. Many workers fear retribution if they report violations of laws governing occupational hazards.

Some farm workers unintentionally expose their families to toxic chemicals by coming home wearing clothing contaminated with pesticides (NIOSH). In addition, the National Center for Farmworker Health estimates that up to 300,000 children are directly employed in the agricultural sector every year (NCFH).

EPA estimates that there are currently 155,000 nail salon workers in the U.S., the majority of whom are Asian women, especially of Vietnamese origin. The nail polishes and solvents used in these salons often contain known endocrine disruptors and carcinogens. Many salon owners do not provide adequate protective gear and ventilation (EPA 2008). Surveys of nail salon workers have found that they experienced more rashes, headaches and breathing problems after they began working at the salons (Quach 2008).

Residents of urban neighborhoods often lack access to high-quality, affordable fresh fruits and vegetables. Many of these neighborhoods often only have small markets that stock processed foods, alcohol and tobacco products. (Frumkin 2005).

Dr. Jane Hightower of the California Pacific Medical Center and coauthors found that 27 percent of study participants who self-identified as Asian, Pacific Islander, Native American or multiracial had elevated mercury levels, while only 10.8 percent of participants from other ethic groups had unsafe levels.

The primary source of mercury exposure in the U.S. is contaminated seafood. High mercury levels, especially during pregnancy, affect the development of the brain and nervous system. In adults, high mercury levels have been associated with cardiac disease and neurological problems (Hightower 2006).

Researchers at the University of Pittsburgh Center for Environmental Oncology have found that African American women use more personal care products that contain hormone disruptors than other populations. The researchers hypothesized that these products may contribute to decreasing age of puberty and increased rates of pre-menopausal breast cancer among African American girls and women (Donovan 2007).

It is clear that minority populations in the U.S. have higher exposures to many chemical pollutants. In recognition of the growing problem of environmental inequality, in 1994 President Clinton issued Executive Order 12898, requiring federal agencies to incorporate environmental justice considerations into their programs.

But that initiative withered once Clinton left office. A 2004 report by the EPA Office of Inspector General (OIG) concluded that during the Bush administration, the agency had failed to consider environmental justice issues sufficiently when setting policies and regulations (EPA 2004).

In a 2006 report, the OIG recommended that the EPA conduct environmental justice reviews of its existing programs and develop protocols to "make environmental justice policies a priority" (Obama-Biden 2008). In November 2009, EPA Administator Lisa Jackson recruited two seasoned advisors to advance the adgency's environmental justice and civil rights agenda.

Appendix A: Methodology

Cord blood sample acquisition: The Environmental Working Group contracted with Cryobanks International, an organization that specializes in collecting and storing umbilical cord blood, to obtain cord blood from 10 newborns of minority background, born between December 2007 and June 2008. EWG obtained no identifying information other than racial or ethnic identity. Samples consisted of a minimum of 90 milliliters (mL) of cord blood and 35 ml of citrate-phosphate-dextrose (CPD) anticoagulant in a 250 mL Baxter Fenwal Blood-Pack unit (Baxter Healthcare Corporation, Deerfield, IL). The 35 mL of CPD anticoagulant consisted of 921 mg sodium citrate, 893 mg dextrose, 105 mg citric acid, and 78 mg monobasic sodium phosphate. Samples were frozen upon collection at -20 degrees Celsius and shipped from the hospital where they were obtained to Cryobank's international headquarters in Altamonte Springs, Florida.

Cryobanks repacked the samples with gel ice packs and shipped them to AXYS Analytical Services (Sydney, British Columbia). Samples were stored at AXYS at 4 degrees Celsius until the last one was collected in June 2008.

Sample preparation: AXYS took multiple sub-samples of blood for secondary laboratory analyses (musks, perchlorate, bisphenol A and metals) and AXYS analyses of DX/Fs, PCBs, PBDEs, BrDX/F, PCNs, PFCs and TBBPA). Blood collection bags containing just anticoagulant were submitted to each lab for analysis. Sub-samples were stored at -20 degree Celsium prior to secondary labs shipments or prior to extraction and analysis for the PFC/TBBPA portion at AXYS.

Sample extraction: Samples were analyzed in two batches. Each batch had its own QC including a procedural blank and a spiked matrix sample. An empty blood bag proof extract was prepared with a water/ethanol mixture added to the bag and collected. This extract was split into two equal portions to be analyzed with each batch.

Analysis of Chlorinated Dioxins and Furans: AXYS method MLA-017: Samples were spiked with a suite of isotopically labeled PCDD/F surrogate standards prior to analysis, then solvent extracted and cleaned up on a series of chromatographic columns. The extract was concentrated and spiked with an isotopically labeled recovery (internal) standard. Analysis was performed using a high-resolution mass spectrometer coupled to a high-resolution gas chromatograph equipped with a DB-5 capillary chromatography column (60 m, 0.25 mm i.d., 0.1 um film thickness). All procedures were carried out according to protocols as described in EPA Method 1613B, with some additional internal AXYS guidelines applied.

Analysis of Brominated Dioxins and Furans: AXYS method MLA-024: Samples were spiked with a suite of isotopically labeled PBDD/F surrogate standards prior to analysis, then solvent extracted and cleaned up on a series of chromatographic columns. The extract was spiked with isotopically labeled recovery (internal) standards prior to analysis by high-resolution mass spectrometer (HRMS) coupled to a high-resolution gas chromatograph (HRGC) equipped with a DB-5HT capillary chromatography column (20 m, 0.25 mm i.d. x 0.1 um film thickness). To minimize photo-degradation of the PBDD/F's, manipulations and analysis of samples and standards were conducted using low light levels and aluminum foil was used to provide protection from ambient lighting.

Analysis of Polychlorinated Biphenyls (PCBs): AXYS method MLA-010: Samples were spiked with isotopically labeled PCB surrogate standards prior to analysis, then solvent extracted and cleaned up on a series of chromatographic columns. The final extract was spiked with isotopically labeled recovery (internal) standards prior to instrumental analysis. Analysis of the extract was performed on high-resolution mass spectrometer (HRMS) coupled to a high-resolution gas chromatograph (HRGC) equipped with a SPB-Octyl chromatography column (30 m, 0.25 mm i.d., 0.25 µg film thickness). The method was carried out in accordance with the protocols described in EPA Method 1668A with some additional internal AXYS guidelines applied.

Analysis of Brominated Diphenylethers (PBDEs): AXYS method MLA-033: Samples were spiked with isotopically labeled BDE surrogate standards prior to analysis, then solvent extracted and cleaned up on a series of chromatographic columns. The final extracts were spiked with isotopically labeled recovery (internal) standards prior to instrumental analysis. Analysis of extracts was performed on a high-resolution mass spectrometer (HRMS) coupled to a high-resolution gas chromatograph (HRGC) equipped with a DB-5HT chromatography column (30 m, 0.25 mm i.d., 0.10 um film thickness). The method was carried out in accordance with the protocols described in EPA Method 1614 with some additional internal AXYS guidelines applied.

Analysis of Polychlorinated Naphthalenes (PCNs): AXYS method MLA-030: Samples were spiked with isotopically labeled PCN surrogates prior to analysis, then solvent extracted and cleaned up on a series of chromatographic columns, done using a solvent extraction procedure. The final extracts were spiked with isotopically labeled recovery (internal) standards prior to instrumental analysis. Analysis of extracts were performed on a high-resolution mass spectrometer (HRMS) coupled to a high-resolution gas chromatograph (HRGC) equipped with a DB-5 chromatography column (30 m, 0.25 mm i.d., 0.10 um film thickness).

Calculations for Dioxin, Furans, PCBs, PBDEs, and PCNs: Target concentrations for each analysis were determined by isotope dilution or internal standard quantification procedures using Micromass OPUSQUAN and/or MassLynx software. Sample specific detection limits (DL's) were determined from the analysis data by converting three times the height of the average noise signal to a response, using the area/height ratio of the labeled standard, and then to a concentration following the same procedures used to convert target peak responses to concentrations. If the OPUSquan or MassLynx software selected an unrepresentative area for the detection limit calculation, the data interpretation chemist or the QA chemist made corrections.

Analysis of Perfluorinated Chemicals (PFC) and Tetrabromobisphenol-A (TBBPA)- AXYS method MLA-049/042 and AXYS Method 4226: Samples were spiked with isotopically labeled PFC and TBBPA surrogate, extracted in acetonitrile, cleaned up on SPE cartridges, split into two portions (1) PFC and (2) for TBBP-A and submitted for separate instrumental analysis runs. Samples were analyzed by liquid chromatography/mass spectrometry (LC-MS/MS). Analysis of sample extracts for perfluorinated organics was performed on a high performance liquid chromatograph column (Agilent Zorbax XDB Reverse phase C18, 7.5cm, 2.1mm i.d., 3.5 um particle size or equivalent) coupled with a triple quadrupole mass spectrometer, running MassLynx v.4.0 software. Final sample concentrations were determined by isotope dilution/internal standard quantification against matrix calibration standards carried through the analysis procedure alongside the samples.

Calculations for PFCs and TBBPA: Target concentrations for each analysis were determined by isotope dilution or internal standard quantification procedures using Micromass MassLynx software. Sample specific detection limits (DL's) were determined from the analysis data by converting three times the height of the average noise signal to an area using the area/height ratio of the labeled standard, and then to a concentration following the same procedures used to convert target peak responses to concentrations. If the MassLynx software selected an unrepresentative area for the detection limit calculation, the data interpretation chemist or the QA chemist made corrections. Reporting limits were equal to the greater of the lowest calibration standard concentration equivalent or the sample specific detection limit (SDL).

Analysis of Lead: Whole blood samples were diluted 50x with a one percent HNO3. Digests are analyzed using Inductively Coupled Plasma: Mass Spectrometry (ICP-MS) for the analysis of Lead (Pb). Results were blank corrected as per Brooks Rand SOPs for EPA 1638 Modified method.

Analysis of Total Mercury: All samples were prepared and analyzed in accordance with the Appendix to EPA Method 1631E. Blood samples were first digested with nitric acid/sulfuric acid (HNO3/H2SO4) and further oxidized with bromine monochloride (BrCl). All samples were analyzed with stannous chloride (SnCl2) reduction, gold amalgamation and cold vapor atomic fluorescence spectroscopy (CVAFS) using a BRL Model III CVAFS Mercury Analyzer. Summarized sample results were blank corrected as described in EPA Method 1631 E.

Analysis of Monomethyl Mercury: Blood samples were prepared by potassium hydroxide/methanol (KOH/MeOH) digestion followed by distillation. All samples were analyzed by aqueous phase ethylation, Tenax trap collection, gas chromatography separation, isothermal decomposition, and cold vapor atomic fluorescence spectrometry (CVAFS). The samples were analyzed by a modification of EPA Draft Method 1630, as detailed in the BRL SOP BR-0011. All results were blank corrected as described in the method.

Analysis of Bisphenol A: Blood samples were analyzed for bisphenol A (BPA) by HPLC with CoulArray detection. The standard curve in our assay ranges from 0.05 – 4 nanograms per HPLC run. Values below and above the range of the standard curve are outside the limit of quantitation (LOQ) of the assay, and these values are indicated by asterisks. These estimated values are different from samples labeled as "non detectable (ND)", where there was no evidence for the presence of BPA in the sample. For concentrations below this limit of quantitation (LOQ), a value equal to the LOQ divided by the square root of 2 was substituted for the estimated value (Hornung and Reed 1990; Calafat, 2008.)

In more detail, two separate measurements were made for each sample. The samples were first extracted with methyl tert-butyl ether to remove free (unconjugated) BPA. The sample remaining after extraction was then treated with glucuronidase and sulfatase to deconjugate glucuronides and sulfates, and then re-extracted. Bisphenol A was quantified using HPLC with CoulArray detection. Aliquots of human serum (from Fisher Scientific), either untreated or spiked with BPA, were run as recovery controls for serum extractions. Additional recovery estimates were made for blood samples using spiked aliquots of the samples provided. An aliquot of the travel blank was extracted in the same way as the serum and blood samples. The blood bag was filled with HPLC-grade water, and a sample of the water was extracted in the same way as the serum and blood samples.

Analysis of Musks: Each sample is weighed into a clean glass 60 ml vial. Methanol, 0.1 M HCl and a set of internal standards (one or more for each group of chemicals) is added to the sample. The sample is extracted three times with a hexane-diethyl ether mixture and centrifuged after each extraction to separate the organic phase. The combined extracts are washed with a 1 percent KCl-solution and dried with anhydrous sodium sulphate. The serum extract is concentrated to a small volume and purified using a florisil clean-up procedure. The purified extracts are concentrated to a small volume and an injection standard is added. The final extracts are analyzed with gas chromatography coupled with mass spectrometry (GC/MS) in the selected ion monitoring mode (SIM). The identification of analytes is based on correct retention times and/or qualifier ion ratios, compared to an external standard. The quantification was based on an external standard analyzed together with the samples. The recovery of added internal standards (musk xylene-d 15 and Tonalide-d3) were used to determine the performance of the analysis, but not to correct the results of the target compounds. The results are expressed in ng/g matrix. The matrix is blood.

Analysis of Perchlorate: Blood samples were spiked to a final concentration of 1 ppb with an isotopically labeled perchlorate internal standard. 2.5 ml of blood sample was diluted with 2.5 ml DI water and each sample was placed in the top portion of an Amicon Ultra 15 centrifugal filter device and centrifuged at 5000 rpm at 20C for 90 min. The resulting liquid that passed through the filter was added to 0.5 g of Amberlyst 15 cation exchange resin that was pre-washed with methanol and water. Sample was vortexed for 60 seconds. Liquid sample was passed through a 0.45 um syringe filter and placed into an autosampler vial for analysis. Samples were analyzed using IC-MS/MS using Dionex AS-16 (2mm x 250 mm) column with AG-16 guard column. A Quantum Discovery Max ESI-MS with HESI probe was used in the MS/MS mode for quantification.

QA/QC: All organic analyses were conducted in accordance with AXYS' accredited QA/QC program including regular analysis of QC samples and participation in international inter-laboratory comparison programs. Each analysis batch included a procedural blank to demonstrate cleanliness and a spiked laboratory control sample to monitor precision and recovery. The sample results were reviewed and evaluated in relation to the QA/QC samples worked up at the same time. The sample surrogate standard recoveries and detection limits, procedural blank data and the laboratory control sample data were evaluated against method criteria to ensure acceptable data quality.

We analyzed two background samples for each of the contaminants studied. One was an in-laboratory blank, and the other an empty blood bag with added anticoagulant.

We applied the following criteria to account for background contamination:

1. If the two background tests were non-detects, we simply used the reported result for that sample.
2. If either of the background samples had detected contamination we counted the detection as a hit if it were at least 20 percent over the larger background value and at least three times the detection limit for the particular test.

The laboratory flagged some values for not meeting certain analytical criteria. These related to ion abundance ratios and the method calibration limit. We used these values but note the data quality flags in the data section of our Human Toxome website.

The number of chemicals detected is reported as a range due to the co-eluting chemicals in the PCB, PBDE and PCN families. The minimum value counts each co-eluting value as only one chemical, and the maximum value in the range counts each of the co-eluting chemicals.

Chemicals in cord blood -- literature review

We searched the published literature for chemicals detected in umbilical cord blood samples. We used two publicly available search engines: NIH-sponsored PubMed and Google Scholar. We queried a variety of search terms including "cord blood," "umbilical cord," "contaminants," "xenobiotic" and "toxic." We also did a targeted search for individual chemicals, chemical families and categories like "pesticides." In addition to scientific publications we included a several conference abstracts and NGO reports (white papers) that reported unique chemicals in cord blood.

We did not include essential trace elements (such as zinc, manganese, magnesium), but included natural elements that can be toxic. We also excluded pharmaceutical drugs. We also excluded chemicals detected in other biological media: maternal blood or urine during pregnancy, follicular or amniotic fluid, meconium, infant urine or DNA adducts from our analysis.

For each study we cataloged information about the study location, population, time of sample collection and the full reference for the study.

Chemicals were not included in our review unless the specific chemical names were mentioned in the text or supplemental materials, and it was clear that the chemical was detected in at least one sample. This may under-represent some trace chemicals, especially in the PCB, Dioxin, Furan and PBDE families, since scientists many times do not name and quantify the detections for trace congeners. Instead researchers may report the total measurements by chemical family or use a TEQ (toxicity equivalent factor) to sum up overall toxicity of detected chemicals.

Appendix B A Review of All U.S. Cord Blood Contaminant Studies

The Centers for Disease Control and Prevention (CDC) calls biomonitoring measurements "the most health-relevant assessments of exposure" for their ability to define precisely "the amount of chemicals that actually enter people's bodies" (CDC 2009). The agency devoted $13.8 billion to its biomonitoring programs in 2009 alone and has launched a significant new national children's study that initially will test 525 pregnant women and their babies for a broad range of pollutants.

CDC rarely tests cord blood, even though it has acknowledged that "for children age 5 years and younger, minimal information exists on exposure to priority environmental chemicals, and this lack of information is a major gap in protecting children from harmful exposures."

EWG set out to address this gap, focusing on exposures for newborns. EWG researchers conducted a comprehensive survey of the published scientific literature, identifying every study in which scientists tested umbilical cord blood for industrial chemicals. They then compiled a database of all published cord blood studies and the chemicals detected and cross-referenced it against EWG's database of cord blood contaminants found in its own studies.

EWG's findings agree with CDC's – the peer-reviewed literature contains surprisingly little biomonitoring information for newborns. The vast majority of chemicals found in cord blood have been identified in EWG-led research.

Altogether, biomonitoring studies report finding between 288 and 358 chemicals in cord blood from U.S. newborns. (The range occurs because analytical instruments cannot distinguish between some chemicals, and so laboratories report them together as "co-eluting" chemicals. One or both could be present in the sample.)

Large, population-scale biomonitoring studies could fill this critical gap in biomonitoring data. Such studies could help scientists and policymakers to determine how infant exposure to chemicals in the womb varies across populations; what other industrial compounds may be present in umbilical cord blood; and what health risks those pollutants may pose, alone or in combination, to developing fetuses.

CORD BLOOD BIOMONITORING STUDIES

Nationally, cord blood biomonitoring studies have detected up to 358 chemicals

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns for 12 brominated dioxins and furans and found at least one of these chemicals in 7. In the 7 newborns, 6 to 7 different congeners were found. Mean total level was 12 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	6-7
Dioxin & Furan	Brominated dioxin	EWG tested cord blood from 10 newborns of minority background for 12 brominated dioxins and furans and found at least one in 4 of the subjects. Six different congeners were found. Mean total level was 10.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Dioxin & Furan	Chlorinated dioxin	Researchers at the SUNY Health Science Center tested cord blood from 5 babies delivered via C-section from late 1995 to early 1996 for dioxins, dibenzofurans, and coplanar PCBs. Mean measured levels of total PCDDs, PCDFs, and coplanar PCBs were 165 pg/g for cord blood. (EWG 2005)	5	N.Y.	1
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Eleven different congeners were found. Mean total level was 56.3 pg/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	11

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Dioxin & Furan	Chlorinated furan	EWG tested cord blood from 10 newborns of minority background for 17 chlorinated dioxins and furans and found at least one in all 10 subjects. Fifteen (15) different congeners were found. Mean total level was 59.7 pg/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	15
Fire Retardant	Brominated Fire Retardant	EWG measured TBBPA levels in cord blood from 10 newborns of minority background. TBBPA was found in 3 samples with a mean level of 11 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Metal	Cadmium	Researchers at Harvard measured cord blood concentrations of cadmium in 94 healthy babies, finding concentrations ranging from 0.003 to 0.210 µg/dl, with mean of 0.045 µg/dl. (Rabinowith 1984)	94	Boston, Mass.	1
Metal	Lead	Researchers at SUNY Oswego, the New York State Department of Health, the University of Albany and Penn State University measured cord blood lead levels in 154 children and correlated lead levels with adrenocortical responses to acute stress in children. They divided cord blood levels into the following 4 quartiles: < 1.0 (1st quartile; n = 37), 1.1–1.4 µg/dL (2nd quartile; n = 39), 1.5–1.9 µg/dL (3rd quartile; n = 36), and 2.0–6.3 µg/dL (4th quartile; n = 42). (Gump 2008)	154	N.Y.	1

Pollution in People - Cord Blood Contaminants in Minority Newborns

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Metal	Lead	Researchers at Harvard University, Emory University and University of Massachusetts at Amherst tested lead levels in cord blood from 527 babies born between 1993 and 1998 and found mean levels of 1.45 µg/dL. (Sagiv 2008)	527	New Bedford, Mass.	1
Metal	Mercury	Researchers at Columbia University and the CDC tested for cord blood levels of mercury in women who live and or work close to the World Trade Center site between Dec. 2001 and June 2002. The researchers found a mean cord mercury level of 7.82 µg/L. (Lederman 2008)	289	New York City, N.Y.	1
Musk	Musk	EWG measured nitro and polycyclic musk levels in cord blood from 10 newborns of minority background. Galoxolide was found in 6 samples at a mean level of 0.483 ng/g, and Tonalide was found in 4 samples at a mean level of 0.147 ng/g. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	2
PAH	Polyaromatic hydrocarbons (PAHs)	Researchers at Columbia University measured levels of benzoA-pyrene DNA adduct levels in 203 babies from New York City mothers who were pregnant during 9/11. (Perera 2005)	203	New York City, N.Y.	1
PAH	Polyaromatic hydrocarbons (PAHs)	EWG tested cord blood from 5 newborns for 18 polyaromatic hydrocarbons and found at least one in all 5 subjects. Nine (9) different chemicals were found with total mean concentration of 279 ng/g lipids in blood serum. (EWG 2005)	5	U.S. hospitals	9

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers at Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 8 PBDE congeners. They report that 94% of the samples contained at least one of the tested congeners. (Herbstman 2007)	297	Baltimore, MD	7
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers at Indiana University measured levels of 6 PBDEs in 12 paired samples of maternal and cord blood from live births that occurred from Aug. to Dec., 2001. They found that concentrations of PBDEs in both sets of samples were 20-to-106 fold higher than levels reported in a similar study from Sweden, leading them to conclude "human fetuses in the United States may be exposed to relatively high levels of PBDEs." (Mazdai 2003)	12	Indianapolis, Ind.	6
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns for 46 polybrominated diphenol ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 27 to 32 different congeners were found. Mean total level was 4.53 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	27-32

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Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PBDE	Polybrominated diphenyl ether (PBDE)	EWG tested cord blood from 10 newborns of minority background for 46 polybrominated diphenyl ethers (PBDEs) and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 26 to 29 different congeners were found. Mean total level was 72.9 ng/g lipids in blood serum. (EWG 2009)	10	U.S. hospitals	26-29
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers at Columbia University and Johns Hopkins tested 288 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 3 PBDE congeners. In all the 288 subjects, all three congeners were found. (Herbstman 2008)	288	Baltimore, MD	3
PBDE	Polybrominated diphenyl ether (PBDE) Metabolite	Researchers at the School of Public and Environmental Affairs at Indiana University tested PBDE and PBDE metabolities in 20 pregnant women and their newborn babies who had not been intentionally or occupationally exposed. They noted that metabolites in humans seem to be accumulating. (Qiu 2009)	20	Indianapolis, Ind.	10

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PCB	Polychlorinated biphenyl (PCB)	Researchers at Columbia University and Johns Hopkins tested 297 cord blood samples from babies born at Johns Hopkins Hospital from Nov. 26, 2004 to March 16, 2005 for 35 PCB congeners. They report levels for 4 of the 35 but note that ">99% (of samples) had at least one detectable PCB congener." (Herbstman 2007)	297	Baltimore, Md.	18
PCB	Polychlorinated biphenyl (PCB)	Researchers at SUNY Oswego investigated cord blood levels of PCBs in children born between 1991 and 1994 and correlated levels with response inhibition when the children were 4.5 years of age. The researchers found that "results indicated a dose-dependent association between cord blood PCBs and errors of commission." (Stewart 2003)	10	U.S. hospitals	98-147
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns for 209 polybrominated diphenol ethers (PBDEs) and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 98 to 147 different congeners were found. Mean total level was 6.2 ng/g lipids in blood serum. (EWG 2005)	10	Mich. Fla. Wis. Mass. Calif.	98-144

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Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PCB	Polychlorinated biphenyl (PCB)	Researchers at Harvard, Emory, and the University of Massachusetts at Amherst tested levels of 51 PCB congeners in cord blood from 542 babies born between 1993 and 1998. No information on levels of individual congeners is given; however, the mean sum of PCB congeners 118,138,153, and 180 is 0.25 ng/g and the TEF-weighted sum of mono-ortho PCB congeners 105, 118, 156, 167, and 189 is 6.75 pg/g lipid. (Sagiv 2008)	542	New Bedford, Mass.	>4
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from10 newborns for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 31 to 50 different congeners were found with total mean concentration of 0.574 ng/g lipids in blood serum. (EWG 2005)	10	U.S. hospitals	31-50
PCN	Polychlorinated naphthalene (PCN)	EWG tested cord blood from10 newborns of minority background for 70 polychlorinated naphthalenes and found at least one in all 10 subjects. In all, 17 to 24 different congeners were found, with total mean concentration of 0.637 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	17-24

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Pesticide	Carbamate	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept.1998 and May 2001. 48% of the babies had exposure to 2-Isopropoxyphenol, 45% to carbofuran, and 36% to bendiocarb. All of the babies were exposed to at least one carbamate. (Whyatt 2003)	211	New York City, N.Y.	5
Pesticide	Fungicide	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% of the babies had exposure to dicloran, 70% to phthalimide. All of the babies had exposure to at least one fungicide. (Whyatt 2003)	211	New York City, N.Y.	4
Pesticide	Herbacide	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 38% had exposure to chlorthal-dimethyl and 20% had exposure to Alachor. All had exposure to at least one herbicide. (Whyatt 2003)	211	New York City, N.Y.	5

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Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Pesticide	Imide	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 83% had exposure to dicloran and 70% had exposure to phthalimide. All had exposure to at least one fungicide. (Whyatt 2003)	211	New York City, N.Y.	1
Pesticide	Mosquito Repellent	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between September 1998 and May 2001. 33% of the babies had exposure to diethyltoluamide. (Whyatt 2003)	211	New York City, N.Y.	1
Pesticide	Organochlorine Pesticide (OC)	Researchers at Harvard, Emory and the University of Massachusetts at Amherst tested levels of 2 organochlorine pesticides in cord blood from 542 babies born between 1993 and 1998. Mean DDE levels were 0.48 ng/g serum. Levels of HCB were not given. (Sagiv 2008)	542	U.S. hospitals	1
Pesticide	Organochlorine Pesticide (OC)	EWG tested cord blood from10 newborns for 28 organochlorine pesticides and found at least one in all 10 subjects. In all, 21 different pesticides were found. (EWG 2005)	10	U.S. hospitals	21

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
Pesticide	Organophosphate Pesticides and Metabolites	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept. 1998 and May 2001. 71% had exposure to chlorpyrifos (mean 4.7 pg/g) and 49% had exposure to diazinon (mean 1.2 pg/g), the two most commonly detected pesticides. All other pesticides were found in 4% or less of the samples and all babies had exposure to at least one of the organophosphates. (Whyatt 2003)	211	New York City, N.Y.	8
Pesticide	Pyrethroid	Researchers at Columbia University, the CDC and the Southwest Research Institute measured the levels of 29 pesticides in cord plasma from 211 babies born into an urban community in New York City between Sept 1998 and May 2001. 7% had exposure to trans-permethrin and 13% had exposure to cis-permethrin. (Whyatt 2003)	211	New York City, N.Y.	2
PFC	Perfluorochemical (PFC)	Researchers at CDC, Columbia University and Johns Hopkins tested cord blood from 299 babies born at Johns Hopkins Hospital between Nov. 26, 2004 and March 16, 2005 for 10 PFCs. They detected PFOS in 99% and PFOA in 100% of samples. Eight other PFCs were detected at lesser frequency. (Apelberg 2007)	299	Baltimore, Md.	9

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Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PFC	Perfluorochemical (PFC)	EWG tested cord blood from 10 newborns for 12 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 9 of 12 different chemicals were found with total mean concentration of 5.86 ng/g in whole blood. (EWG 2005)	10	U.S. hospitals	9
PFC	Perfluorochemical (PFC)	EWG tested cord blood from10 newborns of minority background for 13 perfluorochemicals and found at least one of these chemicals in 10 out of 10 participants. Among all 10 participants who tested positive for the chemicals, 6 of 13 different chemicals were found with total mean concentration of 2.38 ng/g in whole blood. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	6
Plastic	Bisphenol A & BADGE	Researchers at the Environmental Working Group measured BPA levels in cord blood from 10 newborns of minority background. BPA was found in 9 of 10 samples with a mean level of 2.18 ng/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1
Rocket fuel	Perchlorate	Researchers at the Environmental Working Group measured perchlorate levels in cord blood from 10 newborns of minority background. Perchlorate was found in 9 of 10 samples with a mean level of 0.209 ug/L. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	1

Appendix C: References

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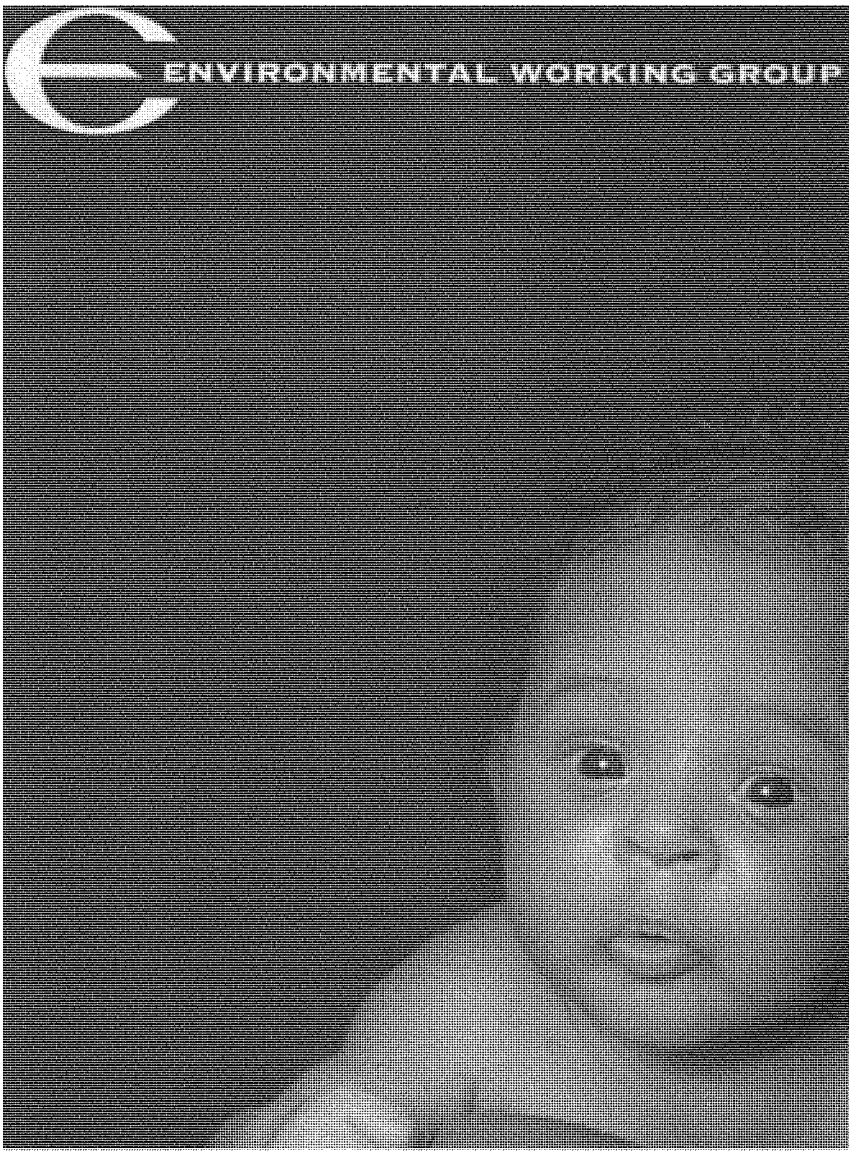
ENVIRONMENTAL WORKING GROUP

Senator LAUTENBERG. According to a 2002 study, 5 percent of cancers, 10 percent of neural behavioral disorders, and 30 percent of asthma cases in children are associated with toxic chemicals. And it is time to sound the alarm. America's system for regulating these toxic chemicals is broken. Industrial chemicals are everywhere, from flame retardants in furniture and carpets to other chemicals in cleaning products, personal care products, food containers, and even children's products as simple as nipples and baby bottles.

The current law, the Toxic Substances Control Act, puts a high burden on EPA to prove chemicals are unreasonably dangerous before the Agency can take steps to restrict their use. The burden is so high. In fact, the EPA has been able to ban only 5 of the more than 80,000 substances on EPA's inventory of chemicals on the market, and it has only tested about 200. That means the majority of chemicals used and products that make their way into our homes and our children's hands are untested. And we must strengthen our chemical laws to give Americans confidence that products are safe before they are sold and used throughout the United States.

Most of the thousands of chemicals that we use every day are safe, but we need a law that will separate those safe chemicals from the ones that are not. And I believe that we are in an excellent position to accomplish that goal with a broad group of agencies and organizations coming to the table to work for reform.

President Obama's Administration is here today. They are represented by the distinguished Administrator of EPA, Lisa Jackson, by the way, a good friend from New Jersey. The EPA recently released its principles for reforming TSCA. The Government Accountability Office, which recently put our chemical regulatory system on its list of high risk areas of the law, is here, as is the National Institute of Environmental Health Science, which has funded research showing the potential risks from toxic chemicals.

In addition, everyone from chemical manufacturers to businesses that use chemicals in their products, to environmental, labor and health groups have called for the reforming of the Toxic Substances Control Act. The trade association for the chemical manufacturers, the American Chemistry Council, has agreed that the status quo is not working. In August, they released principles for TSCA reform which matched up closely with the principles released by the Obama administration and had substantial overlap with principles released by environmental, health and labor groups.

Now, I ask unanimous consent to enter the American Chemistry Council's principles into the record, as well as a letter from their President, Cal Dooley.

[The referenced information follows:]

December 1, 2009

The Honorable Barbara Boxer
Chairman, Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

The Honorable James Inhofe
Ranking Member, Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Chairman Boxer and Ranking Member Inhofe:

The Senate Committee on Environment and Public Works is scheduled to hear testimony from several U.S. government witnesses on December 2, 2009, concerning the Toxic Substances Control Act (TSCA). The American Chemistry Council (ACC), a national trade association representing 140 member companies and 800,000 workers, would like to share some thoughts in advance of the Committee's hearing.

As I testified before a House of Representatives Subcommittee in February 2009, ACC and its members welcome Congress' review of TSCA and the measures that might be taken to improve the statute. In our view, Congress should have several objectives in modernizing TSCA:

- Ensuring the protection of public health is a top priority.
- Enhancing confidence in the federal chemical regulatory system and ensuring the safe, beneficial use of chemicals.
- Reflecting the scientific and technological advances that have been made since TSCA was enacted.
- Assuring continued innovation from the U.S. chemical industry so that we can keep and grow jobs making the products that save lives, make our economy more energy efficient, and reduce greenhouse gas emissions.

In August 2009, ACC released a set of ten principles (attached) that should be reflected in efforts to modernize TSCA. We were gratified to see that the Environmental Protection Agency's (EPA) six principles for TSCA modifications released in September 2009 reflect substantial agreement with industry's principles and those released by other stakeholders. I strongly believe that the national interest in a robust federal chemical management system would be well-served if those areas of agreement become the focal points for dialogue among all stakeholders. ACC's principles go to the heart of the federal government's efforts to assess and address potential risks to human health and the environment from chemical exposures. In ACC's view, TSCA should include an effective system to screen and prioritize chemicals for assessment by

the Agency. Without a prioritization system, the capacity of both EPA and the private sector to identify and address those substances requiring additional risk management considerations will be compromised. The prioritization decision should identify those chemicals and exposures subject to a subsequent safety review by the Agency. EPA should be provided appropriate human and financial resources to ensure the robust implementation of a modified TSCA.

ACC believes that the prioritization screening and safety review elements should use the best possible data and information, including data developed through new and emerging scientifically sound and validated techniques. While new technologies are constantly being developed, such as EPA's high throughput screening program (ToxCast), EPA should have the resources to validate the methodologies and interpret their results to make informed decisions. In addition, EPA should have the ability to leverage the significant amounts of relevant information likely to be produced under revamped chemicals management programs in Canada and Europe in the coming.

ACC also believes that a modernized TSCA should be built upon a strong, integrated testing and assessment framework. That framework should rely on existing data and information in the first instance, and where appropriate should avoid further animal testing if other scientifically sound and validated test methods are available.

ACC and its members look forward to working with you and the entire Committee as discussions around modifications to TSCA continue. If we can provide any additional information on ACC's position on TSCA modernization, please contact me.

Sincerely,

Cal Dooley
President and CEO

cc: Committee on Environment and Public Works

Enclosure

10 Principles for Modernizing TSCA

The American Chemistry Council and its members support Congress' effort to modernize our nation's chemical management system. Such a system should place protecting the public health as its highest priority, and should include strict government oversight. It should also preserve America's role as the world's leading innovator and employer in the creation of safe and environmentally sound technologies and products of the business of chemistry.

The current chemical management law, the Toxic Substances Control Act (TSCA), is more than 30 years old. It should be modernized to keep pace with advances in science and technology. Moreover, the law must provide the Environmental Protection Agency with the resources and the authority to do its job effectively.

We have previously offered general concepts on which to base a modern chemical management system. This document expands upon those concepts and begins to provide more detail, which we hope will be useful to policy makers. We will continue to refine the details of our principles for modernizing TSCA and are committed to working with all stakeholders toward enactment of effective legislation.

1. Chemicals should be safe for their intended use.
    - Ensuring chemical safety is a shared responsibility of industry and EPA.
    - Industry should have the responsibility for providing sufficient information for EPA to make timely decisions about safety.
    - EPA should have the responsibility for making safe use determinations for high priority chemicals, focusing on their most significant uses and exposures.
    - Safe use determinations should integrate hazard, use, and exposure information, and incorporate appropriate safety factors.
    - Consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives should be part of EPA's risk management decision-making, but should not be part of its safe use determinations.
    - Other agencies, such as FDA and CPSC, should continue to make safety decisions for products within their own jurisdictions.

2. EPA should systematically prioritize chemicals for purposes of safe use determinations.

   - Government and industry resources should be focused on chemicals of highest concern.

   - The priorities should reflect considerations such as the volume of a chemical in commerce; its uses, including whether it is formulated in products for children; its detection in biomonitoring programs; its persistent or bioaccumulative properties; and the adequacy of available information.

3. EPA should act expeditiously and efficiently in making safe use determinations.

   - Since a chemical may have a variety of uses, resulting in different exposure potentials, EPA should consider the various uses and focus on those resulting in the most significant exposures.

   - EPA should complete safe use determinations within set timeframes.

4. Companies that manufacture, import, process, distribute, or use chemicals should be required to provide EPA with relevant information to the extent necessary for EPA to make safe use determinations.

   - Companies throughout the chain of commerce should be responsible for providing necessary hazard, use, and exposure information.

   - EPA should be authorized to require companies, as appropriate, to generate relevant new data and information to the extent reasonably necessary to make safe use determinations without having to prove risk as a prerequisite or engaging in protracted rulemaking.

   - Testing of chemicals should progress to more complex and expensive tests through a tiered approach as needed to identify hazards and exposures of specific concern.

   - To minimize animal testing, existing data should be considered prior to new testing, and validated alternatives to animal testing should be used wherever feasible.

   - Existing data and information should be leveraged in EPA's safe use determinations, including data and information from other mandatory and voluntary programs such as REACH and the U.S. High Production Volume challenge.

5. Potential risks faced by children should be an important factor in safe use determinations.

   - Safe use determinations should consider the effects of a chemical on children and their exposure to the chemical.

   - Safe use determinations should consider whether an extra margin of safety is needed to protect children.

6. EPA should be empowered to impose a range of controls to ensure that chemicals are safe for their intended use.

   - The controls could range from actions such as labeling, handling instructions, exposure limits and engineering controls to use restrictions and product bans.

   - The controls should be appropriate for managing the risk, taking into account alternatives, benefits, costs, and uncertainty.

7. Companies and EPA should work together to enhance public access to chemical health and safety information.

   - EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.

   - Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.

   - Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.

   - Reasonable protections for confidential as well as proprietary information should be provided.

8. EPA should rely on scientifically valid data and information, regardless of its source, including data and information reflecting modern advances in science and technology.

   - EPA should establish transparent and scientifically sound criteria for evaluating all of the information on which it makes decisions to ensure that it is valid, using a framework that addresses the strengths and limitations of the study design, the reliability of the test methods, and the quality of the data.

   - EPA should encourage use of good laboratory practices, peer review, standardized protocols, and other methods to ensure scientific quality.

9. EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.

   - EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.

10. A modernized TSCA should encourage technological innovation and a globally competitive industry in the United States.

    - A new chemical management system should preserve and enhance the jobs and innovative products and technologies contributed by the business of American chemistry.

    - Implementation of TSCA should encourage product and technology innovation by providing industry certainty about the use of chemicals.

Senator LAUTENBERG. Now, just a couple of hours ago, 13 States released a statement calling for a strong Federal system to keep people safe from chemicals. And at this time, I ask for unanimous consent to place that statement into the record.

[The referenced information follows:]

STATES' PRINCIPLES ON REFORM OF THE TOXIC SUBSTANCES CONTROL ACT
DECEMBER 2, 2009

Require Chemical Data Reporting. Chemical and product manufacturers should be required to develop and provide chemical health and safety information, as well as exposure and use data, including the presence of toxic chemicals in products and the associated chemical hazards and risks, to regulators, businesses, and the public.

Demonstrate Chemicals and Products are Safe. Manufacturers should provide the necessary information to regulators to conclude that new and existing chemicals and products in commerce are safe and do not endanger the public or the environment. The public has a right to expect that the products they use are safe.

Prioritize Chemicals of Concern. Government should identify and prioritize chemicals of concern in order to regulate the most problematic chemicals in commerce, and have the authority to take timely action to protect people and the environment. Sufficient resources should be made available to support these actions.

Protect the Most Vulnerable. Chemical regulation should be designed to protect the most vulnerable, including pregnant women and children.

Promote Safer Chemicals and Products. Based on green chemistry principles, manufacturers should be required to assess and identify safer alternatives to problematic chemicals of concern. Government should establish protocols for evaluating potential alternatives to chemicals of concern.

Address Emerging Contaminants. Emerging chemicals of concern, including nanoscale materials, need to be assessed for public and environmental safety before they go into widespread commerce and use.

Strengthen Federal Law & Preserve States' Rights. States acknowledge the need for a strong federal chemical regulation system, while expressly preserving the authority of state and localities to implement measures to manage chemicals of concern.

Fund State Programs. Effective state-federal governance should enhance the role of states in TSCA implementation, promote data and information sharing, and provide sustained funding for state programs. The states are in a unique position to provide innovative, cost-effective solutions for chemicals of concern prioritization, interstate data sharing, and safer chemical alternatives assessments.

States' Principles on Reform of the Toxic Substances Control Act
December 2, 2009 State Signatures

Linda S. Adams, Secretary
California Environmental
Protection Agency

Amey W. Marrella, Commissioner
Connecticut Department of
Environmental Protection

Douglas P. Scott, Director
Illinois Environmental Protection Agency

David P. Littell, Commissioner
Maine Department of
Environmental Protection

Shari T. Wilson, Secretary
Maryland Department of the Environment

Laurie Burt, Commissioner
Massachusetts Department of
Environmental Protection

Steven E. Chester, Director
Michigan Department of Environmental
Quality

Thomas S. Burack, Commissioner
New Hampshire Department of
Environmental Services

Mark N. Mauriello, Acting Commissioner
New Jersey Department of Environmental
Protection

Pete Grannis, Commissioner
New York State Department of
Environmental Conservation

Dick Pedersen , Director
Oregon Department of
Environmental Quality

Justin G. Johnson, Commissioner
VT Department of
Environmental Conservation

Ted Sturdevant, Director
Washington State Department of Ecology

Senator LAUTENBERG. The States have said we have general agreement on the problem, and now we have to work together on the solution, and often when Government tries to write new laws or modify old ones, there is resistance. But this is a case where everyone, I hope, agrees on the need for change, and we need to make good on this unique opportunity.

And that is why in the coming weeks, I plan to reintroduce legislation to strengthen our chemical laws. Our bill will put the burden of proving chemicals safety where it belongs, on chemical companies. Instead of waiting for a chemical to hurt somebody, it will require companies to prove their products are safe before they end up in the store, further in our homes, and in our being.

We are already regulating pesticides and pharmaceuticals this way, and it is just common sense that we do the same for chemicals that are used in everyday consumer products.

So I look forward to working with these witnesses to put common sense back into our environmental laws and better protect the health of the American public. And I thank all of you for being here, and I would turn to the Ranking Member of the committee, Senator Inhofe, my dear friend with whom we may occasionally differ, but we don't differ on the fact that we have respect for one another.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. That is true. That is true, and it has been true for quite a while now, too.

Since we have two Chairmen here now, I will refer to the Chairman as Madam Chairman and Mr. Chairman, so we know who we are talking to.

And I am glad we are having this oversight hearing on TSCA. Senator Lautenberg has indicated that he will again introduce legislation to amend TSCA. In the interest of moving balanced, effective TSCA reform legislation, I urge you, Senator, to introduce a bill driven by risk-based analysis, rather than by precautionary principle.

Now, for the record, I want to get this into the record, I believe that any changes in TSCA must adhere to the following fundamental principles. Reviews must use data and methods based on the best available science and risk-based assessments. Reviews must include cost-benefit considerations for the private sector and consumers. Processes must protect proprietary business information as well as information that should be protected for security reasons. Procedures should prioritize reviews for existing chemicals. Processes must not include any provision that encourages litigation or citizen suits. And reviews must not include any provisions that compel product substitution by commercial interests or consumers.

Now, before I close, I want to follow up on a letter that I sent yesterday, and actually an e-mail last week to you, Madam Chairman, requesting hearings on what is now colloquially referred to as Climategate. And whatever one's position on the science of global warming, and Madam Chairman, I think you know mine, one cannot deny that the e-mails raised fundamental questions concerning,

among other things, transparency and openness in science, especially taxpayer funded science.

What do I mean? Well, in addition to apparent attempts to manipulate data and vilify scientists with opposing viewpoints, there is evidence that some of the world's preeminent scientists, who received or have received taxpayer funded grants, evaded laws requiring information disclosure, including the Freedom of Information Act.

Not only is this a potential violation of the law, but it violates a fundamental principle of the scientific method, that is to put everything on the table and allow anyone so inclined to attack it. If the research sustains the attack, then the researcher, the scientific community and the taxpayers can rightly have confidence that the conclusions are sound. If not, then it is back to the drawing board.

Now, Madam Chairman, as I state in my letter, for the taxpayers' sake, let's look at this controversy from top to bottom. It has already forced Bill Jones, the head of the U.K.'s Climate Research Unit, to step down. The CRU is investigating his behavior, and Representative Markey had a hearing today on the e-mail controversy. I wasn't privileged to sit in on that committee hearing.

I hope this committee meets its oversight responsibility by holding hearings, and I hope you will join me in calling on the Obama administration and the IPCC not only to investigate this matter but to release all of the data in question to ensure that taxpayer funded research is conducted according to the highest legal, ethical and professional standards.

And I think it goes without saying that the East Anglia operation that we are talking about is really at the head of the science of the IPCC, and that is what makes this so significant.

Thank you again, Mr. Chairman, for holding this hearing.

Senator LAUTENBERG. Thank you.

Chairman Boxer.

OPENING STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE STATE OF CALIFORNIA

Senator BOXER. Yes. I will respond to Senator Inhofe before I make my statement. And so if I could just ask to have a minute to respond to him.

First of all, my understanding is the hearing Representative Markey had was on climate science in general, and this issue was raised, and it was discussed, just as you have raised it at this hearing.

You call it Climategate. I call it e-mail theft-gate. Whatever it is, the main issue is are we facing global warming, or are we not. I am sure you would agree that is the basic question for us.

I am looking at these e-mails that have been—even though they were stolen, they are now out in the public, and we are looking through these e-mails. We are also calling the leading scientists of the world. We may well have a hearing on this. We may not. We may have a briefing for Senators. We may not. We are looking at this.

This is a crime, and I would ask unanimous consent to place into the record section 1030 of the U.S. Criminal Code, Fraud and Related Activity in Connection With Computers. Having knowingly

accessed a computer without authorization, it goes on calling it a crime. So part of our looking at this will be looking at a criminal activity which could well have been coordinated.

Now, what I have in my hand here is a letter from the Chair of the Board of Directors of the American Association for the Advancement of Science, Mr. James McCarthy. And I ask unanimous consent to place it into the record.

[The referenced information follows:]

1 of 1 DOCUMENT

*** CURRENT THROUGH PL 111-138, APPROVED 2/1/2010 ***

TITLE 18. CRIMES AND CRIMINAL PROCEDURE
PART I. CRIMES
CHAPTER 47. FRAUD AND FALSE STATEMENTS

Go to the United States Code Service Archive Directory

18 USCS § 1030

§ 1030. Fraud and related activity in connection with computers

(a) Whoever--

(1) having knowingly accessed a computer without authorization or exceeding authorized access, and by means of such conduct having obtained information that has been determined by the United States Government pursuant to an Executive order or statute to require protection against unauthorized disclosure for reasons of national defense or foreign relations, or any restricted data, as defined in paragraph y.[(y)] of section 11 of the Atomic Energy Act of 1954 [*42 USCS § 2014(y)*], with reason to believe that such information so obtained could be used to the injury of the United States, or to the advantage of any foreign nation willfully communicates, delivers, transmits, or causes to be communicated, delivered, or transmitted, or attempts to communicate, deliver, transmit or cause to be communicated, delivered, or transmitted the same to any person not entitled to receive it, or willfully retains the same and fails to deliver it to the officer or employee of the United States entitled to receive it;

(2) intentionally accesses a computer without authorization or exceeds authorized access, and thereby obtains--

(A) information contained in a financial record of a financial institution, or of a card issuer as defined in section 1602(n) of title 15, or contained in a file of a consumer reporting agency on a consumer, as such terms are defined in the Fair Credit Reporting Act (*15 U.S.C. 1681* et seq.);

(B) information from any department or agency of the United States; or

(C) information from any protected computer;

(3) intentionally, without authorization to access any nonpublic computer of a department or agency of the United States, accesses such a computer of that department or agency that is exclusively for the use of the Government of the United States or, in the case of a computer not exclusively for such use, is used by or for the Government of the United States and such conduct affects that use by or for the Government of the United States;

(4) knowingly and with intent to defraud, accesses a protected computer without authorization, or exceeds authorized access, and by means of such conduct furthers the intended fraud and obtains anything of value, unless the object of the fraud and the thing obtained consists only of the use of the computer and the value of such use is not more than $ 5,000 in any 1-year period;

(5) (A) knowingly causes the transmission of a program, information, code, or command, and as a result of such conduct, intentionally causes damage without authorization, to a protected computer;

(B) intentionally accesses a protected computer without authorization, and as a result of such conduct, recklessly causes damage; or

(C) intentionally accesses a protected computer without authorization, and as a result of such conduct, causes damage and loss.[;]

(6) knowingly and with intent to defraud traffics (as defined in section 1029 [*18 USCS § 1029*]) in any password or similar information through which a computer may be accessed without authorization, if--

(A) such trafficking affects interstate or foreign commerce; or

(B) such computer is used by or for the Government of the United States; [or]

(7) with intent to extort from any person any money or other thing of value, transmits in interstate or foreign commerce any communication containing any--

(A) threat to cause damage to a protected computer;

(B) threat to obtain information from a protected computer without authorization or in excess of authorization or to impair the confidentiality of information obtained from a protected computer without authorization or by exceeding authorized access; or

(C) demand or request for money or other thing of value in relation to damage to a protected computer, where such damage was caused to facilitate the extortion;

shall be punished as provided in subsection (c) of this section.

(b) Whoever conspires to commit or attempts to commit an offense under subsection (a) of this section shall be punisbed as provided in subsection (c) of this section.

(c) The punishment for an offense under subsection (a) or (b) of this section is--

(1)

(A) a fine under this title or imprisonment for not more than ten years, or both, in the case of an offense under subsection (a)(1) of this section which does not occur after a conviction for another offense under this section, or an attempt to commit an offense punishable under this subparagraph; and

(B) a fine under this title or imprisonment for not more than twenty years, or both, in the case of an offense under subsection (a)(1) of this section which occurs after a conviction for another offense under this section; or an attempt to commit an offense punishable under this subparagraph;

(2) (A) except as provided in subparagraph (B), a fine under this title or imprisonment for not more than one year, or both, in the case of an offense under subsection (a)(2), (a)(3), or (a)(6) of this section which does not occur after a conviction for another offense under this section, or an attempt to commit an offense punishable under this subparagraph;

(B) a fine under this title or imprisonment for not more than 5 years, or both, in the case of an offense under subsection (a)(2), or an attempt to commit an offense punishable under this subparagraph, if--

(i) the offense was committed for purposes of commercial advantage or private financial gain;

(ii) the offense was committed in furtherance of any criminal or tortious act in violation of the Constitution or laws of the United States or of any State; or

(iii) the value of the information obtained exceeds $ 5,000; and

(C) a fine under this title or imprisonment for not more than ten years, or both, in the case of an offense under subsection (a)(2), (a)(3) or (a)(6) of this section which occurs after a conviction for another offense under this section, or an attempt to commit an offense punishable under this subparagraph;

(3)

(A) a fine under this title or imprisonment for not more than five years, or both, in the case of an offense under subsection (a)(4) or (a)(7) of this section which does not occur after a conviction for another offense under this section, or an attempt to commit an offense punishable under this subparagraph; and

(B) a fine under this title or imprisonment for not more than ten years, or both, in the case of an offense under subsection (a)(4), or (a)(7) of this section which occurs after a conviction for another offense under this section, or an attempt to commit an offense punishable under this section;

(4) (A) except as provided in subparagraphs (E) and (F), a fine under this title, imprisonment for not more than 5 years, or both, in the case of--

(i) an offense under subsection (a)(5)(B), which does not occur after a conviction for another offense under this section, if the offense caused (or, in the case of an attempted offense, would, if completed, have caused)--

(I) loss to 1 or more persons during any 1-year period (and, for purposes of an investigation, prosecution, or other proceeding brought by the United States only, loss resulting from a related course of conduct affecting 1 or more other protected computers) aggregating at least $ 5,000 in value;

(II) the modification or impairment, or potential modification or impairment, of the medical examination, diagnosis, treatment, or care of 1 or more individuals;

(III) physical injury to any person;

(IV) a threat to public health or safety;

(V) damage affecting a computer used by or for an entity of the United States Government in furtherance of the administration of justice, national defense, or national security; or

(VI) damage affecting 10 or more protected computers during any 1-year period; or

(ii) an attempt to commit an offense punishable under this subparagraph;

(B) except as provided in subparagraphs (E) and (F), a fine under this title, imprisonment for not more than 10 years, or both, in the case of--

(i) an offense under subsection (a)(5)(A), which does not occur after a conviction for another offense under this section, if the offense caused (or, in the case of an attempted offense, would, if completed, have caused) a harm provided in subclauses (I) through (VI) of subparagraph (A)(i); or

(ii) an attempt to commit an offense punishable under this subparagraph;

(C) except as provided in subparagraphs (E) and (F), a fine under this title, imprisonment for not more than 20 years, or both, in the case of--

(i) an offense or an attempt to commit an offense under subparagraphs (A) or (B) of subsection (a)(5) that occurs after a conviction for another offense under this section; or

(ii) an attempt to commit an offense punishable under this subparagraph;

(D) a fine under this title, imprisonment for not more than 10 years, or both, in the case of--

(i) an offense or an attempt to commit an offense under subsection (a)(5)(C) that occurs after a conviction for another offense under this section; or

(ii) an attempt to commit an offense punishable under this subparagraph;

(E) if the offender attempts to cause or knowingly or recklessly causes serious bodily injury from conduct in violation of subsection (a)(5)(A), a fine under this title, imprisonment for not more than 20 years, or both;

(F) if the offender attempts to cause or knowingly or recklessly causes death from conduct in violation of subsection (a)(5)(A), a fine under this title, imprisonment for any term of years or for life, or both; or

(G) a fine under this title, imprisonment for not more than 1 year, or both, for--

(i) any other offense under subsection (a)(5); or

(ii) an attempt to commit an offense punishable under this subparagraph.

(5) [Deleted]

(d)

(1) The United States Secret Service shall, in addition to any other agency having such authority, have the authority to investigate offenses under this section.

(2) The Federal Bureau of Investigation shall have primary authority to investigate offenses under subsection (a)(1) for any cases involving espionage, foreign counterintelligence, information protected against unauthorized disclosure for reasons of national defense or foreign relations, or Restricted Data (as that term is defined in section 11y of the Atomic Energy Act of 1954 (*42 U.S.C. 2014(y)*), except for offenses affecting the duties of the United States Secret Service pursuant to section 3056(a) of this *title [18 USCS § 3056(a)]*.

(3) Such authority shall be exercised in accordance with an agreement which shall be entered into by the Secretary of the Treasury and the Attorney General.

(e) As used in this section--

(1) the term "computer" means an electronic, magnetic, optical, electrochemical, or other high speed data processing device performing logical, arithmetic, or storage functions, and includes any data storage facility or communications facility directly related to or operating in conjunction with such device, but such term does not include an automated typewriter or typesetter, a portable hand held calculator, or other similar device;

(2) the term "protected computer" means a computer--

(A) exclusively for the use of a financial institution or the United States Government, or, in the case of a computer not exclusively for such use, used by or for a financial institution or the United States Government and the conduct constituting the offense affects that use by or for the financial institution or the Government; or

(B) which is used in or affecting interstate or foreign commerce or communication, including a computer located outside the United States that is used in a manner that affects interstate or foreign commerce or communication of the United States;

(3) the term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, and any other commonwealth, possession or territory of the United States;

(4) the term "financial institution" means--

(A) an institution, with deposits insured by the Federal Deposit Insurance Corporation;

(B) the Federal Reserve or a member of the Federal Reserve including any Federal Reserve Bank;

(C) a credit union with accounts insured by the National Credit Union Administration;

(D) a member of the Federal home loan bank system and any home loan bank;

(E) any institution of the Farm Credit System under the Farm Credit Act of 1971;

(F) a broker-dealer registered with the Securities and Exchange Commission pursuant to section 15 of the Securities Exchange Act of 1934 [*15 USCS § 78o*];

(G) the Securities Investor Protection Corporation;

(H) a branch or agency of a foreign bank (as such terms are defined in paragraphs (1) and (3) of section 1(b) of the International Banking Act of 1978 [*12 USCS § 3101(1)* and (3)]); and

(I) an organization operating under section 25 or section 25(a) of the Federal Reserve Act;

(5) the term "financial record" means information derived from any record held by a financial institution pertaining to a customer's relationship with the financial institution;

(6) the term "exceeds authorized access" means to access a computer with authorization and to use such access to obtain or alter information in the computer that the accesser is not entitled so to obtain or alter;

(7) the term "department of the United States" means the legislative or judicial branch of the Government or one of the executive department enumerated in section 101 of title 5;

(8) the term "damage" means any impairment to the integrity or availability of data, a program, a system, or information;

(9) the term "government entity" includes the Government of the United States, any State or political subdivision of the United States, any foreign country, and any state, province, municipality, or other political subdivision of a foreign country;

(10) the term "conviction" shall include a conviction under the law of any State for a crime punishable by imprisonment for more than 1 year, an element of which is unauthorized access, or exceeding authorized access, to a computer;

(11) the term "loss" means any reasonable cost to any victim, including the cost of responding to an offense, conducting a damage assessment, and restoring the data, program, system, or information to its condition prior to the offense, and any revenue lost, cost incurred, or other consequential damages incurred because of interruption of service; and

(12) the term "person" means any individual, firm, corporation, educational institution, financial institution, governmental entity, or legal or other entity.

(f) This section does not prohibit any lawfully authorized investigative, protective, or intelligence activity of a law enforcement agency of the United States, a State, or a political subdivision of a State, or of an intelligence agency of the United States.

(g) Any person who suffers damage or loss by reason of a violation of this section may maintain a civil action against the violator to obtain compensatory damages and injunctive relief or other equitable relief. A civil action for a violation of this section may be brought only if the conduct involves 1 of the factors set forth in subclauses (I), (II), (III), (IV), or (V) of subsection (c)(4)(A)(i). Damages for a violation involving only conduct described in subsection (c)(4)(A)(i)(I) are limited to economic damages. No action may be brought under this subsection unless such action is begun within 2 years of the date of the act complained of or the date of the discovery of the damage. No action may be brought under this subsection for the negligent design or manufacture of computer hardware, computer software, or firmware.

(h) The Attorney General and the Secretary of the Treasury shall report to the Congress annually, during the first 3 years following the date of the enactment of this subsection [enacted Sept. 13, 1994], concerning investigations and prosecutions under subsection (a)(5).

(i) (1) The court, in imposing sentence on any person convicted of a violation of this section, or convicted of conspiracy to violate this section, shall order, in addition to any other sentence imposed and irrespective of any provision of State law, that such person forfeit to the United States--

(A) such person's interest in any personal property that was used or intended to be used to commit or to facilitate the commission of such violation; and

(B) any property, real or personal, constituting or derived from, any proceeds that such person obtained, directly or indirectly, as a result of such violation.

(2) The criminal forfeiture of property under this subsection, any seizure and disposition thereof, and any judicial proceeding in relation thereto, shall be governed by the provisions of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (*21 U.S.C. 853*), except subsection (d) of that section.

(j) For purposes of subsection (i), the following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) Any personal property used or intended to be used to commit or to facilitate the commission of any violation of this section, or a conspiracy to violate this section.

(2) Any property, real or personal, which constitutes or is derived from proceeds traceable to any violation of this section, or a conspiracy to violate this section.

HISTORY:

(Added Oct. 12, 1984, P.L. 98-473, Title II, Ch XXI, § 2102(a), 98 Stat. 2190; Oct. 16, 1986, P.L. 99-474, § 2, 100 Stat. 1213; Nov. 18, 1988, P.L. 100-690, Title VII, Subtitle B, § 7065, 102 Stat. 4404; Aug. 9, 1989, P.L. 101-73, Title IX, Subtitle F, § 962(a)(5), 103 Stat. 502; Nov. 29, 1990, P.L. 101-647, Title XII, § 1205(e), Title XXV, Subtitle I, § 2597(j), Title XXXV, § 3533, 104 Stat. 4831, 4910, 4925; Sept. 13, 1994, P.L. 103-322, Title XXIX, § 290001(b)-(f), 108 Stat. 2097; Oct. 11, 1996, P.L. 104-294, Title II, § 201, Title VI, § 604(b)(36), 110 Stat. 3491, 3508; Oct. 26, 2001, P.L. 107-56, Title V, § 506(a), Title VIII, § 814(a)-(e), 115 Stat. 366, 382; Nov. 2, 2002, P.L. 107-273, Div B, Title IV, §§ 4002(b)(1), (12), 4005(a)(3), (d)(3), 116 Stat. 1807, 1808, 1812, 1813; Nov. 25, 2002, P.L. 107-296, Title II, Subtitle C, § 225(g), 116 Stat. 2158.)

(As amended Sept. 26, 2008, P.L. 110-326, Title II, §§ 203, 204(a), 205-208, 122 Stat. 3561.)

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

December 2, 2009

Chairman Barbara Boxer
410 Dirksen Senate Office Bldg.
Washington, DC 20510-6175

Dear Chairman Boxer:

The body of evidence that human activity is the prominent agent in global warming is overwhelming. The content of a few personal emails has no impact whatsoever on our overall understanding that human activity is driving dangerous levels of global warming. The scientific process depends on open access to methodology, data, and a rigorous peer-review process. The robust exchange of ideas in the peer-reviewed literature regarding climate science is evidence of the high degree of integrity in this process.

Sincerely,

James J. McCarthy

Harvard University
Alexander Agassiz Professor of
Biological Oceanography

American Association for the Advancement of Science
Chair of Board of Directors

Union of Concerned Scientists
Chair of Board of Directors

www.ucsusa.org Two Brattle Square · Cambridge, MA 02238-9105 · TEL: 617.547.5552 · FAX: 617.864.9405
1825 K Street NW · Suite 800 · Washington, DC 20006-1232 · TEL: 202.223.6133 · FAX: 202.223.6162
2397 Shattuck Avenue · Suite 203 · Berkeley, CA 94704-1567 · TEL: 510.843.1872 · FAX: 510.843.3785
One North LaSalle Street · Suite 1904 · Chicago, IL 60602-4064 · TEL: 312.578.1750 · FAX: 312.578.1751

Senator BOXER. The body of evidence of human activity as the prominent agent in global warming is overwhelming, and he says there were these e-mails, but these facts remain. I will put that in the record.

Also put in the record a press release from the Union of Concerned Scientists that says opponents of climate change legislation are trying to deceive the American public on climate science. After years attacking the science on its merits and failing, they are now using stolen e-mails to attack climate scientists directly.

[The referenced information follows:]

Union of Concerned Scientists

November 23, 2009 Subscribe for news

Contrarians Using Hacked E-mails to Attack Climate Science

Statement by Peter Frumhoff, the director of science and policy at the Union of Concerned Scientists and a lead author of the Fourth Assessment Report of the Intergovernmental Panel on Climate Change

WASHINGTON (November 23, 2009) — Some opponents of climate action are attacking climate science by misrepresenting illegally-obtained private e-mails from the Climate Research Unit at the University of East Anglia in Great Britain.

Below is a statement by Peter Frumhoff, the director of science and policy at the Union of Concerned Scientists and a lead author of the Fourth Assessment Report of the Intergovernmental Panel on Climate Change:

"Climate science contrarians are using the release of e-mails from several top scientists to attack climate science. Unfortunately for these conspiracy theorists, what the e-mails show are simply scientists at work, grappling with key issues, and displaying the full range of emotions and motivations characteristic of any urgent endeavor. Any suggestions that these e-mails will affect public and policymakers' understanding of climate science give far too much credence to blog chatter and boastful spin from groups opposed to addressing climate change.

"We should keep in mind that our understanding of climate science is based not on private correspondence, but on the rigorous accumulation, testing and synthesis of knowledge often represented in the dry and factual prose of peer-reviewed literature. The scientific community is united in calling on U.S. policymakers to recognize that emissions of heat-trapping gases must be dramatically reduced if we are to avoid the worst consequences of human-induced climate change.

"The oil and coal industries and the front groups they finance have long sought to sow doubt about climate science. Now that governments around the world are finally taking steps to address climate change, these industries and their surrogates are turning up the volume of their attacks.

"Policymakers and the general public should reject these attacks and not be distracted from building solutions to this urgent threat."

The Union of Concerned Scientists is the leading U.S. science-based nonprofit organization working for a healthy environment and a safer world. Founded in 1969, UCS is headquartered in Cambridge, Massachusetts, and also has offices in Berkeley, Chicago and Washington, D.C.

Union of Concerned Scientists

December 2, 2009 Subscribe for news

More Scientists Join Call to Reject Stolen E-Mail Claims

WASHINGTON (December 2, 2009) – James McCarthy, a former Intergovernmental Panel on Climate Change lead author, sent a letter (pdf) to Sen. Barbara Boxer (D-Calif.) today stressing that e-mails stolen from climate scientists have no bearing on our overall understanding of climate science.

Dr. McCarthy is board chair of both the American Association for the Advancement of Science and the Union of Concerned Scientists (UCS).

The letter reads in full: "The scientific process depends on open access to methodology, data, and a rigorous peer-review process. The robust exchange of ideas in the peer-reviewed literature regarding climate science is evidence of the high degree of integrity in this process. The body of evidence that human activity is prominent agent in global warming is overwhelming. The content of these a few personal emails has no impact what-so-ever on our overall understanding that human activity is driving dangerous levels of global warming."

Similarly, a Nature editorial published today states there is no reason for its editors to revisit papers submitted by scientists whose e-mails were stolen. The American Meteorological Society also recently stated the e-mails gave them no reason to revisit its conclusion that human activity is driving climate change.

According to UCS, the evidence for climate change is incontrovertible. While it is still not clear any wrongdoing actually took place, the group said, scientists in general should do more to address concerns about openness.

For more comments on the stolen e-mails, climate blogger Josh Nelson has assembled a compilation of reactions from scientists and other groups to the stolen e-mails.

The Union of Concerned Scientists is the leading U.S. science-based nonprofit organization working for a healthy environment and a safer world. Founded in 1969, UCS is headquartered in Cambridge, Massachusetts, and also has offices in Berkeley, Chicago and Washington, D.C.

Statements of the AMS

AMS Statements in Process

Statement Writing Committee Volunteering

Guidelines for Statements of the AMS (PDF)

Impact of CRU Hacking on the AMS Statement on Climate Change

AMS Headquarters has received several inquiries asking if the material made public following the hacking of e-mails and other files from the Climate Research Unit (CRU) at the University of East Anglia has any impact on the AMS Statement on Climate Change, which was approved by the AMS Council in 2007 and represents the official position of the Society.

The AMS Statement on Climate Change continues to represent the position of the AMS. It was developed following a rigorous procedure that included drafting and review by experts in the field, comments by the membership, and careful review by the AMS Council prior to approval as a statement of the Society. The statement is based on a robust body of research reported in the peer-reviewed literature. As with any scientific assessment, it is likely to become outdated as the body of scientific knowledge continues to grow, and the current statement is scheduled to expire in February 2012 if it is not replaced by a new statement prior to that.

The beauty of science is that it depends on independent verification and replication as part of the process of confirming research results. This process, which is tied intrinsically to the procedures leading to publication of research results in the peer-reviewed literature, allows the scientific community to confirm some results while rejecting others. It also, in a sense, lessens the impact of any one set of research results, especially as the body of research on any topic grows. The AMS plays an important role in the scientific process through its peer-reviewed publications, as well as through its many other activities, such as scientific conferences. The Society strives to maintain integrity in the editorial process for all its publications.

For climate change research, the body of research in the literature is very large and the dependence on any one set of research results to the comprehensive understanding of the climate system is very, very small. Even if some of the charges of improper behavior in this particular case turn out to be true — which is not yet clearly the case — the impact on the science of climate change would be very limited.

The AMS encourages ethical behavior in all aspects of science and has established a record of affirming the value of scientists presenting their research results "objectively, professionally, and without sensationalizing or politicizing the associated impacts" (see AMS Statement on the Freedom of Scientific Expression).

Keith L. Seitter, CCM
Executive Director

Updated: 11/25/2009
Headquarters: 45 Beacon Street Boston, MA 02108-3693
DC Office: 1120 G Street, NW, Suite 800 Washington DC, 20005-3826
amsinfo@ametsoc.org Phone: 617-227-2425 Fax: 617-742-8718

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Climatologists under pressure

Stolen e-mails have revealed no scientific conspiracy, but do highlight ways in which climate researchers could be better supported in the face of public scrutiny.

The e-mail archives stolen last month from the Climatic Research Unit at the University of East Anglia (UEA), UK, have been greeted by the climate-change-denialist fringe as a propaganda windfall (see page 551). To these denialists, the scientists' scathing remarks about certain controversial palaeoclimate reconstructions qualify as the proverbial 'smoking gun': proof that mainstream climate researchers have systematically conspired to suppress evidence contradicting their doctrine that humans are warming the globe.

This paranoid interpretation would be laughable were it not for the fact that obstructionist politicians in the US Senate will probably use it next year as an excuse to stiffen their opposition to the country's much needed climate bill. Nothing in the e-mails undermines the scientific case that global warming is real — or that human activities are almost certainly the cause. That case is supported by multiple, robust lines of evidence, including several that are completely independent of the climate reconstructions debated in the e-mails.

First, Earth's cryosphere is changing as one would expect in a warming climate. These changes include glacier retreat, thinning and areal reduction of Arctic sea ice, reductions in permafrost and accelerated loss of mass from the Greenland and Antarctic ice sheets. Second, the global sea level is rising. The rise is caused in part by water pouring in from melting glaciers and ice sheets, but also by thermal expansion as the oceans warm. Third, decades of biological data on blooming dates and the like suggest that spring is arriving earlier each year.

Denialists often maintain that these changes are just a symptom of natural climate variability. But when climate modellers test this assertion by running their simulations with greenhouse gases such as carbon dioxide held fixed, the results bear little resemblance to the observed warming. The strong implication is that increased greenhouse-gas emissions have played an important part in recent warming, meaning that curbing the world's voracious appetite for carbon is essential (see pages 568 and 570).

Mail trail

A fair reading of the e-mails reveals nothing to support the denialists' conspiracy theories. In one of the more controversial exchanges, UEA scientists sharply criticized the quality of two papers that question the uniqueness of recent global warming (S. McIntyre and R. McKitrick *Energy Environ.* **14**, 751–771; 2003 and W. Soon and S. Baliunas *Clim. Res.* **23**, 89–110; 2003) and vowed to keep at least the first paper out of the upcoming Fourth Assessment Report of the Intergovernmental Panel on Climate Change (IPCC). Whatever the e-mail authors may have said to one another in (supposed) privacy, however, what matters is how they acted. And the fact is that, in the end, neither they nor the IPCC suppressed anything: when the assessment report was published in 2007 it referenced and discussed both papers.

If there are benefits to the e-mail theft, one is to highlight yet again the harassment that denialists inflict on some climate-change researchers, often in the form of endless, time-consuming demands for information under the US and UK Freedom of Information Acts. Governments and institutions need to provide tangible assistance for researchers facing such a burden.

The e-mail theft also highlights how difficult it can be for climate researchers to follow the canons of scientific openness, which require them to make public the data on which they base their conclusions. This is best done via open online archives, such as the ones maintained by the IPCC (www.ipcc-data.org) and the US National Climatic Data Center (www.ncdc.noaa.gov/oa/ncdc.html).

Tricky business

But for much crucial information the reality is very different. Researchers are barred from publicly releasing meteorological data from many countries owing to contractual restrictions. Moreover, in countries such as Germany, France and the United Kingdom, the national meteorological services will provide data sets only when researchers specifically request them, and only after a significant delay. The lack of standard formats can also make it hard to compare and integrate data from different sources. Every aspect of this situation needs to change: if the current episode does not spur meteorological services to improve researchers' ease of access, governments should force them to do so.

The stolen e-mails have prompted queries about whether *Nature* will investigate some of the researchers' own papers. One e-mail talked of displaying the data using a 'trick' — slang for a clever (and legitimate) technique, but a word that denialists have used to accuse the researchers of fabricating their results. It is *Nature*'s policy to investigate such matters if there are substantive reasons for concern, but nothing we have seen so far in the e-mails qualifies.

> "The theft highlights the harassment that denialists inflict on some climate-change researchers."

The UEA responded too slowly to the eruption of coverage in the media, but deserves credit for now being publicly supportive of the integrity of its scientists while also holding an independent investigation of its researchers' compliance with Britain's freedom of information requirements (see http://go.nature.com/zRBXRP).

In the end, what the UEA e-mails really show is that scientists are human beings — and that unrelenting opposition to their work can goad them to the limits of tolerance, and tempt them to act in ways that undermine scientific values. Yet it is precisely in such circumstances that researchers should strive to act and communicate professionally, and make their data and methods available to others, lest they provide their worst critics with ammunition. After all, the pressures the UEA e-mailers experienced may be nothing compared with what will emerge as the United States debates a climate bill next year, and denialists use every means at their disposal to undermine trust in scientists and science. ■

Senator BOXER. So we are looking at these e-mails. We are talking to the leading scientists, and Senator, I will share with you as these letters come in. And I am sure you and I could discuss how to proceed on this.

In terms of the matter that is before us, I would ask to put my full statement in the record, Mr. Chairman.

Senator LAUTENBERG. Without objection.

[The prepared statement of Senator Boxer was not received at time of print.]

Senator BOXER. And I want to compliment you for taking on this issue of chemicals in our environment, chemicals that our children are exposed to every single day, pregnant women are exposed, all of our families are exposed.

And you know, I have often thought, Senator, that you have worked on this for so long. If I were to invite someone over to have a glass of water at my home, and I said, I am not sure that this water is safe. It could be poisonous, but why don't you drink it, and then we will talk about it later.

That is the way we deal with our laws today. It seems to me, you would say, well, do you mind testing it first? If it is safe, I will drink it.

So I think we need to reverse this whole system that we have in place, and I am happy to say my State is doing that. We want to make sure chemicals are safe before we say they can be used.

President Ford signed the Toxic Substances Control Act into law in 1976, a Republican President, and he believed very strongly because he said at that time that we want toxic chemicals restricted in their use or banned if they were hazardous. Somehow along the road here, we have lost our way. And I don't believe that TSCA because of court decisions and poor implementation sufficiently protects pregnant women, infants, children and others.

And Senator Lautenberg has really been my leader on this. He has had many bills in the past, and I am looking forward to his writing his new bill, which I am sure is one of the reasons he wanted to have this hearing.

So here is what we are saying. We are saying thank you to Lisa Jackson because EPA in September issued principles for TSCA reform that included common sense steps to help address the risks of dangerous toxic chemicals. And I am looking forward to hearing from you, Administrator Jackson, on how you want to proceed.

And again, my State took the lead on phthalates, and I am glad that we did something here; the Consumer Protection Safety and Improvement Act of 2008 banned those. There is a growing consensus that time is now to act on our chemical policies.

People come up to me in California, Senator Lautenberg, and they say, I decided to have myself tested to see what kind of chemicals I may be carrying around in my body, because they don't feel well, and they want to check it out. Some of the answers that come back are kind of shocking. And a lot of people have a lot of mercury inside them. They don't know it. They haven't been feeling well. They are told to eat fish, then they eat too much fish, and they feel sick.

We just need to get our arms around this. The American Chemistry Council has issued principles that support our effort to mod-

ernize our Nation's chemical management system, so this is good. I hope they are going to work with us in a good way, because we have a responsibility to our families to make sure that the products that are used by our families, by our children every day are safe.

And we can strengthen our Nation's toxic load. I just want to say, as the Chairman of this committee, that this issue is really at the top of my agenda. But I am so happy to have you chair this hearing because you have been my leader on this for so very long. And I view this hearing as a very important step forward in the process. And I thank you again.

Senator LAUTENBERG. Thank you very much.

Senator INHOFE. I have something to put in the record here, too, if I could, Mr. Chairman.

I also want to put a document in the record. This is, since we are talking about the credibility of scientists, this is the Congressional Research Service, and what they say about the CRU Director.

Senator LAUTENBERG. May I ask you this, Senator Inhofe, that we get to the other two Senators here.

Senator INHOFE. I ask unanimous consent to make this a part of the record.

Senator LAUTENBERG. Yes.

Senator INHOFE. OK.

Senator LAUTENBERG. Absolutely.

[The referenced information was not received at time of print.]

Senator LAUTENBERG. Senator Barrasso.

OPENING STATEMENT OF HON. JOHN BARRASSO, U.S. SENATOR FROM THE STATE OF WYOMING

Senator BARRASSO. Thank you very much, Mr. Chairman.

And I appreciate the witness, Mr. Chairman. I am going to send a letter today to Senator Whitehouse as Chairman of the Subcommittee on Oversight along the lines of my concerns about the recently disclosed e-mails regarding the Climate Research Unit at the University of East Anglia. I think the actions by scientists and others to suppress data that contradicts their conclusions are unacceptable, and this conduct should be investigated. So I am requesting that our Subcommittee on Oversight begin an immediate investigation into the matter.

Mr. Chairman, we do need to protect our children no matter what age from the effects of harmful chemicals. I doubt that anyone in this room would not support that goal. There is nothing we wouldn't provide for our children. Children need safe drinking water. They need life saving medications. They need safe food to eat.

One question we might ask ourselves in this hearing is the following: Have the chemistry industry and the EPA under the Toxic Substance Control Act helped improve the lives and health of our children? And to me, I think it has.

Chlorine is one of the best examples of a successful chemical which has saved lives. According to the World Health Organization, diseases associated with untreated water kill more than 25,000 people every day in developing countries, and the chlorination of drinking water has been credited by the U.S. Centers for Disease

Control and Prevention for helping to control infectious diseases and increase life expectancy.

Ninety-eight percent of our water supply systems now use chlorine-based disinfectants. Chemistry using chlorine plays a role in producing 93 percent of the top selling medications in the United States. Children benefit from these drugs, including the drugs that treat epilepsy, asthma and depression.

An antibiotic, Vancomycin, which is made with the chlorine chemical, has saved the lives of patients suffering from serious stubborn bacterial illnesses. Chemicals make prosthetic devices used as polyvinyl chloride or PVC, which is a common chlorine containing plastic used to construct prosthetic legs and arms for children whose lose limbs or have a birth defect.

So thanks to these devices, many of these children can lead normal lives and participate in most activities. PVC is used to make blood bags, IV fluid tubes, tubing to deliver needed care to young patients. Incubators for prematurely born infants are constructed of chlorine-based polycarbonate plastic.

The chemical industry also makes the plastics used to manufacture child car seats, safer playground equipment. There are still areas of concern, such as increased rates of childhood obesity and low birth weight babies, but we must be ever vigilant. We need a strong and a viable regulatory framework, the same framework under TSCA that has spurred advancements to help our children, not gotten in the way of them.

This framework can provide the next series of advancements that can make the future better for all Americans.

So every chemical at some exposure level is toxic. Fluoride used in toothpaste and purposely put in drinking water, if ingested in massive amounts, can cause harmful health effects. So as I say, the dose makes the poison.

We must not enact policies that hamstring new chemical development that would prevent those new advancements. My point is that we don't need to scare folks about risks that are not there or are very low probability. Otherwise, the next child vaccine, the next bike helmet, the next prosthetic leg will not be there when families need it the most.

And then finally, Mr. Chairman, today Senator Vitter and colleagues in the House and I are sending a letter to Administrator Jackson with regard to asking her to conduct a thorough and transparent investigation into the questions raised by the disclosure of e-mails from the Climatic Research Unit. We will go into that and release that letter today, and I ask that Ms. Jackson give serious consideration to this request.

Thank you, Mr. Chairman.

Senator LAUTENBERG. Thank you.

Senator Whitehouse.

OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator WHITEHOUSE. Thank you, Mr. Chairman.

I look forward with interest to the letter from the distinguished Senator from Wyoming. As far as I know so far, there is no role on the part of EPA alleged in the theft and dissemination of these

e-mails, so I am not sure that there is much jurisdiction there. But nonetheless, I look forward to the letter.

And I would not want to have whatever this little e-mail squabble is about distract from the relentlessly strong and unified scientific conclusion expressed most recently in a letter from the American Association for the Advancement of Science, the American Chemical Society, the American Geophysical Union, the American Institute of Biological Sciences, the American Meteorological Society, the American Society of Agronomy, the American Society of Plant Biologists, the American Statistical Association, the Association of Ecosystem Research Centers, the Botanical Society of America, the Crop Science Society of America, the Soil Science Society of America, and various other scientific organizations numbering I would guess about 15 or 16, which concludes this: Observations throughout the world make it clear that climate change is occurring, and rigorous scientific research demonstrates that the greenhouse gases emitted by human activities are the primary driver. These conclusions are based on multiple independent lines of evidence, and contrary assertions—I will cut into the quotation here by saying the contrary assertions such as we often hear around here—contrary assertions are inconsistent with an objective assessment of the vast body of peer reviewed science.

I think we need to bear that in mind as we take a look at what I think is a relatively minor concern and one that does not involve EPA.

And Senator Lautenberg, I appreciate very much your long leadership on this toxic issue and look forward to working with you and supporting you as you work toward this legislation.

Senator LAUTENBERG. Senator Bond.

OPENING STATEMENT OF HON. CHRISTOPHER S. BOND, U.S. SENATOR FROM THE STATE OF MISSOURI

Senator BOND. Thank you very much, Mr. Chairman.

And thank you, Ms. Jackson.

I am very much concerned not that these are incidental e-mails, but the allegedly unethical and potentially illegal behavior by leading climate scientists may undermine the credibility of EPA actions.

In the toxics program, the subject of today's hearing, many of EPA's decisions on whether to regulate a particular chemical are based upon science conducted by outside third parties. Indeed, EPA emphasizes over and over in its proposal to impose expensive new regulation on carbon dioxide emissions that EPA is acting based upon the findings of international scientists, including the Climatic Research Center in England, at the current center of the controversy.

And yet we now discover, through the e-mails of scientists themselves, that climate scientists in England, the United States and across the world may have manipulated data to support their climate change theories, manipulated peer reviewed journals, sought to blackmail and get fired dissenting scientists, avoid legal requirements to make public their data, and destroy data instead of releasing it to the public.

An American public you are asking to pay higher energy taxes and shed jobs in the middle of a recession deserves to know whether EPA is acting based upon some unethical and potentially illegal behavior by those so-called scientific organizations on which the Agency relies.

I thank the Chair and I—actually, I said "black-ball", "blackmail," I meant "black-ball."

But in any event, with that correction, I will stand by that statement and have more questions for you later.

Thank you, Mr. Chairman.

Senator LAUTENBERG. Thank you.

Senator Carper.

OPENING STATEMENT OF HON. THOMAS R. CARPER, U.S. SENATOR FROM THE STATE OF DELAWARE

Senator CARPER. Thanks, Mr. Chairman, and thank you and our Chair, Senator Boxer, for holding this hearing today. We want to thank our witnesses for joining us today, especially our lead-off witness, our Administrator.

The use of chemicals in this country either saves, or in many cases improves the quality of not just thousands of lives, but tens of thousands, hundreds of thousands of lives every day, even more than that.

Companies like DuPont, which has a major presence in our State, headquartered in our State, companies like BASF, which has a growing presence in our State, put science to work to create chemicals to provide safer, healthier lives for peoples from all walks of life, such as helping us refrigerate our foods or keep bacteria and disease from spreading.

However, as we all know, exposure to some chemicals or combination of chemicals can be toxic to human health and to our environment. High doses of exposure to certain kinds of chemicals can lead to, among other things, cancer, birth defects and death.

I was in Seaford, Delaware, earlier this week, where there is a small company—a large company, but a small plant. The large company is BASF, and the small facility employs about 30 people. The major ingredients for the products they make come from for the most part by rail, and they are dangerous if not properly handled. Put them all together, and they create products from these potentially dangerous substances, and they create non-toxic, very healthful compounds and products for the rest of us to use every, every single day.

Understanding the risks from certain chemicals, Congress attempted, I think it was in 1976, to give the EPA the tools necessary to protect public health from certain toxic chemicals in our country through the Toxic Substances Control Act. Unfortunately, we did not give EPA the right tools. And 33 years later, I am told the EPA has a list of over 80,000 chemicals being used in this country and can only regulate fewer than a dozen, maybe fewer than a half-dozen.

As a result of our failing national policy, what we are seeing happen is a patchwork quilt of chemical regulations are emerging from our States, from our local governments, and even Congress has seen legislation banning particular chemicals.

What we need, I believe, is a comprehensive national approach to chemical regulation. We need to find a way to keep using the chemicals that make our lives safer each day, and we need to restrict, to the extent that it makes sense, the use of chemicals that are dangerous to our health.

Again, I applaud Senator Lautenberg's efforts on this issue. I look forward to working with him and all the stakeholders as we move forward on TSCA reform.

Thank you.

Senator LAUTENBERG. Thank you very much.

Senator Klobuchar.

OPENING STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator KLOBUCHAR. Well, thank you very much. Thank you, Senator Lautenberg, for your leadership, and Chairwoman Boxer.

And thank you, Administrator Jackson. I also wanted to thank you for your pledge to move ahead on the E15 request. I know that it is not quite complete, and I urge you to do it as soon as possible, but we appreciate that there has been some practical and positive studies coming out on this topic. So thank you for that.

Today, we are here to talk about the Toxic Substances Control Act. Since I entered the Senate, I have made safe products and safe toys and the safety of the people of this country one of my No. 1 priorities, coming from my work as a prosecutor. The first thing that we have done, and Senator Boxer, a member of the Commerce Committee, as well as Senator Lautenberg, was involved in this, was passing the Consumer Product Safety Act, which the Wall Street Journal called the most sweeping consumer legislation in 16 years, to deal with toxic toys. We banned lead in children's products, and I was very proud of that work.

We have a bill right now that I have with Senator Crapo. We have 17 authors. It is a completely bipartisan bill, with people from all over the country to bring national standards in for formaldehyde in composite wood products that I wanted to call to your attention. It is supported by the timber industry all over this country because, in fact, the timber industry has agreed to follow voluntary standards that are similar to the standards they have in California, in the United States.

However, some of the foreign composite wood that is coming in does not abide by those standards. And so we are proud to have a bill that is supported by the timber industry and many consumer groups and health groups as well. As you know, formaldehyde in small concentrations is a normal part in our environment, but the problem is exposure to formaldehyde in high concentrations like we saw in the trailers in Katrina, especially over a prolonged period, can cause problems with nausea, asthma and other serious health problems.

So we are very excited about this bill and just wanted to call that to your attention in the toxic substance area.

As you know, the Toxic Substances Control Act was a landmark piece of legislation in the 1970s, but a lot has happened in the last 30 years. New chemicals have been developed. New science is avail-

able, and new regulatory regimes have been created in Europe and in other countries around the world.

I am interested today to hear from you, Administrator Jackson and other distinguished panelists, about how we can update this Toxic Substances Control Act and how we can do it in a way to protect our children and our families, how we can do it so that we can provide more information for consumers, and work with our businesses to produce safe and healthy products.

So thank you for being here today.

Senator LAUTENBERG. Thank you very much, Senator Klobuchar.

Senator Boxer.

Senator BOXER. Yes, if I could just put into the record the letter that Senator Whitehouse alluded to, from all these organizations, American Association for the Advancement of Science, the Geophysical Union, on climate change. Put that in the part of the record that deals with this back and forth with Senator Inhofe.

Senator LAUTENBERG. May I just take a moment here to look at what is in this letter that has meaning. This is written by a group of organizations, sent to us in October, or a month ago, and when these problems came about. And they say, "As you consider climate change legislation, we, as leaders of scientific organizations write to state the consensus scientific view," and I will read another sentence or two here. "Observations throughout the world make it clear that climate change is occurring, and rigorous scientific research demonstrates that greenhouse gases emitted by human activities are the primary driver." And they go on to explain how they arrive at that.

But these are a group of distinguished organizations, without any possible criticism of their importance or their research. We enter this into the record.

[The referenced letter follows:]

October 21, 2009

American Association for the Advancement of Science

American Chemical Society

American Geophysical Union

American Institute of Biological Sciences

American Meteorological Society

American Society of Agronomy

American Society of Plant Biologists

American Statistical Association

Association of Ecosystem Research Centers

Botanical Society of America

Crop Science Society of America

Ecological Society of America

Natural Science Collections Alliance

Organization of Biological Field Stations

Society for Industrial and Applied Mathematics

Society of Systematic Biologists

Soil Science Society of America

University Corporation for Atmospheric Research

Dear Senator:

As you consider climate change legislation, we, as leaders of scientific organizations, write to state the consensus scientific view.

Observations throughout the world make it clear that climate change is occurring, and rigorous scientific research demonstrates that the greenhouse gases emitted by human activities are the primary driver. These conclusions are based on multiple independent lines of evidence, and contrary assertions are inconsistent with an objective assessment of the vast body of peer-reviewed science. Moreover, there is strong evidence that ongoing climate change will have broad impacts on society, including the global economy and on the environment. For the United States, climate change impacts include sea level rise for coastal states, greater threats of extreme weather events, and increased risk of regional water scarcity, urban heat waves, western wildfires, and the disturbance of biological systems throughout the country. The severity of climate change impacts is expected to increase substantially in the coming decades.[1]

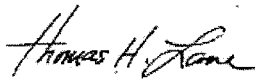
If we are to avoid the most severe impacts of climate change, emissions of greenhouse gases must be dramatically reduced. In addition, adaptation will be necessary to address those impacts that are already unavoidable. Adaptation efforts include improved infrastructure design, more sustainable management of water and other natural resources, modified agricultural practices, and improved emergency responses to storms, floods, fires and heat waves.

We in the scientific community offer our assistance to inform your deliberations as you seek to address the impacts of climate change.

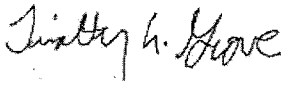
[1] The conclusions in this paragraph reflect the scientific consensus represented by, for example, the Intergovernmental Panel on Climate Change and U.S. Global Change Research Program. Many scientific societies have endorsed these findings in their own statements, including the American Association for the Advancement of Science, American Chemical Society, American Geophysical Union, American Meteorological Society, and American Statistical Association.

American Association for the Advancement of Science
1200 New York Avenue, NW, Washington, DC 20005 USA
Tel: 202 326 6600 Fax: 202 289 4950 www.aaas.org

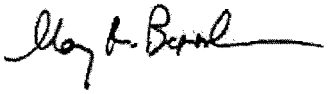
Alan I. Leshner
Executive Director
American Association for the
Advancement of Science



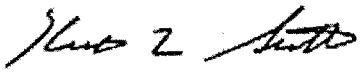
Thomas Lane
President
American Chemical Society



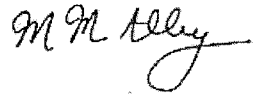
Timothy L. Grove
President
American Geophysical Union



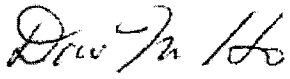
May R. Berenbaum
President
American Institute of Biological
Sciences



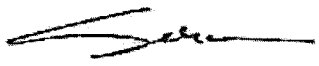
Keith Seitter
Executive Director
American Meteorological Society



Mark Alley
President
American Society of Agronomy

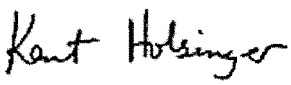


Tuan-hua David Ho
President
American Society of Plant Biologists



Sally C Morton
President
American Statistical Association

Lucinda Johnson
President
Association of Ecosystem Research
Centers



Kent E. Holsinger
President
Botanical Society of America

Kenneth Quesenberry
President
Crop Science Society of America

Mary Power
President
Ecological Society of America

William Y. Brown
President
Natural Science Collections Alliance

Brian D. Kloeppel
President
Organization of Biological Field Stations

Douglas N. Arnold
President
Society for Industrial and Applied Mathematics

John Huelsenbeck
President
Society of Systematic Biologists

Paul Bertsch
President
Soil Science Society of America

Richard A. Anthes
President
University Corporation for Atmospheric Research

Senator LAUTENBERG. With that, we welcome New Jersey's gift to the country. Notice I left out the couple of Senators, but Ms. Jackson, New Jersey's former DEP Administrator and now the EPA Administrator for the country. Ambassador Jackson did an outstanding job as head of New Jersey's Department of Environmental Protection. She has continued the work of protecting public health and the environment at EPA.

And I tell you as a long time observer of what is going on and what has gone on at EPA that Administrator Jackson has put her foot on the gas pedal, and things are happening. I hear through people that I—who I discuss that either are within the organization or have contact with it, and we thank you for your energy and your leadership.

And please, Ms. Jackson, make your remarks.

STATEMENT OF LISA JACKSON, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY

Ms. JACKSON. Thank you so much. It is good to be at EPA.

So thank you, Chairman Lautenberg, Chairman Boxer, Ranking Member Inhofe, and other members of the committee, for the opportunity to speak about how we can improve the framework for assessing and managing chemical risks.

The United States holds an enviable position in the global chemical industry. Since the mid-20th century, we have led the world in chemical production and innovation. That has brought new products to our markets and created new possibilities for manufacturing, for communications, and changed the ways we live our daily lives.

That leadership has also provided jobs for Americans across the country. As we move into the 21st century, everything from our cars to baby bottles to the cell phones we all carry in our pockets is constructed with plastics and chemical additives. Chemicals are ubiquitous in our economy and in our products as well as in our environment and in our bodies.

Naturally, that has raised concerns. A child born in America today will grow up potentially exposed to more chemicals than a child from any other generation in our history. At the same time, advances in toxicology and analytical chemistry are revealing new pathways of exposure. There are subtle and troubling effects of chemicals on hormone systems, human reproduction, intellectual development, and cognition.

The public is turning to government, to us, for assurance that chemicals have been assessed using the best available science and that unacceptable risks have been eliminated. There have been calls to action from parents, public health groups, and environmental advocates. Those calls have been seconded by State and local authorities. And the chemical industry, too, has stepped up to ask for the law to provide consistency and predictability and assure the American people that this multi-billion dollar industry is not a threat to their health and the health of their children.

So we are here today because under existing law we cannot give that assurance. Restoring confidence in our chemical management system is a top priority for me and a top environmental priority for the Obama administration. The American people expect that all

chemicals used in the American economy are safe. But Mr. Chairman, the 30-year-old law that gives EPA that authority is outdated. In the rapidly changing marketplace, it does not allow us to adequately protect human health and the environment as the American people expect, demand and deserve.

The Toxic Substances Control Act was signed into law in 1976 and was intended to provide protection of health and the environment against risks posed by chemicals in commerce. However, when TSCA was enacted it authorized manufacture and use without any evaluation or requirement for data on their toxicity of all chemicals that were produced for commercial purposes in 1976 or earlier years. As a result, there are troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce.

In the rare cases where EPA has adequate data on a chemical and wants to protect the public against well known, unreasonable risk to human health and the environment, there are often legal obstacles to quick and effective regulatory action. In 1989, after years of study, EPA issued a rule phasing out most uses of asbestos, a chemical whose health effects have been exhaustively studied and demonstrated to cause lung cancer, mesothelioma and asbestosis in humans. Yet, a Federal court overturned the rule because EPA failed to clear the many hurdles imposed under TSCA before existing chemical risk can be controlled.

Due to these legal and procedural hurdles in the law, EPA has only been able to require testing on around 200 chemicals produced and used in the United States, and it has only issued regulations to control five existing chemicals, 5 from a total universe of more than 80,000 existing chemicals listed on the TSCA inventory.

Though many of these chemicals likely cause little or no risk, the story is clear. We have only been able to effectively regulate a handful of chemicals, and we know very little about the rest. TSCA must be updated and strengthened.

Earlier this fall, I announced the Obama administration's legislative principles for how this law should be revised and modernized. Let me highlight our principles.

First, chemicals should be reviewed against safety standards that are based on science and reflect risk-based criteria protective of human health and the environment.

Second, the responsibility for providing adequate health and safety information should rest on industry.

Third, EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard with flexibility to take into account a range of considerations, including children's health, economic cost, social benefits, and equity concerns. EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities, particularly children.

Fourth, EPA should have clear authority to set priorities for conducting safety reviews.

Fifth, we must encourage innovation in green chemistry and support research, education, recognition and other strategies that will lead us down the road to safer and more sustainable chemicals and

processes. All of this must happen with transparency and concern for the public's right to know.

Finally, implementation of the law should be adequately and consistently funded in order to meet the goal of assuring the safety of chemicals and to maintain public confidence that EPA is meeting that goal.

I know that legislative reform may take time, so I have directed by Assistant Administrator for Toxic Substances, Steve Owens, to utilize our current authority under TSCA to the fullest extent possible, including section 6 authority to label, restrict or ban a chemical to ensure that we do everything we can now to protect the American people and the global environment from dangerous chemicals.

While fundamental reform is needed to fully protect against chemical risk, this is also a step forward. But let me be clear, there is no substitute for meaningful reform of the underlying law. The time has come to bring TSCA into the 21st century, and we need Congress to do it.

EPA looks forward to working with this committee on this very important issue.

Thank you so much.

[The prepared statement of Ms. Jackson follows:]

Testimony of Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
before the
Committee on Environment and Public Works
U.S. Senate

Chairman Lautenberg, Chairman Boxer, Ranking Member Inhofe and other members of the committee, thank you for the opportunity to speak about how we can improve our framework for assessing and managing chemical risks.

Understandably, the public is turning to government for assurance that chemicals that are ubiquitous in our economy, our environment and our bodies have been assessed using the best available science, and that unacceptable risks have been eliminated.

But, under existing law, we cannot give that assurance. Restoring confidence in our chemical management system is a top priority for me and a top environmental priority for the Obama Administration.

EPA is the agency tasked with ensuring that the chemicals used in the American economy are safe. But, Mr. Chairman, the current law that gives EPA that authority is outdated, and does not provide the tools to adequately protect human health and the environment as the American people expect, demand and deserve.

Chairman Lautenberg, I commend you for your long standing leadership on this issue and look forward to working with you, Chairman Boxer and other Members of this committee as you consider ways to improve the safety of chemicals.

The Toxic Substances Control Act (TSCA) was signed into law in 1976 and was intended to provide protection of health and the environment against risks posed by chemicals in

commerce. However, when TSCA was enacted, it authorized manufacture and use, without any evaluation, of all chemicals that were produced for commercial purposes in 1976 or earlier years. Thus, manufacturers of these "grandfathered" chemicals weren't required to develop and produce the data on toxicity and exposure that are needed to properly and fully assess potential risks. Further compounding this problem, the statute never provided adequate authority for EPA to reevaluate existing chemicals as new concerns arose or as new scientific information became available.

TSCA does provide some authority to EPA to mandate industry to conduct testing, but even in these cases it has taken years to obtain data and information. As a result, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce.

TSCA also doesn't place any legal obligation on producers to conduct testing on new chemicals being introduced into commerce. They are required only to supply existing data to EPA and are not required to provide all the data necessary to fully assess a chemical's risks.

In the rare cases where EPA has adequate data on a chemical, and wants to protect the public against well-known, unreasonable risks to human health and the environment, there are too many legal hurdles to take quick and effective regulatory action.

For example, in 1989, after years of study, EPA issued a rule phasing out most uses of asbestos – a chemical whose health effects had been exhaustively studied and demonstrated to cause lung cancer, mesothelioma and asbestosis in humans. Yet, a federal court overturned the rule because EPA failed to clear the many hurdles imposed under TSCA before existing chemical risks can be controlled.

Due to these legal and procedural hurdles in the law over the last 30 years, EPA has only been able to require testing on around 200 chemicals produced and used in the United States, and it has only issued regulations to control five existing chemicals determined to present an unreasonable risk under Section 6 of TSCA. Five from a total universe of more than 80,000 existing chemicals listed on the TSCA Inventory. Though many of these chemicals likely pose little or no risk, the story is clear---we've only been able to effectively regulate a handful of chemicals and we know very little about the rest.

TSCA must be updated and strengthened.

Earlier this fall, I announced the Obama Administration's legislative principles for how this law should be revised and modernized. Let me highlight the Obama Administration's principles:

First, chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment. Safety standards should be driven solely by scientific evidence of risks. EPA should have the clear authority to establish safety standards that reflect the best available science while recognizing the need to assess and manage risk in the face of uncertainty.

Second, the responsibility for providing adequate health and safety information should rest on industry. Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals under review are safe. If industry doesn't provide the information, EPA should have the necessary tools to quickly and efficiently require testing, or obtain other information from manufacturers that are relevant to determining the safety of chemicals, without the delays and obstacles currently in place, or excessive claims of confidential business information.

Third, EPA should have clear authority to take risk management actions when chemicals do

not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns. EPA and industry must include special consideration for exposures and effects on groups with higher vulnerabilities – particularly children. For example, children ingest chemicals at a higher ratio to their body weight than adults, and are more susceptible to long-term damage and developmental problems. Our new principles offer them much stronger protections.

Fourth, EPA should have clear authority to set priorities for conducting safety reviews. In all cases, EPA and chemical producers must act on priority chemicals in a timely manner, with firm deadlines to maintain accountability. This will not only assure prompt protection of health and the environment, but provide business with the certainly that it needs for planning and investment.

Fifth, we must encourage innovation in green chemistry, and support research, education, recognition, and other strategies that will lead us down the road to safer and more sustainable chemicals and processes. All of this must happen with transparency and concern for the public's right to know.

Finally, implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

I know that legislative reform may take time. Consequently, I have directed my Assistant Administrator of Prevention, Pesticides, and Toxic Substances, Steve Owens, to utilize our current authority under TSCA to the fullest extent possible, including Section 6 authority to label, restrict, or ban a chemical, to ensure that we do everything we can to protect the American people and the global environment from dangerous chemicals. While fundamental reform is needed to fully protect against chemical risks, this is a step forward.

Specifically, EPA is currently evaluating an initial set of chemicals based on available hazard, exposure, and use information, for potential action. We will complete and make public "action plans" for the chemicals which will outline the risks that the use of these chemicals may present and what steps we may take to address those concerns. Following this, we aim to complete and make publicly available a group of chemical action plans every four months. EPA intends to engage stakeholders and dialogue with other federal partners, as well as the public, in the discussion about prioritizing chemicals for future risk management action over the coming months through public notices and public meetings.

But let me be clear – this is no substitute for meaningful reform of the underlying law. The need for fundamental TSCA reform has been recognized by industry groups, including the American Chemistry Council, environmental groups, public health groups, several States and cities, and many other groups who have all called on Congress to Act. I too call on Congress to act on this issue and give EPA the tools to adequately protect human health and the environment.

The time has come to bring TSCA into the 21st Century. EPA looks forward to working with this committee on this very important issue.

Senator LAUTENBERG. Thank you very much, Ms. Jackson.

The one thing that struck me that deals so directly with the concerns about whether or not we are off on some useless pursuit when only 200 of some 80,000 chemicals have been tested, despite the fact that the numbers are very small in terms of those that have been banned, who knows how much damage any one of those could be.

So we know that exposure to toxic chemicals has been linked to a wide range of diseases, lower IQs, and birth defects. And yet opponents of government regulation often point to economic concerns.

Well, wouldn't restricting the most dangerous chemicals actually help reduce health care costs and benefit the economy? I know that in my own family, my father, who worked in a mill—and he was a hard worker, very energetic—got sick from chemicals in the company and in 13 months died of cancer at age 43. So we know that exposure to these harmful things can be extremely serious, and we shouldn't miss any opportunities to try to find them out and ban them.

So what do you say, Ms. Jackson?

Ms. JACKSON. Yes, Mr. Chairman. I don't think that there is dispute that chemicals can have impacts on our health. I don't think anybody has any quibble with that statement. It is not inflammatory. It is just a simple fact, which means that we must manage that risk. We must manage against it.

And certainly, if you take that as a fact, and you say chemicals impact our health, then that means that they have the potential to have good and bad impacts on our health if they are well managed or if they are not managed at all.

Senator LAUTENBERG. How might a more transparent, effective law for regulating toxic chemicals benefit the companies that buy, use these large amounts of chemicals in their product?

Ms. JACKSON. Well, the secondary users, the people who don't manufacture or import, but end up with these materials in their product, their businesses can be the first ones affected, and in many cases they are affected even though those industries don't have adequate information to make a decision themselves on whether or not to take on a chemical in their manufacturing. So it can help them, in my opinion.

Transparency and information about risk, along with scientific data to assess and manage that risk, can help protect the people who often the public turn to when something goes wrong with a product.

Senator LAUTENBERG. Yes, and certainly the economic benefit of finding these things early that might be damaging is quite obvious. It is going to be a positive influence.

EPA has overseen the regulation of pesticides for years and has succeeded in taking some of the most dangerous pesticides off the market. Now, my TSCA reform bill will require testing of chemicals using a standard similar to the one that applies to pesticides. Has EPA's regulation of toxic pesticides hurt that industry? Or has the industry been able to grow, while allowing EPA to restrict the most dangerous uses?

Ms. JACKSON. Yes, contrary to hurting the pesticide industry, I believe regulation is key to the industry's ability to innovate and

then produce and market their products. They need the Government oversight to be able to say to people who eventually use their products, our products are tested and evaluated to be safe.

So my belief—and I use this example all the time—is there are times when regulation and oversight, which is what Government can do, actually are needed. And I think that is why—I don't want to speak for them—you see a group like ACC saying that it is time for us to take this on.

Senator LAUTENBERG. Yes, and included in that, of course, is the protection of the organizations that produce these products from lawsuits, from damaging publicity, et cetera, and that terrible record that would be a blight to any company.

I thank you very much, Ms. Jackson.

Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

And again, it is good to see you, Administrator Jackson. I am glad both of our families had a great Thanksgiving.

As I indicated in my opening statement, I am very concerned about the e-mails disclosed between some of the world's leading climate scientists. Administrator Jackson, these are not the run of the mill scientists. In fact, according to a memo from the Congressional Research Service sent to my staff this morning, Phil Jones, who announced he was stepping down yesterday as a part of the investigation, was the lead author of the IPCC Science Working Group. And according to the Congressional Research Service, the Climate Research Unit, CRU, that we have been referring to from the University of East Anglia, where Phil Jones was director, is the world renowned Climate Research Center. I think everyone has stipulated to that.

I am sure some of these e-mails were troubling to you.

And by the way, I appreciate, Madam Chairman, your willingness to get in and look at these e-mails and make a determination as to what you think the proper action would be.

But as I look at these e-mails, one of them, I am quoting from it right now. Now, the two Ms are referring to McKitrick and McIntyre. We are all familiar with them. They are scientists from Canada. "The two Ms have been after the CRU station data for years. If they ever hear there is a Freedom of Information Act in the U.K., I think I will delete the file rather than send it to anyone." This is Phil Jones. That was his e-mail. "So please don't pass this along to others." In other words, disclose, hide this cover up—"cover up" is the word. "Please don't pass this along to others without checking with me first. This sort of dirty laundry one doesn't want to fall into the hands of those who might potentially try to distort things."

Now, that is Michael Mann. We all remember Michael Mann from the very beginning of this. In fact, I remember back during the early Kyoto days, it was his hockey stick that started this whole thing, which has been pretty much refuted in terms of the science many, many years ago.

Now, I could go on and on, but let me get to the question. Just this morning in the House climate hearing, President Obama's scientific adviser, Dr. John Holdren, said he did not think that Congress needed to investigate this. His reason, he said, is the scientific process would work itself out.

Now, that is interesting to me because if these e-mails show anything, they show scientists obstructing the scientific process. They show scientists refusing to turn over their data so other scientists could reproduce it. That is an essential step in the scientific process. These scientists didn't want the scientific process to work.

So my concern is—well, first of all, I would just ask you as to whether or not you agree with Dr. Holdren in his response to these questions. Is an investigation not warranted because the scientific process will work itself out? That was his position.

Ms. JACKSON. Dr. Holdren has probably spent more time thinking about that aspect of this issue than I have. From my perspective, I have been focused on the science that undergirds EPA's regulatory actions to date, and you are very familiar with them, Senator. And my ear is to the ground for any information that comes to light at any time, whether it is a result of this e-mail issue or otherwise, that causes me to believe that the overwhelming consensus has changed.

And while I would absolutely agree that these e-mails show a lack of interpersonal skills, as I would say to my kids. Be careful who you write, and maybe more. I have not heard anything that causes me to believe that that overwhelming consensus that climate change is happening and that manmade emissions are contributing to it has changed.

Senator INHOFE. Yes, even though these scientists were the lead scientists, everyone agrees that the CRU of East Anglia was certainly at the very top of this, and the IPCC relied upon these lead scientists. It is interesting, the matter that is submitted for the record is dated the 21st of October, before any of this happened. And I would strongly suspect that these organizations relied on the science of the IPCC. That is what is called into question.

Now, the question I have, the reason I am bringing this up with you is, we are in the process of pursuing an endangerment finding right now. And the endangerment finding, according to almost everyone, including you, is based on the information given by the IPCC. So I would say that if we agree with Dr. Holdren that the science will work itself out, that we should suspend any further activity in the endangerment finding until the science is worked out.

Would you agree with that?

Ms. JACKSON. Senator, I believe that what we should be looking for are any changes in the consensus opinion of scientists around the world about climate change, about man's contribution to it. And when it comes to the endangerment finding, you know quite well that that goes to whether greenhouse gases endanger public health and welfare.

And so it is EPA's obligation, it is my job to keep ear to the ground on that issue as far as how the science impacts our regulatory decision, and I am committed to doing that.

Senator INHOFE. Well, let me ask you one other question. I know my time is running out here. But many of the individuals on the other side of this issue, on the alarmist side, like George Monbiot with The Guardian, he said, and this is a quote, I think it was just yesterday. He said, "Pretending that this isn't a real crisis isn't going to make it go away." And he goes on to talk about these things, they have got to be looked at.

And I would say that, yes, I know what the endangerment finding is, but I also strongly suspect, and I have some documentation to show, that it is reliant to a great degree on findings by the IPCC. And here we have the two lead scientists in the IPCC that everyone else is depending on under investigation now and relieved from their positions

For that reason, I would encourage you to delay until we do have findings any further processes that could be made or are in the process of being made in the Environmental Protection Agency that would depend on the authenticity of the science that comes from the IPCC.

Senator LAUTENBERG. Thank you.

Senator INHOFE. Do you agree?

[Laughter.]

Ms. JACKSON. I certainly hear your encouragement, and I appreciate your position.

Senator LAUTENBERG. Thank you.

Senator Whitehouse.

Senator BOXER. What about me?

Senator LAUTENBERG. Oh, I am sorry.

[Laughter.]

Senator LAUTENBERG. I am so unaccustomed to being after Senator Boxer.

Senator BOXER. Right, well, you mean, you didn't think I wanted to respond to my esteemed Ranking Member?

Senator LAUTENBERG. Well, I try to keep a sparring partner.

Senator BOXER. You are trying to keep us apart. You are trying to keep us apart.

[Laughter.]

Senator BOXER. You're doing a good job.

[Laughter.]

Senator BOXER. That is right. That is exactly right.

Well, let me say this, first of all, I thought this hearing was going to be about TSCA, and you have my word that TSCA is very high up on my agenda and also the other members of this committee, I think on both sides, because here is where we are going. Right now, we are learning about these toxic chemicals, and there is outrage in the public, Administrator Jackson, because we are not doing anything. Our hands are tied. You yourself said you were so upset about this.

And of 80,000 chemicals, what did you say? You are regulating 2, did you say, of those?

Ms. JACKSON. Five.

Senator BOXER. Banned 5.

Ms. JACKSON. We have taken action on 5.

Senator BOXER. Now, that is why you see in the Senate, we are moving against lead in toys. And several of us, as Senator Klobuchar reiterated, were involved in that. We are moving against phthalates. We are going to move against BPA. We are going to move against all these things one at a time.

And it makes no sense because we need to have a process that we all believe in, that we all know is working.

Now, I just want to say as Chairman of this committee and representing the majority, we don't want you to delay on this

endangerment finding. We know on climate change, the Bush administration did all the legwork. We had a whistleblower, Jason Burnett, who worked for the Bush administration, tell us, talk about e-mails. There was an e-mail that was sent from the EPA that the White House under George W. Bush never opened because they said if they opened it, they would have to act.

Now, finally, you sent an e-mail to the Obama administration and my understanding is they opened it, and we should have this endangerment finding.

Now, here is the thing. If you think, as you just said, that the science is real, don't delay because lives are at stake. Don't delay. Now, this whole flap reminds me a lot of the flap over tobacco. There were scientists who said smoking causes lung cancer, and there were outliers who said no. A lot of them were paid by the tobacco companies.

And let me just say this. I am sure there were many, many e-mails, because I remember that there were letters and e-mails on this. I only care about one thing, seriously. If anyone broke the law by hacking in, put them in jail. If anyone broke the law by defaming somebody, and you could prove defamation, do what you have to do.

All I care about is one thing, and that is the real science and whether or not people are in danger. And I urge you to move forward because, again, we have a letter from the head of the American Association for the Advancement of Science saying e-mails aside, the fact is the evidence is overwhelming. And then we have other scientists stepping up to the plate.

Now, people write ridiculous e-mails when they are in the middle of a fight. And to me what is important is, e-mails aside, is there global warming? Is it being affected by human activity? And there is nothing out there, nothing, that says otherwise.

To delay an endangerment finding would be a very dangerous thing to do. That would endanger the public. That would endanger the public. We need to move forward.

The Bush administration hung up that e-mail and never got to it because they knew. And to their credit, their people, their scientists, their lawyers, they knew that this was a danger. And now, finally, we are on the verge of getting that endangerment finding.

So, I always, whenever my Ranking Member asks me to hold a hearing to look at an issue, I always say I will absolutely work with him to do that. But as I look at this, you have to understand we are dealing with the breaking of the law here. We are dealing with probably a criminal act of hacking into a computer. And to me, what is important here is what is the science, regardless of what one scientist thinks of another, and he writes the nastiest e-mail, I think it is a foolish waste of his time. Ridiculous.

But what impacts my constituents, who live in a State that borders on the coast, who live in a State that is dependent on agriculture, on the forests, on a water system that depends on snowfall? What I want to know is the truth about global warming, not what one scientist is snipping or at another one. It is silly. It is ridiculous.

And I am happy to look at it. We have those e-mails, even though they were gotten illegally, they have been put up so we are

going through them. It seems to me they must have been hacking this for years, and just before Copenhagen, they came out with these. That is what is seems to be because these e-mails, they go back—how many are there? Over 1,000 e-mails? So I don't know how long, 1,000 e-mails. And now all of a sudden they came out with these e-mails.

So yes, we will look at Senator Inhofe's request, and I want you to know, Senator, we have written to the leading scientists in America to ask them their opinion. Have they changed their point of view? And so far, we are getting the letters in. They have not. And to me, that is all that matters. This is the Environment Committee, not the committee where we look at who broke laws and what it means, and if someone defames somebody. So that is where we are.

On TSCA, I reiterate my commitment. I apologize that this hearing got turned around on us. It is wrong, but I cannot possibly in good faith not lay out what I think is the truth here because there are some over the top speeches going on that I think are crazy, not the people giving them, but the speeches make no sense to me. They are talking about Climategate. I think it is e-mail theft-gate.

So let's just get to where we want to get to, which is make sure the science is real, and we are going to do your TSCA bill, and we are looking forward to seeing it introduced.

Senator LAUTENBERG. Thank you.

Senator INHOFE. Mr. Chairman.

Senator LAUTENBERG. I wonder whether there is an intention, Senator Boxer, to discredit science support for these things by introducing the other subject, and it is not appropriate for this committee hearing.

Senator INHOFE. Well, let me answer that question, Mr. Chairman. And I want to put something in the record also that I think is appropriate.

The reason it is important for me to ask the question is because in response to our questions, Madam Administrator, you stated during the proposed endangerment findings, quote, now these are your words, "The Agency relied in large part on the assessment reports developed by the Intergovernmental Panel on Climate Change."

Now, I know that is true, and here we have the two top scientists in IPCC under investigation, and that is why I think it is perfectly legitimate for us to make the request that you suspend anything further on this.

I ask that this be——

Senator LAUTENBERG. I ask that you try and move things along here.

Senator INHOFE. OK.

Senator LAUTENBERG. Right, I mean, just because they may have done something that is inappropriate, and I don't know there was, I think in all fairness, Senator Inhofe, we have got to move with the subject here at hand, and then take whatever action you would like at a later time.

Senator INHOFE. Sure. Thank you.

Senator LAUTENBERG. Senator Whitehouse, will you please speak up?

Senator WHITEHOUSE. Thank you, Chairman Lautenberg.

Senator LAUTENBERG. Oh, wait. I am sorry. It goes to Senator Bond. Forgive me.

Senator BOND. Thank you very much, Senator. You are an excellent subcommittee Chair. And I appreciate so much the opportunity to pursue what I think is a very real question about the science that we must address, and it is critically important.

Madam Administrator, let me read you some e-mails, and I would ask your comments.

From Phil Jones, the head of U.K. Climate Research Unit, who e-mailed on July 8th, 2005, to Mike Mann: "I can't see either of these papers being in the next IPCC report. Kevin and I will keep them out somehow, even if we have to redefine what the peer-review literature is! Cheers, Phil."

Now, that is the Intergovernmental Panel on Climate Change, the fellow scientist is Kevin.

Madam Administrator, would you condone EPA scientists trying to block publication of dissenting views?

Ms. JACKSON. I have committed to transparency at EPA. I believe that scientific rigor comes from transparency and openness.

Senator BOND. I agree, and I appreciate that.

Next, from Tom Wigley, a scientist at the U.S. University Corporation for Atmospheric Research, e-mailed on April 24, 2003: "One approach is to direct to the publishers. Mike's idea to get editorial board members to resign probably will not work. Must get rid of Hans von Storch." He was the journal editor.

Would you condone EPA scientists trying to blackball or get rid of holders of dissenting opinions?

Ms. JACKSON. I would hope that EPA scientists would spend their time working on science and on working in a more collegial matter than may be inferred from the e-mails that you are reading.

Senator BOND. Thank you.

From Michael Mann of the Pennsylvania State University, e-mailed on February 9, 2006: "I wanted you guys to know that you are free to use R.C. in any way you think would be helpful," and I would note that that is the Real Climate Internet blog, parenthetically, "use R.C. in any way you think would be helpful. We can hold comments up in the queue and contact you about whether or not you think they should be screened through or not, and if so, any comments you would like us to include."

Does that sound to you like they are manipulating the comment record to block comments? I assume that would be intolerable at the EPA, would it not?

Ms. JACKSON. We have standards that have to go toward regulation. It is hard for me to tell from the context there whether he is talking about a personal blog or some other document. It is very difficult for me to know what he is talking about there.

Senator BOND. We will make these available to you and I am sure you will be——

Ms. JACKSON. Yes, I have seen the ones online for sure.

Senator BOND. A fourth question is from Kevin Trenberth of the U.S. National Center for Atmospheric Research on October 12, 2009: "The fact is that we can't account for the lack of warming at the moment, and it is a travesty that we can't."

Now, Madam Administrator, would you be concerned if EPA scientists were saying one thing publicly, but behind the scenes were voicing fundamental doubts over the ability to square the actual scientific facts with their assertions?

Ms. JACKSON. I smile, Senator, because EPA scientists are an outspoken bunch, but they tend to make their opinions known, and they have, because they are Government employees, an obligation to public trust to be honest and open and forthright.

Senator BOND. I would have thought that these people from the IPCC would have had some obligations as well, but it is appearing that they don't.

Finally, all these e-mails indicate unethical and potentially illegal behavior by climate scientists around the world, the ones who are the strongest supporters and the real authorities for the assertions and the extrapolations on climate change.

The Union of Concerned Scientists said yesterday that if true, these actions are "a serious breach of scientific ethics and public trust," from the BNA 2009, December 2.

Would you agree that these actions, if they represent—if true, do represent a serious breach of scientific ethics and public trust?

Ms. JACKSON. Senator, I hesitate to pass judgment on something that I have not reviewed, and I am not an attorney by training. What I do know is that from the standpoint of the idea of scientific openness, collegiality, transparency, sharing of information, certainly there are at least questions and discussion, it sounds like, will continue on those.

Senator BOND. OK. Well, we appreciate your looking at it because if this pattern of egregious misbehavior of the scientists does raise real and significant questions about the validity of the views they have presented, then I think we have to take a much deeper look.

I thank you, and I thank the Chair for your indulgence.

Senator LAUTENBERG. Thank you very much.

I was asked by the Chairman of the committee to enter a copy of an interview that was done with Dr. Pachauri, who chairs the Intergovernmental Panel on Climate Change. He stood by his panel's 2007 findings, called the fourth assessment report of the panel. "This private communication in no way," referring to the hacking, "in no way damages the credibility of the findings," he told Reuters in an e-mail exchange.

[The referenced information was not received at time of print.]

Senator LAUTENBERG. And we have verification by so many science organizations that asked to be recognized that I think that to go further here is an interrogatory that we ought not to carry on with.

Now, Senator Whitehouse, please.

Senator WHITEHOUSE. Thank you, Chairman.

To sort of I hope put somewhat to rest this question, does anything that you are aware of from this e-mail kerfuffle raise any problem with the ethics or the credibility or the validity of findings made by the American Association for the Advancement of Science or the American Chemical Society or the American Geophysical Union or the American Institute of Biological Sciences or the American Meteorological Society, the American Society of Agronomy, the

American Society of Plant Biologists, the American Statistical Association, the Association of Ecosystem Research Centers, the Botanical Society of America, the Crop Science Society of America, the Ecological Society of America, the Natural Science Collections Alliance, the Organization of Biological Field Stations, the Society for Industrial and Applied Mathematics, the Society of Systematic Biologists, the Soil Science Society of America, or the University Corporation for Atmospheric Research?

Ms. JACKSON. I am not aware of anything, Senator, that goes to their credibility or the longstanding, and it sounds like continuing consensus, overwhelming number of scientists who continue in their consensus regarding climate science.

Senator WHITEHOUSE. In terms of, turning to the TSCA issues, it is frequently the tactic of the polluting industries and of those who serve their ends to engage in the spread of doubt about the science—not to challenge it directly, but just to encourage the spread of doubt, and also to seek delay so that dangerous products can be marketed for a longer period of time before regulators can catch up with them and protect the public.

There is a bit of a conflict between those two in that if you wait for absolute scientific certainty, if there even is such a thing, since science is a process of questioning, you probably are defeated on the delay front. And if you try to make reasonable accommodation for delay, that raises the issue of scientific doubt, which improperly understood, can be used as an unfair and improper rhetorical tool.

In that context and in terms of these—what is it? There are 80,000 chemicals out there?

Ms. JACKSON. Eighty-thousand.

Senator WHITEHOUSE. Eighty-thousand. So it is 79,995 that have not received regulatory action. That is a lot of work ahead of you. How do you balance the need to avoid delay where public health is concerned, the incredible workload of trying to plow through 79,995 TSCA chemicals that have not had a determination yet, and at the same time reach adequate science so that you don't fall too vulnerable to the doubt challenge that is raised so often on behalf of polluters?

Ms. JACKSON. That balance is one that is not unfamiliar to EPA or to me in my career. Allow me a moment to just simply point out that in the space between that doubt and that delay stands the American consumer, the American people who simply want some assurance that Government is looking out for their interests in that space.

So they want a high quality of living. Of course, they want to be able to buy things for their family and give them what they want or need and sometimes want. But we, as the Government, and I believe EPA in particular have a role to play and needs some help from Congress to play it.

To answer your question more directly, prioritization will be key. Efficiency in the rulemaking process will be key. EPA's success will be tied initially to a strong piece of legislation that gives us clear standards and clear direction but also gives us some amount of flexibility to make decisions.

And our obligation, if we are able to get that obligation, will be to do it in an efficient and timely manner. Because if you don't

make a decision, as I have said often during my career, that answer is really no, because that delay, that time period is time when a concern grows and builds and may become even ubiquitous in the marketplace such that by the time you know you have a problem, it is too late.

Senator WHITEHOUSE. Thank you, Administrator Jackson.

Senator LAUTENBERG. Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much.

Just one quick question at the beginning here. As we move forward with energy legislation, I have always said one way to build support for it is by making sure that people have skin in the game across the country, that they see part of the action here.

And certainly biofuels are a piece of this. I have talked—I know Secretary Chu is a fan of moving ahead to the next level of research with biofuels. And I just wanted to quickly follow up. I sent a letter to you yesterday urging you to move forward with the E15 waiver request. And if you could just reiterate what you announced yesterday and what the studies are showing.

Ms. JACKSON. Thanks, Senator. Thanks for your letter, and thanks for the conversations we have had along the way during the process on the waiver, and of course, the outstanding renewable fuels to regulation that is out there as well.

What we did yesterday was announce that December 1st was actually the deadline for a decision on the waiver. And we did not want that date to pass without saying anything because we were afraid that the industry would construe that to be more negative than the current amount of data that we have are.

We have testing from two vehicles. We are waiting for testing from about a dozen and a half more. Two vehicles doesn't seem enough to make a determination on the waiver, but that data shows that E15 is appropriate for newer vehicles, 2001 model year and newer.

So what we said was that—we stated where we are with data. We said we need more time. We acknowledged that the Department of Energy—you mentioned Secretary Chu—they are doing the testing, with our money, in part, and that that testing would come in in May.

And in the meantime, because EPA foresees a need to be forward-looking about biofuels in general, as we see our country continuing to move in that direction, that we would look at a labeling work group because if you are talking about a fuel that can be used in some applications and potentially not others, if the data continued to show what they are showing now, we are going to need to make sure that consumers understand that, have appropriate labeling so they can't accidentally or inadvertently make a decision and not realize what is going on with fuels.

Senator KLOBUCHAR. Very good. Thank you very much, Administrator Jackson.

I wanted to follow up also on, as we get to the chemicals here, the formaldehyde issue. I notice that Mr. Stephenson, who will be testifying on the next panel, in his written testimony noted that there has been some push to adopt the California formaldehyde regulation. EPA recently issued an advance notice of proposed rule-

making suggesting some regulatory options to limit the exposure to formaldehyde.

However, because of the legal hurdles the Agency would face in regulating formaldehyde under TSCA, some stakeholders have recommended that EPA pursue legislation instead. As you know, we are working on, for at least this piece of it, for the wood products that we are dealing with here, that we have introduced some legislation.

I just wondered if you could talk about the importance of regulating formaldehyde and the dangers that it poses at high concentration levels.

Ms. JACKSON. Well, Senator, EPA is pursuing regulatory action for formaldehyde. Formaldehyde is, as we sit here, a known eye, nose, throat irritant, currently classified as a carcinogen. The difference is in time, I think. And right now, the risk information and science that EPA is doing is going to take longer than this year. In fact, I believe the risk assessment will be for cancer and noncancer effects, and the target completion date is fall of next year.

So we have a bit of a disconnect in terms of timing from a regulatory perspective.

Senator KLOBUCHAR. All right. Thank you. And that is one of the reasons with the composite wood products, at least, so we are pursuing this.

Just in general, with the TSCA legislation, can you talk about new scientific methods and discoveries that are necessary to determine risks that are posed by chemicals, reasons that we would want to be updating this legislation?

Ms. JACKSON. Well, certainly, our analytical capability has improved over the years so that we can see lower and lower doses, if you will, amounts of chemicals that might be present, biomonitoring indicators. Things like cord blood, we heard about earlier, are available to help us understand what is showing up and where so that we can prioritize what we work on and also use that information on the dose side.

And then on the response side, we are learning more about end points that we never considered along the way. And the industry is as well. I mean, I think it is very important to note that the vast majority of this data comes from industry. One of the great failings right now with the current statute is on the information exchange piece. EPA doesn't have the ability to quickly get the data that industry may already have.

And although we have a standard of care to ensure we don't do anything to hamper competitiveness with real confidential information, a lot of information is currently marked confidential that EPA either can't or doesn't challenge in terms of being able to get information out to other scientists who might be able to also evaluate that material as well.

So a lot has changed, a lot for the good, but I think this statute is one that where there is tremendous opportunity to modernize it in a way that will helpful to the public sector, to the private sector, but most importantly to Americans.

Senator KLOBUCHAR. Thank you very much.

Ms. JACKSON. Thank you.

Senator LAUTENBERG. Senator Merkley. Senator Udall.

Senator UDALL. That is OK, Senator Lautenberg. We are both from the West anyway.

[Laughter.]

Senator LAUTENBERG. That is the conclusion I came to.

OPENING STATEMENT OF HON. TOM UDALL, U.S. SENATOR FROM THE STATE OF NEW MEXICO

Senator UDALL. Senator Lautenberg, thank you for your leadership on these very important issues that are before us and in particular your leadership with regard to toxic substances.

Administrator Jackson, I believe that your testimony laid out very clearly the current problems with TSCA, and I would like to add my voice to those here today calling for reform.

It is really sad to me that where we are today—you look back in history, and 50 years ago Rachel Carson wrote a book, Silent Spring, and she talked about how toxic substances were impacting wildlife. And the country became outraged, and there was this huge uproar, and we took action to do something about toxic substances in that context.

And as you have said the public expects— and I think the public believes today—the Government is out there filling the space, trying to do and take very important actions on toxic substances. And in fact, as we have heard today through your testimony and what the committee has put together, there are big holes, and there are big voids in terms of our ability to move forward.

And what I would like to ask you about revolves around what the European Union is doing, because there are countries that are very active in trying to protect their citizens, and the European Union recently finalized its new chemical regulatory program called—the acronym is REACH, but it is registration, evaluation, authorization and restriction of chemical substances.

It is my understanding that most chemical producers in the U.S. are producing for the global market or are producing chemicals that are also produced in Europe. As a result, despite the weaknesses of our laws, will EPA and State regulators be getting a wealth of information on these chemicals due to the E.U. program? And will EPA be able to take advantage of this new information submitted to the E.U. program to take action under our existing laws?

Ms. JACKSON. Yes, Senator. I think the opportunity here is to avoid duplication as much as possible. And you are absolutely right that the E.U. and some States have started to move down this pathway in varying degrees, and certainly our neighbors in Canada as well.

Now, the E.U. process is probably the most data intensive of them all. And it would be foolish of us to not use data that is coming in from other sources and be informed by it. We have a good relationship. We intend to continue to work that, so hopefully we can have that result.

Senator UDALL. Now, you are talking about you have banned five substances. Is that correct? How many has the European Union banned that you are aware of?

Ms. JACKSON. I actually don't know the answer to that, Senator.

Senator UDALL. OK, if you could submit that, that would be very helpful to me. I would like to look at what we have banned, what they have banned, what other State regulators have banned, and how far behind are we at the national level in looking at chemicals that are out there that have already been banned when there has been an intensive scientific process.

As many of the witnesses said before me and many of the Senators, this idea we want this to be based on science, but we also, after it is based on science, want to take action based on science to protect the public.

Now, let me ask you an additional question here, because you, despite the limitations of TSCA here in the United States, you are taking a number of actions on certain known dangerous chemical compounds such as BPA and phthalates, which led to the public—is that the way to say it?—which led to the public scare about toxic chemicals in baby toys and water bottles.

How did EPA determine the priorities for acting on potentially toxic chemicals given that our laws do not provide EPA with adequate information? EPA has stated its intent to formally engage stakeholders and the public in a discussion of prioritizing chemicals for future risk management. Recently, there has been a great deal of concern about endocrine disrupters and other chemicals that can have a very large developmental impact at very low doses. These impacts are not fully understood by the public.

Which types of chemicals will EPA be looking at when it sets priorities for action next year?

Ms. JACKSON. As you mentioned, we are on 4 out of 80,000, and so as you can imagine, that was a relatively easy decision. We tried to stick to ones that were almost, I hate to use the word no brainers, because people can argue over things, but phthalates——

Senator UDALL. Where the science was very strong.

Ms. JACKSON. Yes, where we know that if we can, the American people expect us to take action if we can. And I should point out also that not every action is a ban. In fact, oftentimes it is not a ban at all. It may be other risk management. It could be labeling. It could be information. It could be an order to get more information.

But to answer your second question, for the next chemicals in the action orientation, we will initiate a stakeholder dialogue to try to continue to expand that list. But I would simply say that what that list is about are not final actions. To the extent that a chemical gets on that list and EPA determines that some action is needed, that entire process is subject to public comment as well.

And so it is once again that idea between delay and trying to move forward aggressively, to show the American people that although as I sit here I say TSCA is broken and needs to be fixed, we are going to do whatever we can to use that statute the best we can in the interim, because we know that we need to give you time to work.

Senator UDALL. All right. Thank you for your hard work over there.

And thank you, Senator Lautenberg, sorry running over a little bit, but her answers are very important, I think, for the record.

Senator LAUTENBERG. Sorry I have to call out the more senior——

Senator UDALL. I do have more seniority than Merkley. You are right about that.

[Laughter.]

Senator LAUTENBERG. Senator Barrasso.

Senator BARRASSO. Thank you very much, Mr. Chairman.

Administrator Jackson, just a couple of quick things. You and I have in the past talked about the Wall Street Journal report this past summer about Dr. Alan Carlin and a colleague who prepared a 98-page analysis, and that analysis argued that the EPA should take another look at the EPA's scientific data behind the endangerment finding that carbon dioxide is a threat to public health.

As reported in the Journal, a senior EPA official suppressed this detailed account produced by Dr. Carlin. The response was that an e-mail from his boss, Al McGartlin, forbidding him "from any direct communication" with anyone outside of the office with regard to his analysis. His credibility was attacked in the press with regard to his report when it was publicly released.

Now that we have this new data coming forth in terms of the U.N.'s IPCC reports, and those reports have been put into question because of the leaked e-mails, we know that the EPA has relied heavily on the U.N. reports. And it would appear that Dr. Carlin may have been vindicated.

Do you think that Dr. Carlin is owed an apology by the Administration?

Ms. JACKSON. I just want to be clear, Senator, because there is absolutely no connection I am aware of between Dr. Carlin's work that went on for years before I got to EPA and this latest e-mail issue that is being discussed here today. I am not aware of any.

And my response to Dr. Carlin's situation was that when he made allegations that his work wasn't being heeded or that he wasn't being allowed to post information on his Web site, the thing I said was let him do it, and give us your information. It turns out he had given it many times in the past to EPA scientists, and his information is part of the record of comments for the endangerment draft finding that now has to be responded to. So his information is in the record and will be responded to by scientists. That is our obligation.

Senator BARRASSO. Well, it seems to me that his criticism was that the EPA was relying too heavily on outside sources for its data, so I think that the criticism would be valid if the EPA truly has been relying on outside sources for its data rather than doing its own research work.

So those are the issues, and as I look at this and the leaked e-mails from the University of East Anglia's Climate Research Unit, do you believe that the EPA has relied too heavily on outside sources of data as now we see that some of this data is being called into question?

Ms. JACKSON. Well, EPA does emissions monitoring. When facilities emit and report, we have information right now. It is voluntary, but as you know, beginning in January of next year, there will be mandatory reporting for large facilities.

But EPA is not, you know, we don't send up weather satellites. We are not authorized to do major atmospheric modeling except in the context of the Clean Air Act. So it is incumbent on EPA in looking at the science to look at other people's data and to look at science's interpretation of that data. And we look at a number of sources, and the endangerment finding in its draft form cites those sources.

Senator BARRASSO. Because I got the impression from Dr. Carlin's comment that he couldn't think of any instance where EPA depended so heavily on non-EPA synthesis reports to justify a proposed regulatory action over all of his years with the Agency.

Ms. JACKSON. Well, that may well be his opinion. I don't know, and I haven't reviewed whatever source you are citing. What I will say is that EPA relies on science all the time. And in fact, it is bit contradictory to say we should get our own data and not look, but then so often what we do at EPA is work with groups who have better science.

When we talk about TSCA here today, the vast majority of the chemicals risk data is generated by producers or importers of chemicals. So much of what we do at EPA relies on science and information that is collected and that we are under obligation to do the very best job we can of evaluating.

Senator BARRASSO. What I just heard you say is you want to rely on reports of better science. And I am just not sure, in light of these recent e-mails, that the things you were relying on actually were better science. And that is why I have written a letter to ask that you look into some of these things.

Ms. JACKSON. And I understand that, Senator. I just have to repeat again for the record that nothing I have seen, and I certainly have my ear to the ground, causes me to be concerned about the validity of the science. And I think we have heard that the consensus on the science, not on the process, not on whether judgment was poor, not even on legal issues, but on the science, has changed.

Senator BARRASSO. Thank you.

Thank you, Mr. Chairman. My time has expired.

Senator LAUTENBERG. Thank you, Senator Barrasso.

And thank you, Administrator Jackson, for your excellent testimony and your unflappability.

[Laughter.]

Senator LAUTENBERG. And the next panel, we have Mr. Stephenson and Ms. Linda Birnbaum. We invite you to the witness table. Thank you for your patience and durability.

Mr. Stephenson is Director of Natural Resources and Environmental Issues at the Government Accountability Office, a very important post. We welcome you here.

And Dr. Linda Birnbaum, Director of the National Institute of Environmental Health Sciences.

And I think each of you has been experienced enough around the Hill to know because there are no other bodies sitting at the table doesn't mean a lack of interest, or rather that the record will clearly show what you have to say. We are pleased to have you here. I am sorry that is has taken so long for me to manage my trip through this chairmanship here.

Everybody is interested in what is going on. Environment is something that we are committed to work on, to recover a lot of years of neglect, and we thank you.

Please, Mr. Stephenson, please.

STATEMENT OF JOHN STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEPHENSON. Thank you, Mr. Chairman.

I am here today to discuss the need to transform EPA's processes for assessing and controlling toxic chemicals. As has been mentioned, EPA's ability to effectively implement its mission of protecting human health and the environment is critically dependent upon credible and timely assessments of the risk posed by toxic chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, regulations and policies.

In over a dozen reports over the past several years, we have recommended both statutory and regulatory changes to, among other things, strengthen EPA's authority to obtain additional information from the chemical industry, shift more of the burden of chemical companies for demonstrating the safety of their chemicals, and enhance the public's understanding of the risk of chemicals to which they may be exposed.

In January 2009, as you mentioned, we added transforming EPA's processes for assessing and controlling toxic chemicals to our high risk list, a designation GAO uses to focus attention on the Government's most intractable problems. EPA has taken positive actions consistent with our recommendations to improve IRIS processes for assessing chemicals.

Now, it is up to Congress to determine the best way to amend TSCA to provide EPA the tools that it needs for controlling toxic chemicals more effectively. TSCA as currently written places nearly all of the burden for obtaining chemical risk data on EPA, rather than on chemical companies, and the procedures EPA must follow to obtain test data from companies takes many resources and years to complete.

For example, the Act requires EPA to demonstrate certain health and environmental risks before it can require companies to further test their chemicals. This is something of a catch-22. EPA cannot require testing to determine the risk of a chemical until it determines that the chemical poses a risk. As a result, EPA does not routinely assess the risk of thousands of chemicals currently in use.

In addition, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce each year for toxicity, and companies generally do not voluntarily perform such testing.

Moreover, while it is true that TSCA authorizes EPA to ban, limit or otherwise regulate existing toxic chemicals, EPA must meet a very high legal threshold before it can do so. For example, TSCA states that EPA must demonstrate that a chemical possesses unreasonable risk. It also must provide substantial evidence in support of any action it takes to ban or limit chemical usage. To meet this legal threshold, EPA must conduct extensive cost-benefit

analysis that can take many taxpayer resources and years to complete.

Since 1976, EPA has used TSCA authority to control only five chemicals, and often-used statistics, five chemicals in 30+ years. The case of asbestos illustrates the problem. After over 10 years of study and nearly unanimous scientific opinion, EPA in 1989 issued a rule phasing out most uses of asbestos. Yet in 1991, a Federal Appeals Court vacated the rule because, in the court's view, it was not justified by substantial evidence.

Meanwhile, the European Union and a number of other countries have long since banned asbestos, a known human carcinogen that can cause lung cancer and asbestosis.

In addition, because of TSCA's prohibitions on the disclosure of confidential business information, EPA has limited ability to share information on chemical production and risk with others such as State and local governments with a legitimate need for the information or with the general public who want information on the potential risk chemicals pose.

About 90 percent of the notices companies have provided to EPA on new chemicals contain some information claimed as confidential. While companies may be overly using this designation, evaluating the appropriateness of such claims presents another burden and is something that EPA simply does not have the time and resources to pursue.

Our work clearly shows that EPA does not currently have the authority it needs to develop sufficient information to support critical decisions regarding how to protect human health and the environment from toxic chemicals. In our previous reports, we have recommended both statutory and regulatory changes to, one, strengthen EPA's authority to obtain additional information from the chemical industry; two, shift more of the burden to chemical companies for demonstrating the safety of their chemicals; and three, enhance the public's understanding of the risk of chemicals to which they may be exposed.

Without greater attention to EPA's efforts to assess and control toxic chemicals, the Nation lacks assurances that human health and the environment are adequately protected.

That concludes the summary of my statement, Mr. Chairman.

[The prepared statement of Mr. Stephenson follows:]

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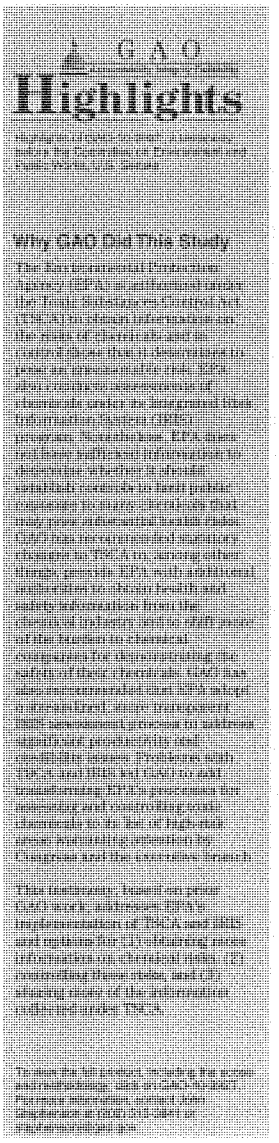
CHEMICAL REGULATION

Observations on Improving the Toxic Substances Control Act

Statement of John Stephenson, Director
Natural Resources and Environment

GAO-10-292T



December 2, 2009

CHEMICAL REGULATION

Observations on Improving the Toxic Substances Control Act

What GAO Found

EPA lacks adequate scientific information on the toxicity of many chemicals. One major reason is that TSCA generally places the burden of obtaining data about existing chemicals on EPA rather than on chemical companies. For example, the act requires EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA does not routinely assess the risks of the over 83,000 chemicals already in use. Moreover, TSCA does not require chemical companies to test the approximately 700 new chemicals introduced into commerce each year for toxicity, and companies generally do not voluntarily perform such testing. Furthermore, the procedures EPA must follow to obtain test data from companies can take years. Regarding IRIS, in 2008, GAO reported that this significant chemical assessment program—which provides EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals—is at serious risk of becoming obsolete because the agency has not been able to complete timely, credible assessments. In May 2009, EPA announced reforms to its IRIS assessment process, citing GAO's past recommendations and its high-risk designation. Overall, GAO believes that, if the reforms are effectively implemented, they will address GAO's recommendations and provide a sound framework for conducting IRIS assessments. However, given the number of obstacles that can impede the progress of IRIS assessments, the viability of this program will depend on effective and sustained management.

While TSCA authorizes EPA to ban, limit, or otherwise regulate existing toxic chemicals, EPA must meet a high legal threshold, which has proven difficult. For example, EPA must demonstrate "unreasonable risk" to ban or limit chemical production, which EPA believes requires it to conduct extensive cost-benefit analyses that can take many years to complete. Since 1976, EPA has issued regulations to control only five existing chemicals. Furthermore, its 1989 regulation phasing out most uses of asbestos was largely vacated by a federal appeals court in 1991 because it was not based on "substantial evidence." In contrast, the European Union and a number of other countries have largely banned asbestos, a known human carcinogen that can cause lung cancer and other diseases. GAO previously suggested that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continues to believe such change warrants consideration.

Because of TSCA's prohibitions on the disclosure of confidential business information, EPA has limited ability to share information on chemical production and risk. According to EPA officials, about 95 percent of the notices companies have provided to EPA on new chemicals contain some information claimed as confidential. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. GAO previously suggested that Congress, among other things, consider amending TSCA to authorize EPA to share the confidential business information that chemical companies provide to EPA with states.

Madam Chairman, Ranking Member and Members of the Committee:

I am pleased to appear here today to discuss the need to transform EPA's processes for assessing and controlling toxic chemicals. The Environmental Protection Agency's (EPA) ability to effectively implement its mission of protecting public health and the environment is critically dependent on credible and timely assessments of the risks posed by toxic chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, and regulations, and policies. In previous reports, we have recommended both statutory and regulatory changes to, among other things, strengthen EPA's authority to obtain additional information from the chemical industry, shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and enhance the public's understanding of the risks of chemicals to which they may be exposed. In 2009, we added transforming EPA's processes for assessing and controlling toxic chemicals to our list of areas at high risk for waste, fraud, abuse, and mismanagement because EPA has failed to develop sufficient chemical assessment information on the toxicity of many chemicals that may be found in the environment and tens of thousands of chemicals used commercially in the United States.[1] We reported that the lack of this information significantly limits the agency's ability to limit public exposure to many chemicals that may pose substantial health risks in fulfillment of its mission of protecting human health and the environment.

The Toxic Substances Control Act (TSCA) was enacted in 1976 to authorize EPA to obtain information on the risks of chemicals and to control those chemicals that EPA determines to pose unreasonable risks. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals). TSCA also provides that certain information, such as data disclosing chemical processes, can be claimed as confidential business information by chemical manufacturers and processors. EPA's ability to provide the public with information on chemical production and risk has been limited by TSCA' s strict confidential business information provisions, which generally prohibit the disclosure of such information. In addition to its authorities under TSCA, EPA conducts assessments of toxic chemicals in the environment under its Integrated Risk Information System (IRIS) program. EPA's IRIS database provides the agency's scientific position on the

[1]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: Jan. 22, 2009).

potential health effects that may result from exposure to more than 540 chemicals in the environment. IRIS toxicity assessments constitute critical steps of the risk assessment process and provide the basic information EPA needs to determine whether it should establish controls to protect the public from exposure to toxic chemicals in the air and water and at hazardous waste sites, among other things.

My testimony today is based on our prior work on EPA's processes for assessing and controlling toxic chemicals, in which we identified challenges associated with implementing TSCA and some of the legislative options available to address these challenges. Specifically, my statement addresses EPA's implementation of TSCA and options for (1) obtaining more information on the risks posed by chemicals, (2) controlling these risks, and (3) sharing more of the information gathered under TSCA.

Background

TSCA provides EPA with the authority, upon making certain determinations, to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. Of the over 83,000 chemicals currently in the TSCA inventory, about 62,000 were already in commerce when EPA began reviewing chemicals in 1979. Since then, over 21,000 new chemicals—about 700 each year, on average—have been added to the inventory and are now in use as existing chemicals. To assess a chemical's risks, EPA examines its toxicity or potential adverse effects and the amount of human and environmental exposures.

TSCA generally requires the industry to notify EPA at least 90 days before producing or importing a new chemical. These notices are to contain such information as the chemical's molecular structure and intended uses, which EPA uses to evaluate the chemical's potential risks. TSCA also authorizes EPA to promulgate rules to require manufacturers to perform tests on chemicals in certain circumstances or to provide other data, such as production volumes, on existing chemicals. In addition, TSCA requires chemical companies to report to EPA any

data that reasonably support a conclusion that a chemical presents a substantial risk. If EPA finds that a chemical's risks are unreasonable, it can prohibit or limit the chemical's production, processing, distribution, use, and disposal or take other action, such as requiring warning labels on the substance. While TSCA authorizes EPA to release some chemical information obtained by the agency under the act, it allows chemical companies to claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must not disclose such information unless such disclosure is necessary to protect against an unreasonable risk of injury to health or the environment. Evaluating the appropriateness of confidentiality claims is time- and resource-intensive, and EPA does not challenge most claims. State environmental agencies and others have expressed interest in obtaining information claimed as confidential business information for use in various activities, such as developing contingency plans to alert emergency response personnel to the presence of highly toxic substances at manufacturing facilities. In previous reports, we have identified options for statutory changes to improve EPA's ability to make more chemical information publicly available.

IRIS was created in 1985 to help EPA develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. Its importance has increased over time. EPA, state and local environmental programs, international regulatory bodies, academia, industry, and others now rely heavily on the IRIS database to support risk-based decision making to protect public health and the environment. A typical IRIS assessment contains a qualitative description of the hazard posed by a chemical and a quantitative assessment of the relationship between exposure and the likelihood and severity of adverse health effects. The focus of IRIS toxicity assessments is on the potential health effects of long-term (chronic) exposure to chemicals. According to the Office of Management and Budget (OMB), EPA is the only federal agency that develops qualitative and quantitative assessments of both cancer and noncancer risks of exposure to chemicals, and EPA does so largely under the IRIS program. The quantitative estimates of potency that EPA provides are particularly important, as they are required to conduct quantitative risk assessments. EPA uses risk assessments developed with IRIS toxicity data to determine whether the identified health risks warrant regulatory or other actions. Examples of subsequent decisions that could stem from a determination that action is necessary to protect public health include how much of a chemical a company may discharge

into a river, which substances may be stored at a hazardous waste facility, the extent to which a hazardous waste site must be cleaned up, levels for air emissions, and allowable levels of contamination in drinking water.

EPA Lacks Adequate Information on Potential Health and Environmental Risks of Chemicals

EPA lacks adequate scientific information on the toxicity of many chemicals that are or may be found in the environment. For existing chemicals, TSCA generally places the burden of obtaining data on EPA, rather than on the companies that produce the chemicals. This approach requires that EPA demonstrate certain health or environmental risks before it can require companies to further test their chemicals. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. Furthermore, while TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Significantly, chemical companies are not required to develop and submit toxicity information to EPA on existing chemicals unless the agency finds that a chemical may present an unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters the environment in substantial quantities. EPA must also determine there are insufficient data on a chemical to reasonably determine its effects on health or the environment and that testing is necessary to develop such data before the agency can require a company to test its chemicals for harmful effects. This structure places the burden on EPA to demonstrate a need for data on a chemical's toxicity rather than on a company to demonstrate that a chemical is safe. As a result, EPA does not routinely assess the risks of the more than 83,000 commercial chemicals in use.

As we have previously reported,[2] TSCA's chemical review provisions could be strengthened by requiring EPA's systematic review of existing chemicals. TSCA could be amended to establish a time frame for the review of existing chemicals, putting existing chemicals on a more equal

[2]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

footing with new chemicals. However, because of the large number of existing chemicals, EPA would need the flexibility to identify which chemicals should be given priority. TSCA could be amended to require individual chemical companies or the industry as a whole to compile and submit chemical data as a condition of manufacture or import above some specified volume or other criteria.

Regarding new chemicals, TSCA generally requires chemical companies to submit a premanufacture notice to EPA before they manufacture or import new chemicals and to provide any available test data. Yet EPA estimates that most premanufacture notices do not include any test data, and only about 15 percent include health or safety test data. These tests may take over a year to complete and cost hundreds of thousands of dollars, and chemical companies usually do not perform them voluntarily. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, EPA uses models to compare new chemicals with chemicals that have similar molecular structures and for which test data on health and environmental effects are available, which can take years. Furthermore, EPA bases its exposure estimates for new chemicals on information contained in premanufacture notices—information that chemical companies generally are not bound by and that may change without notice. For example, companies may increase production levels or expand the uses of a chemical, potentially increasing the risk of injury to human health or the environment.

An option that we have previously reported could make TSCA more effective and provide EPA with adequate information on chemicals—that is, revising the act to require companies to test their chemicals and submit the results to EPA with their premanufacture notices.[3] Currently, such a step is required only if EPA makes the necessary findings and promulgates a testing rule. A major drawback to testing is its cost to chemical companies, which may reduce their willingness to perform chemical research and invest in innovation. To reduce such costs or to delay them until production is sufficient to offset them, requirements for testing could be based on production volume. For example, in Canada and the European Union, testing requirements for low-volume chemicals are less extensive and complex than for high-volume chemicals. We previously reported that Congress could give EPA, in addition to its current

[3]GAO-05-458.

authorities under section 4 of TSCA, the authority to require chemical substance manufacturers and processors to develop test data based on, for example, substantial production volume and the necessity for testing.[4]

Another option we reported was to provide EPA with greater authority to require additional testing in areas where EPA's analysis models do not adequately predict toxicity.[5] Under such an option, EPA could establish a minimal set of tests for new chemicals to be submitted with premanufacture notices. Additional and more complex and costly testing could be required as a new chemical's potential risks increase, based on, for example, production or environmental release levels. According to some chemical companies, the cost of initial testing could be reduced by amending TSCA to require EPA to review new chemicals before they are marketed, rather than before they are manufactured. This could substantially reduce the expense of testing because, according to EPA, about half of the premanufacture notices the agency receives from chemical companies are for new chemicals that, for various reasons, never enter the marketplace.

In addition to TSCA, EPA assesses chemicals under its IRIS program. We reported in March 2008 that this key program was at serious risk of becoming obsolete because the agency has not been able to keep its existing assessments current; decrease its backlog of 70 assessments; or complete assessments of key chemicals of concern, such as dioxin, formaldehyde, and trichloroethylene (TCE).[6] Among other things, we found that EPA's efforts to finalize IRIS assessments were impeded by a combination of factors, including OMB's requiring two additional reviews of IRIS assessments by OMB and other federal agencies with an interest in the assessments, such as the Department of Defense. Moreover, the two interagency reviews involved other federal agencies in EPA's IRIS assessment process in a manner that hindered EPA's ability to manage its assessments and limited their credibility and transparency. For example, the input these agencies provided to EPA was treated as "deliberative" and was not released to the public. As a result, we recommended that EPA adopt a streamlined, more transparent assessment process. A revised process that EPA subsequently adopted in 2008 did

[4]GAO-05-458.
[5]GAO-05-458
[6]GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, GAO-08-440 (Washington D.C.: Mar.7, 2008).

not incorporate our recommendations and actually exacerbated the concerns we identified about productivity and credibility. As a result, we included the IRIS program along with TSCA in our high-risk designation on assessing and controlling toxic chemicals.

However, in May 2009, EPA again announced comprehensive reforms to its IRIS assessment process, citing our designation of this program as high risk as well as key recommendations from our reports. We reviewed EPA's reforms and testified that overall, if implemented effectively, these reforms will address our recommendations and provide a sound framework for conducting IRIS assessments and significantly improve the IRIS process.[7] For example, under the new process EPA is to manage the entire assessment process, including the interagency reviews. Under EPA's prior process, these reviews were required and managed by OMB—and at various stages, EPA was not allowed to proceed with assessments until OMB notified EPA that it had sufficiently responded to comments from OMB and other agencies. The independence restored to EPA under the new process will be critical to ensuring that EPA has the ability to develop transparent, credible IRIS chemical assessments. While the broad reforms provide a sound general framework for conducting IRIS assessments, the manner in which EPA implements the new process will determine whether the agency will be able to overcome its long-standing productivity problems and complete credible and transparent assessments. Specifically, certain aspects of the new process are incomplete or lack clarity and thus warrant management attention. For example, EPA has likely understated the time required to complete an assessment because its estimated time frames do not include the time required to complete two key steps. Overall, the viability of the IRIS program will depend on effective and sustained management, given the number of factors that can impede the progress of IRIS assessments--even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. We note that, unlike some other EPA programs with statutory deadlines for completing various activities, the IRIS program is discretionary. As we have previously stated, we believe the absence of statutory deadlines in completing assessments may contribute to EPA's failure to complete timely IRIS assessments.[8]

[7]GAO, *Scientific Integrity: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes,* GAO-09-773T (Washington, D.C.: June 9, 2009).
[8]GAO, *EPA Chemical Assessment: Process Reforms Offer the Potential to Address Key Problems,* GAO-09-774T (Washington, D.C.: June 11, 2009).

TSCA's Regulatory Framework Impedes EPA's Efforts to Control Risks Posed by Chemicals

While TSCA authorizes EPA to issue regulations that may ban, limit, or otherwise regulate the production or use of existing toxic chemicals, EPA must meet a high legal threshold, which has proven to be difficult. Specifically, in order to regulate an existing chemical under section 6 of TSCA, EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. EPA officials have said that this requires an extensive cost-benefit analysis. In addition, before regulating a chemical under section 6, the EPA Administrator must consider and publish a statement regarding the following:

- the effects of the chemical on human health and the magnitude of human exposure to the chemical;
- the effects of the chemical on the environment and the magnitude of the environment's exposure to the chemical;
- the benefits of the chemical for various uses and the availability of substitutes for those uses; and
- the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Moreover, while TSCA offers EPA a range of control options when regulating existing chemicals, the agency must choose the least burdensome regulation that will be adequately protective. For example, if EPA finds that it can adequately manage the risk of a chemical by requiring chemical companies to place warning labels on the chemical, EPA may not ban or otherwise restrict its use. EPA must also develop substantial evidence in support of the action it proposes to take in order to withstand judicial review. Under TSCA, a court reviewing a TSCA rule must set it aside if such evidence is lacking.[9] As several courts have noted, this standard is more rigorous than the "arbitrary and capricious" standard normally applied to rulemaking. Furthermore, according to EPA officials, the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits

[9]Specifically, a court reviewing a rule "shall hold [it] unlawful and set [it] aside...if the court finds that the rule is not supported by substantial evidence in the rulemaking record." 15 U.S.C.A. § 2618(c)(1)(B)(i).

associated with controlling those risks, and it is difficult to show substantial evidence that EPA is promulgating the least burdensome requirement.

EPA has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and consequently should be regulated. In fact, since Congress passed TSCA in 1976—over 33 years ago—EPA has issued TSCA regulations on only five existing chemicals or chemical classes. In 1991, one of these regulations—the 1989 regulation banning most uses of asbestos—was largely vacated by a federal appeals court decision that cited EPA's failure to meet statutory requirements. In contrast to the United States, the European Union and a number of other countries have banned all, or almost all, asbestos and asbestos-containing products. Asbestos is a known human carcinogen that can cause lung cancer and other diseases if inhaled. Asbestos has been used widely in products such as fireproofing; thermal insulation; and friction products, including brake linings.

EPA spent 10 years exploring the need for the asbestos ban and developing the regulation. On the basis of its review of over 100 studies of the health risks of asbestos as well as public comments on the proposed rule, EPA determined that asbestos is a potential carcinogen at all levels of exposure—that is, that it has no known safe exposure level. EPA's 1989 rule under TSCA section 6 prohibited the future manufacture, importation, processing, and distribution of asbestos in almost all products. In response, some manufacturers of asbestos products filed suit against EPA arguing, in part, that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In October 1991, the U.S. Court of Appeals for the Fifth Circuit agreed with the manufacturers, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban. Specifically, the court concluded that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation that would adequately protect human health or the environment. EPA had not calculated the risk levels for intermediate levels of regulation because it believed there was no asbestos exposure level for which the risk of injury or death was zero. As articulated by the court, the proper course of action for EPA would have been to consider each regulatory option listed in TSCA, beginning with the least burdensome, and the costs and benefits of each option. Since completing the 1989 asbestos rule, EPA has completed only one regulation to ban or limit the production or use of an existing chemical (for hexavalent chromium in 1990).

With EPA's limited actions to control toxic chemicals under TSCA, state and federal actions have filled the void by establishing controls for some toxic chemicals. For example, a California statute enacted in 2007 prohibits the manufacture, sale, or distribution of certain toys and child care articles after January 1, 2009, if the products contain concentrations of phthalates exceeding 0.1 percent. In 2008, Congress took similar action. California has also enacted limits on formaldehyde in pressed wood. In response to a petition asking EPA to use section 6 of TSCA to adopt the California formaldehyde regulation, EPA recently issued an advance notice of proposed rulemaking suggesting several regulatory options the agency could pursue under its TSCA section 6 authority to limit exposure to formaldehyde. However, because of the legal hurdles the agency would face in regulating formaldehyde under TSCA, some stakeholders have recommended that EPA pursue legislation instead.

In our previous reports, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA.[10] Potential changes to TSCA include reducing the evidentiary burden that EPA must meet to take regulatory action under the act by amending (1) the unreasonable risk standard; (2) the standard for judicial review, which requires substantial evidence in the rulemaking record; and (3) the requirement that EPA choose the least burdensome regulatory requirement.

TSCA Limits EPA's Ability to Share Information

TSCA' s confidential business information provisions limit EPA's ability to make the information that it collects under the act available to outside entities if chemical companies designate such information as confidential business information. EPA is required under the act to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures, and this information generally cannot be shared with others, including state health and environmental officials and foreign governments that may have legitimate needs for the information. For example, some state officials said this information would be useful for informing and managing their environmental risk programs.

EPA officials told us that some claims of confidential business information may be unwarranted, but challenging the claims is resource-intensive. EPA has not performed any

[10]GAO/RCED-94-103 and GAO-05-458.

recent studies of the appropriateness of confidentiality claims, but a 1992 EPA study indicated that problems with inappropriate claims were extensive. This study examined the extent to which companies made confidential business information claims, the validity of the claims, and the impact of inappropriate claims on the usefulness of TSCA data to the public. While EPA may suspect that some chemical companies' confidentiality claims are unwarranted, the agency does not have data on the number of inappropriate claims. According to EPA officials, about 95 percent of premanufacture notices contain some information that chemical companies claim as confidential. EPA officials also told us that the agency does not have the resources that would be needed to investigate and challenge claims to determine the number that are inappropriate. Consequently, EPA focuses on investigating primarily those claims that it believes may be both inappropriate and among the most potentially important—that is, claims relating to health and safety studies performed by the chemical companies involving chemicals currently used in commerce. The EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year and that the chemical companies withdraw nearly all of the claims challenged.

As we have previously reported, state officials who have various responsibilities for protecting public health and the environment from the dangers posed by chemicals have said that having access to confidential TSCA information would allow them to examine information on chemical properties and processes that they currently do not possess, which could enable them to better control the risks of potentially harmful chemicals.[11] The general public may also find information provided under TSCA useful. Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations could use such information to engage in dialogue with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

In our June 2005 report, we suggested that Congress consider amending TSCA to authorize EPA to share the confidential business information that chemical companies provide to EPA with states and foreign governments.[12] This amendment would be subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties,

[11]GAO-05-458.
[12]GAO-05-458.

which would protect the information from unauthorized disclosures. In our September 1994 report, we recommended that Congress consider limiting the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality.[13]

Concluding Observations

Although we have identified significant shortcomings with TSCA in numerous reports and made recommendations to remedy them, EPA still does not have the authority to develop sufficient information to support critical decisions regarding how to protect human health and the environment from toxic chemicals. In our previous reports on TSCA, we have recommended both statutory and regulatory changes to (1) strengthen EPA's authority to obtain additional information from the chemical industry, (2) shift more of the burden to chemical companies for demonstrating the safety of their chemicals, and (3) enhance the public's understanding of the risks of chemicals to which they may be exposed, among other things. With regard to IRIS, it is too soon to know if EPA's new IRIS assessment process will enable the agency to develop timely and credible assessments of chemicals of concern. Without greater attention to EPA's efforts to assess toxic chemicals, the nation lacks assurance that human health and the environment are adequately protected.

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Madam Chairman, Ranking Member, this concludes my prepared statement. I would be happy to respond to any questions that you or other Members of the Committee may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this testimony, please contact John B. Stephenson at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Contributors to this testimony include David Bennett, Ben Shouse, Antoinette Capaccio, Christine Fishkin, and Ed Kratzer.

[13]GAO, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective,* GAO/RCED-94-103 (Washington, D.C.: Sept. 26, 1994).

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EPA Chemical Assessment: Process Reforms Offer the Potential to Address Key Problems. GAO-09-774T. Washington, D.C.: June 11, 2009.

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EPA Science: New Assessment Process Further Limits the Credibility and Timeliness of EPA's Assessments of Toxic Chemicals. GAO-08-1168T. Washington, D.C.: September 18, 2008.

Chemical Assessments: EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System. GAO-08-810T. Washington, D.C.: May 21, 2008.

Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals. GAO-08-743T. Washington, D.C.: April 29, 2008.

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Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective. GAO/RCED-94-103. Washington, D.C.: September 26, 1994.

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GAO Response to Questions from Senator Barbara Boxer

1. Does the Government Accountability Office believe that US laws regulating the manufacturing and use of chemicals ensure that EPA has adequate information on chemical risks to protect public health, including the health of infants, children and pregnant women?

As stated in our prior work,[1] EPA's ability to control chemical risks is limited because the agency lacks adequate information on the potential health and environmental risks of chemicals in general. Because EPA generally does not have sufficient data on a chemical's properties and effects when reviewing a new chemical, it uses models to compare new chemicals with chemicals that have similar molecular structures and for which test data on health and environmental effects are available. Furthermore, the procedures EPA must follow in obtaining test data from companies can take years to complete. We have previously suggested that TSCA could be amended to (1) require companies to test their chemicals and submit the results to EPA before they manufacture the chemicals and (2) provide EPA with greater authority to require additional testing in areas where EPA's models do not adequately predict toxicity.

2. Could you please describe what the GAO has found regarding the difficulty that EPA has in enforcing controls against the manufacturing and use of chemicals using the current Toxic Substances Control Act?

TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use. However, as we have reported,[2] the statutory requirements EPA must meet present a legal threshold that has proven difficult for EPA and that discourages the agency from using these authorities. For example, EPA must demonstrate "unreasonable risk," which EPA believes requires it to conduct extensive cost-benefit analyses to ban or limit chemical production. Since 1976, EPA has issued regulations to control only five existing chemicals determined to present an unreasonable risk. We have

[1] GAO, *Chemical Regulation: Observations on Improving the Toxic Substances Control Act*, GAO-10-292T (Washington, D.C.: Dec. 2, 2009).

[2] GAO, *Chemical Regulation: Options for Enhancing the Effectiveness of the Toxic Substances Control Act*, GAO-09-428T (Washington, D.C.: February 26, 2009).

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previously suggested that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continue to believe such change warrants consideration.[3]

[3]GAO-09-428T.

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GAO Response to Questions from Senator Thomas R. Carper

1. Last year, you were before our Committee testifying on a GAO report on the EPA IRIS database. The GAO report stated that despite more resources and more funds, the EPA IRIS assessment process to fill the database is quite flawed. Can you tell me if the agency has addressed this problem?

Since our April 2008 testimony,[4] in May 2009, EPA revised its IRIS assessment process. Overall, the process reforms represent significant improvements, and the changes are largely responsive to our 2008 recommendations. The viability of this critical program will depend on effective implementation of these IRIS reforms as well as sustained management and oversight, especially given the number of factors that can impede the progress of IRIS assessments. We will be initiating work in the next few months to assess how the reforms are working in response to a request by the House Committee on Science.

2. Mr. Stephenson, a follow-up question, the 2008 IRIS GAO report stated that the EPA Office of Research and Development would wait 5, 10, or even 20 years for missing data before updating the IRIS database. Do you know if the Office of Research and Development is now using their resources to decrease these data gaps or are they waiting for outside sources to do the research?

The question you raise about EPA waiting for years for research results, rather than using the best available science, is an important one—EPA's prior practice of waiting for new studies was a factor in the indefinite delay of some key IRIS assessments. This is an issue we will examine in our upcoming work evaluating EPA's revised IRIS assessment process.

[4]GAO, *Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals*, GAO-08-743T (Washington, D.C.: Apr. 29, 2008).

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GAO Response to Questions from Senator Benjamin L. Cardin

1. By the title of the law alone it would seem that the Toxic Substances Control Act would "control," or prevent, toxic chemicals from entering the marketplace. Yet the way the law is structured EPA has to make a case for why a chemical is dangerous once it's in the marketplace rather than a chemical industry needing to demonstrate a chemical product's safety before it reaches consumers. In other words, the burden of proof is on EPA to identify, prove and issue rulemakings on the danger or safety of the thousands of chemicals present in the marketplace.

Is this an effective legal framework for protecting the public from exposure to toxic chemicals?

We have reported that, while TSCA authorizes EPA to issue regulations that may, among other things, ban existing toxic chemicals or place limits on their production or use, the statutory requirements EPA must meet to do so present a legal threshold that has proven to be difficult for EPA.[5] In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA, including

- authorizing EPA to regulate existing chemicals when it identifies "significant," rather than "unreasonable," risks of injury to health or the environment;
- amending TSCA to require that EPA demonstrate that a chemical "may present" an unreasonable risk, rather than requiring a demonstration that a chemical "presents or will present" an unreasonable risk; and
- amending the standard for judicial review of a chemical control action to reflect a rational basis test to prevent arbitrary and capricious administrative decisions rather than the current standard, which requires substantial evidence in the rulemaking record.

2. TSCA also calls for regulators to take the "least burdensome approach" to remedying a situation involving the discovery of a toxic and hazardous chemical. Is this "least burdensome approach" requirement under TSCA providing the most effective protection the public deserves from the threat of toxic chemicals?

[5]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: Jun. 13, 2005).

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As we have previously reported, EPA officials believe that it is difficult to show by substantial evidence that EPA is promulgating the least burdensome requirement. In its ruling that EPA had failed to muster substantial evidence to justify its asbestos ban under section 6 of TSCA, the court in Corrosion Proof Fittings v. EPA concluded that EPA failed to show that the control action it chose was the least burdensome regulation required to adequately protect human health or the environment. Since the court's decision, EPA has only exercised its authority to ban or limit the production or use of an existing chemical under section 6 once. In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA.

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GAO Response to Questions from Senator James M. Inhofe

1. We know that the TSCA inventory contains over 80,000 chemicals. But, for the purposes of protecting human health and the environment, the number of chemicals actually in commerce is a much smaller universe. So, excluding chemicals used in a research setting and other small volume chemicals, how many chemicals actually are in commerce during any given year? How many of the 80,000 chemicals on the TSCA Inventory have been subject to EPA review as new chemicals?

EPA does not track how many of the over 84,000 chemicals now on the TSCA inventory are in commerce during any given year. Approximately 62,000 chemicals were reported when the initial TSCA Inventory was compiled. According to EPA, almost 22,000 chemicals have been added to the Inventory after new chemical reviews since then. In 1986, EPA promulgated the Inventory Update Rule (IUR), which requires companies to update production volume data for certain chemicals on the Inventory. However, because IUR does not require reporting for all chemicals on the Inventory, it is unclear which chemicals not subject to IUR reporting are in commerce at a given point in time.

2. The scope of the European Inventory (EINECS) under REACH does not, other than in a few instances, include polymers. Whereas, all polymers produced in the U.S. are included on the TSCA Inventory. Approximately how many of the TSCA Inventory chemicals are polymers? Of the remaining (nonpolymer) chemicals on the TSCA Inventory, how many are known to be produced above 25,000 lbs at a site based on the Inventory Update Rule? Of these chemicals, how many are known to be high volume chemicals (produced/imported above 1 million lbs)? How many are known to not be produced above 25,000 lbs at a site based on the Inventory Update Rule?

According to EPA estimates, approximately one quarter to one third of the chemicals on the TSCA inventory are polymers. Under the latest IUR reporting period, manufacturers and importers provided information on the chemical substances they manufactured domestically or imported into the United States in amounts of at least 25,000 pounds at a site during the 2005 calendar year. For this reporting period, EPA reports that companies reported certain information on 7,600 chemicals. EPA estimates that approximately 3,200 of these chemicals are manufactured or imported at greater than 1 million pounds per year. EPA generally does not have information on chemicals produced below 25,000 pounds at a site. Furthermore, EPA collects IUR data only every five years. In addition, EPA repots that chemical production volume varies. For example, EPA has noted a 30 percent change in the chemicals reported from one IUR submission period to the next. Moreover, the IUR does not require reporting for all chemicals on the TSCA inventory.

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3. The point has repeatedly been made that "only 5 chemicals have been regulated." This point is accurate only with regard to actions under section 6 of TSCA and fails to take into account the number of existing chemicals regulated under Significant New Use Rules (SNURs) in section 5(a)(2). Or, for that matter, the number of new chemicals that have been regulated under section 5(e) and/or section 5(a)(2), which is relevant to the issue when one talks about the "over 80,000 chemicals," approximately 20,000 of which are former new chemicals.

EPA has authority to control new chemicals using section 5(e) and section 5(b)(4) and to control new and existing chemicals using section 5(a)(2). Hundreds of existing chemicals have been controlled by SNURs, which require advance notification to EPA prior to commencing the significant new use, and thousands of new chemicals have been controlled by 5(e) orders, SNUR, and 5(h)(4) exemptions. Thus, I request that GAO report back to the Committee within 30 days on the use of SNURs for existing chemicals—how many and which types of chemicals—as well as the use of section 5(e) orders, 5(a)(2) SNUR, and section 5(b)(4) regulatory exemptions on new chemicals. At a minimum, I ask that your report including the following information:

How many new chemicals have been controlled using section 5(e)?

According to EPA data through September 30, 2009, for more than 1,450 chemicals, EPA has issued orders requiring chemical companies to implement workplace controls or practices during manufacturing pending the development of information, and/or perform toxicity testing when the chemical's production volumes reached certain levels.

How many new chemicals have been withdrawn by the notifier?

For over 1,800 chemicals, companies withdrew their premanufacture notices, sometimes after EPA officials indicated that the agency planned to initiate the process for placing controls on the chemical, such as requiring testing or prohibiting the production, or certain uses, of the chemical.

How many new chemicals have been allowed into commerce by EPA subject to the terms of section 5(b)(4) exemptions?

EPA may exempt a chemical company from the premanufacture notice requirement when the company's application shows to EPA's satisfaction that the chemical will not present any unreasonable risk of injury to human health or the environment. EPA has exempted from the premanufacture notice requirements (1) about 780 chemicals for Test Marketing Exemption Applications; (2) about 8,900 chemicals for Low Volume Exemptions; (3) about 39

chemicals for Low Release/Low Exposure Exemptions; and (4) about 6,700 chemicals for Polymer Exemptions.

How many new chemicals and how many existing chemicals have been regulated using section 5(a)(2)?

For about 1,500 new chemicals submitted for review and for 360 existing chemicals, EPA required chemical companies to submit premanufacture notices for any significant new uses of the chemical. These notices provide EPA with the opportunity to review the risks of injury to human health or the environment before new uses had begun.

Please elaborate on the effect of these controls on new or existing chemicals.

As we have reported, EPA's reviews of new chemicals provide limited assurance that health and environmental risks are identified before the chemicals enter commerce. Chemical companies are not required by TSCA, absent a test rule, to test new chemicals before they are submitted for EPA's review, and companies generally do not voluntarily perform such testing.

4. In your written testimony, you state that a 1991 Federal appeals court vacated the EPA's asbestos ruling, because it was not based on "substantial evidence;" that the EU and several other countries have found asbestos to be a known carcinogen; and, then, that you recommend TSCA be amended to reduce the evidentiary burden. The way your testimony is written, you appear to imply that because the evidentiary burden is so high, the EPA failed to prove what the EU and other countries have determined: that asbestos causes cancer.

However, the court stated, it was "[t]he failure of the EPA to [show not only that its proposed action reduces the risk ... but also that the actions Congress identified as less burdensome also would not do the job] [that] constitutes a failure to meet its burden of showing[.]"

The court stated in particular regarding friction products:

"We note that of all the asbestos bans, the EPA did the most impressive job in this area, both in conducting its studies and in supporting its contention that banning asbestos products would save over 102 ... lives ... Were the petitions only questioning the EPA's decision to ban friction products ... we would be tempted to uphold the EPA[.]"

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Isn't it true that the court in fact found some of the EPA's science persuasive and essentially just sent the EPA back to finish its homework? Please reconcile your testimony with the actual statements from the court.

In our written testimony we stated that EPA determined that asbestos is a potential carcinogen at all levels of exposure. We noted, however, that despite this determination, the court in Corrosion Proof Fittings v. EPA concluded that the agency had failed to muster substantial evidence to justify the ban under section 6 of TSCA. In our written testimony, we accurately described the ruling, noting how the court concluded that EPA did not consider all necessary evidence and failed to show that the control action it chose was the least burdensome regulation that would adequately protect human health or the environment. We explained that EPA had not calculated the risk levels for intermediate levels of regulation because it believed there was no asbestos exposure level for which the risk of injury or death was zero. Moreover, we articulated the court's finding that the proper course of action for EPA would have been to consider each regulatory option listed in TSCA, beginning with the least burdensome, and the costs and benefits of each option. We noted that EPA has not initiated action under section 6 since the Corrosion Proof decision. We have also reported that the substantial evidence standard is more rigorous than the arbitrary and capricious standard normally applied to rulemaking under the Administrative Procedure Act. In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA, including:

- authorizing EPA to regulate existing chemicals when it identifies "significant," rather than "unreasonable," risks of injury to health or the environment;
- amending TSCA to require that EPA demonstrate that a chemical "may present" an unreasonable risk, rather than requiring a demonstration that a chemical "presents or will present" an unreasonable risk; and
- amending the standard for judicial review of a chemical control action to reflect a rational basis test to prevent arbitrary and capricious administrative decisions, rather than the current standard, which requires substantial evidence in the rulemaking record.

5. There is support for having the government conduct its own risk assessment, rather than accepting chemical company information at face value. Wouldn't a REACH-like program only drown EPA with enormous amounts of information? If you feel the agency isn't doing its job under TSCA now, how would they be able to manage with the enormous new responsibilities they'd have under a program like REACH?

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We have reported that REACH generally requires chemical companies to develop and share with government regulators information on the effects of the chemicals they produce on human health and the environment. In contrast, TSCA places the burden on EPA to demonstrate that data on health and environmental effects are needed before requiring chemical companies to develop the data. We have recognized that, because of the large number of existing chemicals, EPA would need the flexibility to identify which chemicals should be given priority. Furthermore, we have noted that TSCA could be amended to require individual chemical companies or the industry as a whole to compile and submit chemical data as a condition of manufacture or import above some specified volume or other criteria.

6. TSCA requires EPA to consider the environmental, economic, and social impact of any action. When an agency adopts the strictest regulatory action in its stable, does GAO expect the government to undertake the fullest review of the evidence in order to promulgate whole policy?

We expect the agency to comply with all applicable legal requirements. We have noted that under the requirements applicable to chemical control actions under TSCA section 6 as they have been interpreted by the court, EPA has regulated very few chemicals. In our previous reports on TSCA, we identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA.

7. Is it GAO's position that when a government regulation is being promulgated, particularly one that seeks to ban or severely restrict a product, that the issuing agency should: (1) not consider the impact on commerce, (2) show its work for arriving at the decision, and (3) demonstrate that alternatives—including less burdensome ones—are not as protective?

We expect an agency to comply with all applicable legal requirements. Each environmental law strikes its own balance between the environmental effects of the regulated activity and the effects of regulation on covered entities. We have noted that under the requirements applicable to chemical control actions under TSCA section 6 as they have been interpreted by the court, EPA has regulated very few chemicals, and we have identified a number of options that could strengthen EPA's ability to regulate harmful chemicals under TSCA.

8. Does GAO consider the exemptions in federal law for confidential business information, whether under FOIA or TSCA, to be legitimate exercises of legal authority?

We have noted that the confidential business information provisions of TSCA limit EPA's ability to make the information that it collects under the act available to outside entities and

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that EPA's implementation of the provisions could be improved. EPA officials told us that some claims of confidential business information may be unwarranted, but that the agency does not have the resources to investigate and challenge unwarranted claims. Consequently, we have recommended that EPA limit the length of time for which information may be claimed as confidential without resubstantiation of the need for confidentiality. We have also recommended that Congress amend TSCA to require substantiation of confidentiality claims at the time that the claims are submitted to EPA.

9. Your written comments include the statement, "the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits associated with controlling those risks, and it is difficult to show substantial evidence that EPA is promulgating the least burdensome requirement." Given the current state of our economy, please explain to me your rationale for looking so unfavorably on cost-benefit considerations and criticizing minimizing burdens on the private sector.

The statement quoted above was reporting the views of EPA officials. Our written comments include the statement, "Furthermore, according to EPA officials, the economic costs of regulating a chemical are usually more easily documented than the risks of the chemical or the benefits associated with controlling those risks, and it is difficult to show substantial evidence that EPA is promulgating the least burdensome requirement."

Senator LAUTENBERG. Thank you very much.
Ms. Birnbaum, we welcome your testimony.

STATEMENT OF LINDA BIRNBAUM, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Ms. BIRNBAUM. Senator Lautenberg, I am pleased to appear before you today to present testimony on our current understanding of chemical hazards.

My name is Linda Birnbaum. I am a Jersey girl, and I am the Director of the National Institute of Environmental Health Sciences, one of the National Institutes of Health. And I am also Director of the National Toxicology Program.

Environmental health science has made tremendous strides since passage of the original Toxic Substances Control Act. To begin with, our understanding of chemical toxicity has been challenged by the new science of epigenetics. Epigenetics looks at how DNA is packaged and how that affects the expression of our genes. Research is showing us that toxic substances in our environment can cause epigenetic changes that are passed down for several generations. Unfortunately, it appears that health problems associated with these epigenetic changes can also be passed down through several generations. This new understanding heightens the need to protect our children from dangerous substances at critical times in their development.

Research has shown us that normal development of the fetus, the infant and the child can be disrupted by relatively low doses of certain chemicals. These developmental stages are windows of susceptibility or times when people have an increased vulnerability to the effects of toxic chemicals. This concept was first established for neurodevelopmental toxicants like PCBs, lead, mercury and other metals, but it also applies to hormonally active agents such as bisphenol A, which we call endocrine disrupting chemicals.

The NIEHS co-funds with the National Cancer Institute a Breast Cancer and Environment Research Program. Researchers in this program are determining if windows of susceptibility exist in the development of the mammary gland and if exposures to environmental agents during these vulnerable periods of development increases the risk for breast cancer in adulthood.

Toxicity research must extend to health end points beyond cancer and birth defects. For example, NIEHS is supporting research on the origins of obesity and the theory that environmental exposures during a child's development play an important role in the current epidemic of obesity, diabetes and metabolic syndrome. There are data showing weight gain in rats and mice after developmental exposure to a number of different environmental chemicals. That is why we need to start thinking about obesity not just in terms of genetics and lifestyle but also in terms of environmental chemicals. These kinds of health outcomes will need to be considered in assessing toxicity.

Furthermore, all of us are exposed to many different chemicals at the same time, not just one chemical at a time, the way they are usually tested in the lab. Scientists have labored to come up with ways to estimate risk from combinations of compounds. One example is the method used for dioxin and related compounds.

Dioxin is a known human carcinogen. Scientists believe that related chemicals such as furans and some PCBs cause cancer in similar manners as dioxin. The question for public health officials was how health standards could be adjusted to take into account the fact that people are always exposed to mixtures of dioxin-like compounds, not just one at a time.

To address this problem, a method was developed to estimate toxicity of mixtures of dioxin-like compounds based on toxic equivalency factors. The methodology was tested and confirmed by the NTP, by EPA and others. Now, this methodology is also applied to other health end points, including reproductive and developmental, immune and neurological.

The route of exposure must also be considered. For example, initial studies on the inhalation of hexavalent chromium showed it causes lung cancer in humans, but there was question whether its presence in drinking water was a problem when the chemical was ingested.

Additional studies by the NTP showed that oral consumption of hexavalent chromium causes cancer in laboratory animals at concentrations that are not much higher than what can be found in people. This clearly shows the need to test different routes of chemical exposure when assessing toxicity.

The EPA's new arsenic standards for drinking water exemplify how our research can inform decisions to protect public health. The NIEHS Superfund Research Program, which is authorized by this committee, funded research on arsenic metabolism, disease pathogenesis by arsenic, and detailed exposure assessment. These studies provided the scientific basis for a drinking water standard that protects Americans against arsenic exposure and resulting health problems such as cancer, diabetes, neurological and cardiovascular disease.

TSCA reform can be built upon vastly improved and less expensive toxicological testing methods. The NTP is laying the foundation for this testing paradigm in partnership with the National Human Genome Research Institute and the EPA. The new methods for quantitative high throughput screening assays can be used to test a large number of chemicals simultaneously, dramatically increasing the rate at which chemicals can be prioritized for further testing.

Over the past 33 years, we have significantly expanded our understanding of chemical exposures and health. It only stands to reason that TSCA would at some point be updated to account for scientific progress. We must have the ability to harness new technologies and our growing knowledge. We are poised to move forward, and new tools will provide for research and development to create the comprehensive testing our citizens deserve under revitalized TSCA.

Thank you, and I would be happy to answer questions.

[The prepared statement of Ms. Birnbaum follows:]

Statement for the Subcommittee on Superfund, Toxics and Environmental Health
Committee on Environment and Public Works
United States Senate
December 2, 2009
Oversight Hearing on the Federal Toxic Substances Control Act

Statement of
Linda S. Birnbaum, Ph.D., DABT, ATS
Director
National Institute of Environmental Health Sciences
National Institutes of Health
and
Director
National Toxicology Program
U.S. Department of Health and Human Services

Mr. Chairman and distinguished members of the Subcommittee—I am pleased to appear before you today to present testimony on our current understanding regarding chemical hazards. My name is Linda Birnbaum; I am the Director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health, as well as of the National Toxicology Program (NTP).

Environmental health science has made tremendous strides since the original passage of the Toxic Substances Control Act, or TSCA. Our understanding of chemical toxicity has been challenged by the new science of epigenetics, which is the study of changes to the packaging of the DNA molecules that influence the expression of genes, and hence the risks of diseases and altered development. Studies indicate that exposures that cause epigenetic changes can affect several generations. This new understanding heightens the need to protect people at critical times in their development when they are most vulnerable to this kind of toxicity.

The concept of "windows of susceptibility" is an important area. Research has revealed the heightened vulnerability of fetal, infant and child developmental processes to disruption from relatively low doses of certain chemicals. Established first for neurodevelopmental toxicants like PCBs, mercury, lead and other metals, this concept also applies to hormonally active agents (endocrine disrupting chemicals). In our NIEHS Breast Cancer and Environment Research Program, co-funded with the National Cancer Institute, researchers are investigating whether periods of susceptibility exist in the development of the mammary gland, when exposures to environmental agents may impact the breast and endocrine systems that can influence breast cancer risk in adulthood.

There are unanticipated effects of exposure to toxic chemicals, and our research must extend to health endpoints beyond cancer and birth defects. NIEHS is supporting research on the developmental origins of obesity and the theory that environmental exposures during development play an important role in the current epidemic of obesity, diabetes, and metabolic syndrome. There are data showing weight gain in rats and mice after developmental exposure to

a number of different substances. Thus we need to start thinking about obesity not just in terms of genetics and lifestyle but also in terms of exposures. These kinds of outcomes will need to be considered in assessing toxicity.

There are other susceptibilities to consider. For some types of chemicals and health effects, there may be excess risk from specific genes or chronic diseases. For example, the level of a person's risk of bladder cancer from smoking has been shown to depend in part on whether or not that individual's genome contains variants in specific detoxification enzymes. The existence of these subtle variations in susceptibility must be factored into overall toxicity assessments.

Furthermore, exposures do not occur singly, the way they are usually tested in the lab. All of us are exposed to many different chemicals at the same time. Scientists have labored to come up with ways to estimate risk from combinations of exposures. One example was the method used for dioxin and related compounds. Dioxin is an environmental contaminant and known human carcinogen. Scientists believe that related chemicals such as furans and some PCBs may cause cancer in a similar manner. The question for public health officials was how health standards could be adjusted to take into account the fact that people are always exposed to mixtures of dioxin-like compounds, not just one at a time.

To address this problem, a large body of work led to the development of a method to estimate toxicity of mixtures of dioxin-like compounds based upon toxic equivalency factors, or TEFs. To estimate the overall toxicity of a mixture, the contaminants' weighted contributions are added together, adjusting for the fact that some compounds are more toxic than others. The additive methodology has been tested and confirmed by studies done by the NTP, EPA, and others. TEF methodology has also been extended to other health endpoints, including reproductive and developmental, immune, and neurological.

Differences in routes of exposure must also be considered. For example, hexavalent chromium compounds have been shown to cause lung cancer in humans when inhaled, but it was not known how these compounds behaved when ingested. Hexavalent chromium was tested by the NTP because of concerns over its presence in drinking water. The NTP studies showed that a compound containing hexavalent chromium causes cancer in laboratory animals following oral administration in drinking water at concentrations that are not that much higher than what can be found in people, confirming the need to protect people from oral routes of exposure.

The impact of new scientific information we have on effects of environmental chemicals can be seen in the EPA's arsenic standards for drinking water implemented in 2006. The NIEHS Superfund Research Program, which is authorized by this Committee, funded scientists who played a vital role in the process through research on health effects of arsenic in drinking water. This research included studies of arsenic metabolism, mechanistic research on disease pathogenesis by arsenic, and both molecular and traditional epidemiology with detailed exposure assessment. These studies provided the scientific underpinnings for a standard that protects the health of Americans against long-term effects of arsenic exposure such as cancer, diabetes, neurological and cardiovascular disease.

We are poised to move forward into an era of a new kind of toxicological testing that is less expensive and also gives us an improved understanding of the actual effects on humans. Toxicology is advancing from a mostly observational science using disease-specific models to a better predictive science focused upon a broad inclusion of target-specific, mechanism-based, biological observations. This means using alternative assays targeting the key pathways, molecular events, or processes linked to disease or injury, and incorporating them into a research and testing framework. The NTP is laying the foundation for this testing paradigm in partnership with the National Human Genome Research Institute and the EPA. They are using quantitative high throughput screening assays to test a large number of chemicals. The resulting data are being deposited into publicly accessible relational databases. Analyses of these results will set the stage for a new framework for toxicity testing.

Reform of TSCA needs to account for the ways in which our understanding of the effects of chemical exposures has deepened and improved over the past 33 years. We must have the ability to harness new technologies and a growing knowledge base of underlying biology, receptor and other host pathways, variations in susceptibility, and routes and timing of exposure, to obtain a clearer and more accurate picture of the risks posed by these chemicals. Our new tools will provide for research and development to create the comprehensive testing our citizens deserve under a revitalized TSCA

Thank you. I would be happy to answer questions.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Boxer:

1. Could you please describe the findings of the latest science on the potential ability of chemicals to impact human health several generations after a person has been exposed to a chemical?

Response: Studies on "developmental plasticity" show the importance of the environment of the developing organism on subsequent patterns of development and even susceptibility to chronic non-communicable disease in later life.[1] Evidence is growing that developmental exposures to many chemicals, mostly those with endocrine activity (endocrine disruptors) can result in increased disease later in life, long after the chemical is gone from the circulation.[2,3,4] The data suggest that these latent effects occur because the chemical affected epigenetic programming of gene expression during development and these epigenetic changes then remain throughout life, resulting in tissues that have abnormal gene expression resulting in abnormal proteins and protein levels throughout life (even though they may "look" normal in other respects). Over time, the changes result in increased susceptibility to a variety of diseases in animal models. There are few human data in this area but there are some linking developmental exposures to childhood diseases like asthma, ADHD, behavior and learning problems, weight gain and early puberty.[5]

When the experiments described above are carried out, with the male pups mated as adults with unexposed females, there have been instances when the 3rd, 4th and 5th generation animals have

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[1] Gluckman PD, Hanson MA, Buklijas T, Low FM, Beedle AS (2009) Epigenetic mechanisms that underpin metabolic and cardiovascular diseases. Nat. Rev. Endocrinol. 5:401-408.

[2] Anway MD, Cupp AS, Uzumcu M, Skinner MK (2005) Epigenetic transgeneration actions of endocrine disruptors and male fertility. Science 308:1391-1392.

[3] Prins GS, Birch L, Tang W-Y, Ho S-M (2006) Developmental estrogen exposures predispose to prostate carcinogenesis with aging. Reproductive Toxicology 23:374-382.

[4] Salian S, Doshi T, Vanage G (2009) Perinatal exposure of rats to Bisphenol A affects the fertility of male offspring. Life Sciences 85:742-752.

[5] Perera F, Tang W-y, Herbstman J, Tang D, Levin L, et al. (2009) Relation of DNA methylation of 5'CpG island of *ACSL3* to transplacental exposure to airborne polycyclic aromatic hydrocarbons and childhood asthma. PLoS ONE4(2): e4488.

increased incidence of the same diseases as was seen in the pups that were exposed to the environmental chemicals *in utero* and or during the first few months of life.[6][7] Since the 3rd to 5th generation animals have never actually "seen" the environmental chemical, is it proposed that the effect crosses generations due to improper erasure of epigenetic marks across generations. Normally, as the germ cells develop *in utero* in the developing pup, they undergo erasure of all epigenetic marks so they actually become pluripotent stem cells, and then a few days later as they develop into male or female germ cells, the epigenetic marks are reestablished in a gender specific manner. It is hypothesized that in the presence of these exposures there is incomplete erasure of some of the epigenetic marks in these developing germ cells and this allows the "disease" susceptibility to pass from one generation to another. This effect has been shown in animal models for exposure to methoxychlor, vinclozolin, dioxin, phthalates, and bisphenol A: all chemicals for which there is significant human exposure. In each of these instances, the investigators have been able to not only show increased disease susceptibility across 3-5 generations but also altered gene expression and in some cases altered epigenetic marks. The diseases that have been shown to be passed through this transgenerational mechanism include infertility, altered behavior, cancers, and altered kidney and liver functions. The data supporting this new research area are still preliminary. However, if these mechanisms can be replicated and shown to operate in humans, then it means that toxic exposures are not only affecting us and our children but our children's children for generations to come.

2. Could you please describe the findings of the latest science on the importance of being able to analyze the cumulative impacts of exposures to multiple types of chemicals? Could you please also describe whether we currently have the scientific tools and methodologies that can help us to conduct these types of cumulative risk assessments?

Response: Currently the issue of cumulative effects of chemical is an active area of interest and research, especially for NIEHS and NTP. The state of the science is good for chemicals that work in a similar way, and in these cases it is shown that effects are generally dose-additive. That is, the effects of the mixture can be estimated by adding together the effects of specific chemicals in the mixture, after adjusting for the fact that some chemicals in the mixture are more potent than others. In fact, the NTP recently completed an extensive set of studies showing that dose additivity is appropriate for assessing the carcinogenic effect of mixtures of dioxins, an assumption used by EPA and FDA in their risk assessments for dioxins in food and the environment.[8]

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[6] Anway MD, Cupp AS, Uzumcu M, Skinner MK (2005) Epigenetic transgeneration actions of endocrine disruptors and male fertility. Science 308:1391-1392.

[7] Crews D, Gore AC, et al. (2007) Transgenerational epigenetic imprints on mate preference. Proc Natl Acad Sci USA 104:5942-5946.

[8] Walker NJ, Crockett PW et al. (2005) Dose-additive carcinogenicity of a defined mixture of "dioxin-like compounds". Environ Health Perspect. 113:43-48.

There are greater challenges for assessing hazards associated with chemicals that work in a dissimilar manner, but that affect the same organ or organ system. There are mathematical tools and methods that are in use for assessing such potential cumulative effects, but they tend to have a more limited scientific basis for support.

3. The National Academy of Sciences has recently produced two reports on conducting risk assessments. The reports are titled, "Science and Decisions: Advancing Risk Assessment" and "Phthalates and Cumulative Risk Assessment". Could you please provide your opinion on how helpful these reports are in guiding a reform in the way risks are assessed under the Toxic Substances Control Act?

Response: I defer to the EPA on this question, since risk assessment is not part of the NIEHS mission.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Lautenberg:

1. As you know, I held this hearing to consider the problems with the existing TSCA, and draw lessons from where it has fallen short to guide us in strengthening protection for public health and the environment. If we are thinking about ways to improve those protections, should we prevent the introduction of new PBTs into the stream of commerce?

Response: I defer to the EPA on this question.

2. At the hearing, Director Birnbaum testified to the inherent problems with PBT chemicals, which build-up in our bodies and the environment. Those don't lend themselves to traditional risk assessment. Should we act to reduce exposure to existing PBT chemicals to the extent possible?

Response: I defer to the EPA on this question.

3. Are there non-PBT chemicals – substances like asbestos, formaldehyde, or hex chrome – for which we know enough about hazard and exposure so that EPA should move to risk management without having to first conduct additional risk assessment?

Response: Risk assessment and risk management are the purview of EPA, and NIEHS does not have a position on this question.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Carper:

1. As we think about the challenges ahead in modernizing TSCA one in particular seems to be how we strike the balance between the number of chemicals that get reviewed every year and the depth of that review, particularly given the large number of chemicals we need to look at. No one would be happy with one perfect review a year, nor would we want to see a thousand cursory reviews a year. Can you share your thinking on how the EPA could develop a process that is both sufficiently rigorous and adequately productive?

Response: EPA's processes are at its discretion. But it should be noted that EPA is a major partner in our current high throughput screening initiative known as Tox21, for Toxicology in the 21st Century. Tox21 is a collaboration on the research, development, validation, and translation of new and innovative test methods that will better determine the toxicity of chemicals to which humans are or might be exposed. A central component is the exploration of novel high throughput screening assays using human cells to evaluate mechanisms of toxicity. Program success will result in toxicity testing methods that are less expensive, provide higher throughput, and are better able to predict toxic effects in humans. As a result, Tox21 will increase the government's ability to evaluate large numbers of chemicals that currently lack adequate toxicological evaluation, while reducing the use of animals in regulatory testing.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Cardin:

1. The recent concerns over Bisphenol A (BPA) in water and baby bottles I think is a perfect example of how weak TSCA is – yet it also demonstrates the power of public opinion which fortunately stepped in when federal agencies were limited in their ability to address the problem because of the constraints in the law. My questions are:
    a. Did the chemical companies that produced the plastics containing BPA know about the risks their product posed to human health before the public became aware of these risks?

    Response: I have no information on this question.

    b. Does TSCA currently require public disclosure of harmful chemicals present in consumer products?

    Response: No.

    c. While retailers and consumers took a stand against BPA, which the chemical industry took note of by delivering BPA-free plastic products to market, and some states have passed laws against products containing BPA, has BPA been banned under TSCA?

    Response: No.

    d. Can water bottles and baby bottles that contain BPA still be purchased in the U.S.?

    Response: Yes.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Inhofe:

1. I agree with your observation that "reform of TSCA needs to account for the ways in which our understanding of the effects of chemical exposures has deepened and improved over the past 33 years." That is the essence of what we should be discussing in any debate about changing the law. Could you provide more details on what you would consider sufficient data needed to fairly evaluate chemicals?

Response: Over the past several decades, our understanding of the effects of environmental chemicals has grown considerably. As our knowledge base grows, the baseline for what constitutes sufficient information also changes. Years ago, toxicity testing evaluated high dose effects and focused on overt toxicity. Animal testing and human epidemiological studies have demonstrated that these early testing strategies are inadequate. This is particularly the case for endocrine disrupting chemicals. For example, test guidelines used in the 1970's and 1980's for developmental endpoints focused on teratogenicity. These studies would not have detected low dose endocrine effects. Even the multigenerational reproductive studies had weak power to evaluate low dose effects.[9] Traditional rodent cancer bioassays start exposures while the animals are adults and are continued for two years.

At a workshop sponsored by the National Toxicology Program, entitled *National Toxicology Program Workshop on Hormonally Induced Reproductive Tumors—Relevonce of Rodent Bioassays*, one of the conclusions was that this exposure period is inadequate to evaluate hormonally induced tumors.[10] In response to this workshop, the National Toxicology Program has modified their bioassays to begin exposures *in utero* and continue exposures for two years. This new exposure paradigm is consistent with human exposures to environmental chemicals, because, for most environmental chemicals, humans are exposed from "cradle to grave."

In addition, where older bioassays simply tested for the endpoint of cancer, there are a variety of non-cancerous diseases that have rapidly increased over the past several decades including autism, ADHD

[9] Hotchkiss AK et al. (2008) Fifteen years after "Wingspread" – environmental endocrine disrupters and human and wildlife health: where we are today and where we need to go. Toxicol. Sci. 105:235-259.

[10] Thayer KA and Foster PM. (2007) Workgroup report: National Toxicology Program workshop on Hormonally Induced Reproductive Tumors – Relevance of Rodent Bioassays. Environ Health Perspect 115:1351-1356.

and metabolic syndrome. Very few chemicals have been evaluated for developmental neurotoxicity and the potential for metabolic syndrome.

With our current understanding of the toxicity of endocrine disruptors and other environmental chemicals, an adequate testing protocol should include "cradle to grave" exposures, to evaluate neurodevelopmental, reproductive, and immunological effects in addition to cancer. It is clear that these tests would have significant cost and time constraints. This is why the National Toxicology Program, in collaboration with the US EPA, is developing a "high throughput" screening program, called Tox21. It is hoped that this screening program will provide insights into the potential adverse effects of environmental chemicals.

The results from these high-throughput screens will lead to more targeted testing of specific environmental chemicals. We envision that this approach would guide our testing to the most appropriate animal model, including the potential use of novel transgenic animals that serve as better models for specific human diseases.

Finally, recent advances in pharmacokinetic studies allow for more accurate species extrapolation of the absorption, distribution, metabolism and elimination of chemicals. Toxicity testing must continue to advance and incorporate new technologies.

Dr. Linda Birnbaum

Questions for the Record

Senate Environment and Public Works Committee Hearing

December 2, 2009

Sen. Vitter:

1. How can we ensure that EPA works with chemical manufacturers and users to ensure that EPA has timely and adequate information of chemical hazards, exposures and uses, including in children's products?

Response: I defer to the EPA on this question.

2. What steps can Policymakers take to leverage the chemical management programs undertaken by other nations and to integrate the patchwork quilt of laws governing chemical management?

Response: Again chemical management programs are the responsibility of the various regulatory agencies. NIEHS authorities are limited to research, training, and information dissemination.

Senator LAUTENBERG. Thank you both. Again, not for your endurance, but your wonderful testimony. We appreciate it.

I wanted to just ask a couple of questions. First of all, an observation, Dr. Birnbaum. As you recite these connections between the materials and the result, I feel like we are using time that we ought to be getting the law polished up and get it into place in a hurry.

And thank you, Mr. Stephenson. I understand that I pronounced your name incorrectly, and please forgive me. It happens to me a lot.

The bio-monitoring studies have found that bodies of Americans contain hundreds of industrial chemicals, including some that are known or suspected to cause cancer. Should TSCA be reformed to give EPA better authority to restrict chemicals that are found in humans and known to cause health problems? Can enough research be done, or done reliably, to say that because it has already got a presence that we have noted, that EPA should be able to use that information and go-ahead and particularly go to those chemicals, restrict them from use?

Mr. STEPHENSON. Yes, the 83,000 number of existing chemicals is kind of daunting. It is overwhelming. So we are supportive of a risk-based approach. Look at where the science is the strongest, where the chemicals are the most dangerous.

What we are suggesting, though, is the legislation needs to be overhauled to make it easier for EPA to get data from the chemical industry to make it easier to require testing of certain chemicals it deems dangerous. And we think there are changes in the language in the law that can make it more consistent with other pieces of legislation that don't have such a high legal threshold, which will in essence give EPA better tools with which to do its job.

So they have to work their way through this list of chemicals. Best guesses are that may be 20 percent of those are still in use today. A lot of these, 60,000 of these were grandfathered in 1976 when the legislation was passed. Are they still in use? We really don't know.

So there needs to be a vetting process to get it down to a manageable number first and then those have some kind of risk-based approach based on volume, based on uses, based on known scientific risk where they can use that to then start putting controls on those chemicals. And the legislation needs to be reduced for putting controls on chemicals to lower that legal threshold as well.

Senator LAUTENBERG. I am an author of some legislation called the Right To Know, and that here we are. People have a right to know what the products they are using are dangerous in any way, and particularly as we look at infants and see, because of their susceptibility, and see that it doesn't often take a lot to do a lot of damage, a large quantity.

Dr. Birnbaum, new techniques for testing the toxicity of chemicals are being developed so that scientists can obtain faster and more accurate results without relying on animal testing. Now, what might Congress do to accelerate the development and use of these 21st century testing techniques?

Ms. BIRNBAUM. I think it is very important to understand that the TOX–21 Program in which we are involved provides great

promise for the future. At this point in time, as we begin to generate literally reams and reams of data on thousands of chemicals, it will allow us to prioritize which chemicals are the bad actors and require more study.

And frequently, at least for the foreseeable future, some of that study will still require testing in animals. But we will be testing faster and smarter, and we will be testing the chemicals that are of greatest concern.

Senator LAUTENBERG. We have awaited EPA's assessment of the safety of certain chemicals for many years. By way of example, EPA's assessment of dioxin, one of the most potent toxins on the planet, has taken more than 18 years. Should EPA be able to move forward with safety assessments of chemicals in a more timely fashion, even in the face of uncertainty about some of the details of the chemicals' risk?

Mr. Stephenson. Or Dr. Birnbaum.

Ms. BIRNBAUM. Well, I just think the point is, science never provides 100 percent certainty, and I think it is very important that decisions be made in the presence of evidence, but not necessarily in the presence of certainty because that just doesn't happen with science.

The more that you know, the more questions you have. And if you use dioxin as an example, the conclusions of EPA's draft reassessment, which I believe the Administrator has promised to finalize by the end of this year or shortly thereafter, has changed very little from the conclusions that were reached by an external peer panel, the first panel, in 1992, supported by an external panel in 1994 and again by an external panel in 2000.

Mr. STEPHENSON. If I could add, Mr. Chairman, the other part of this we haven't talked a lot about today is the integrated risk information system, which is EPA's process for managing scientific risk assessments of toxic chemicals. We have issued many reports on that and attempted to get EPA to streamline that as well.

Administrator Jackson announced a new process about 6 months ago which looks very promising. In its first test, they just put out a draft assessment on TCE, where all of the agency comments, including OMB's and DOD's and everyone else's are available for public scrutiny. That is real progress in terms of transparency in science from the old process that it replaced.

So we are encouraged by that whole risk assessment process, but we still think it takes too long. As you mentioned, it takes years and years to complete a scientific risk assessment of a given chemical. And so we have offered in our reports over the years, ways in which we think that process can be streamlined.

Senator LAUTENBERG. Yes, because you said overwhelming, 80,000+, I mean. By the time you get to these, and again the first year out to understand whether or not they are still around. Maybe there are 60,000 of them that aren't used, not likely, used anymore. And also the addition of new items, as 700 a year is the estimate of new chemicals that are introduced every year.

So that means that if you only did 1,000 a year, you would barely stay ahead of the growth. And these products I think are important, can be very important as an addition to good health, but they have to be looked at. And frankly, I don't know how they are going

to manage this data base. It is a huge one, but it can be done, and we must do it in the interest of public health.

Dr. Birnbaum, chemicals called PBTs buildup in our bodies, fail to break down over time, are known to be toxic. Other governments have taken action to restrict most uses of these PBTs without putting those chemicals through a traditional risk assessment process. Might we provide a pathway for action to reduce the use of PBTs quickly, without waiting for the risk assessment to run its course?

Ms. BIRNBAUM. Many of the countries of the world have accepted the fact that any chemical which is highly persistent and highly bioaccumulative will become toxic at some concentration. And in fact they utilize, in many cases appropriately, the precautionary principle to say that evidence of overwhelming persistence and bioaccumulation, even in the absence of full toxicity information, is enough to know that it is not a chemical that we want.

And I can say that there probably, or that we know that there are many chemicals that industry started development on and because they were new chemicals, they found that they were persistent, or had the potential to be persistent, had the potential to bioaccumulative, and in many cases had potential to be toxic, those chemicals never entered the marketplace.

And I think part of the problem has been that existing chemicals were not required to be examined with the same lens that new chemicals were looked at.

Senator LAUTENBERG. Yes. What responsibilities do the primary developers of these products have on their own to do health analysis?

Mr. STEPHENSON. Well, right now, I mean, the manufacturer is required to submit what is called a pre-manufacturing notice, which gives a little bit of information about the chemical. But certainly, they aren't required to provide any test data to show the safety of that chemical right now. The burden is essentially on EPA to show that the chemical is risky before they can require further test data from the industry.

That is what we mean by there needs to be a little bit of burden shifting off of the Government and the taxpayer and onto the chemical industry who is producing these chemicals.

Senator LAUTENBERG. Yes. And there is an old expression about polluter pays, and I don't see a lot of difference here. It is certainly something that deserves attention because, A, it expedites the process and reduces the risk to the public. And so whatever we can do there, because the task of analyzing all these, the products that have accumulated, their recognition over lots and lots of years, but it is so overpowering, I mean, to analyze that we ought to find ways to cut into that.

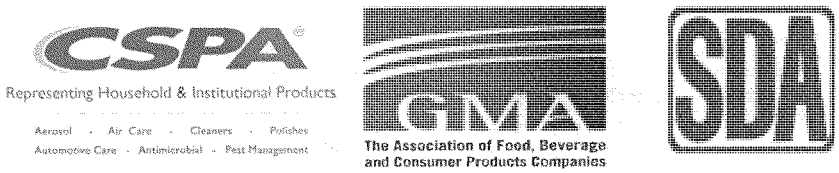
Well, that is why the law is written. I thank you both for your attention and your willingness to stay so long, and excellent data. And we will keep the record open so that if any of the members of the committee have any questions they would like answered, we will hold it open for 2 weeks, so that if you get an inquiry, please respond.

And I enter into the record, to close this meeting, a letter that has come from the Consumer Specialty Products Association, called CSPA, Grocery Manufacturers Association, GMA, and the Soap and

Detergent Association, are pleased that the Senate Committee on Environment and Public Works has scheduled today's hearing concerning the Toxic Substances Control Act.

These are the people who are making and selling products, and they support the modernization of TSCA and continue to urge Congress to establish a stakeholder process to develop the most comprehensive chemicals management policy in the world. And that is part of the record.

[The referenced letter follows:]



December 2, 2009

The Honorable Barbara Boxer
Chairman, Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

The Honorable James Inhofe
Ranking Member, Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Chairman Boxer and Ranking Member Inhofe:

The Consumer Specialty Products Association (CSPA), Grocery Manufacturers Association (GMA) and The Soap and Detergent Association (SDA) are pleased that the Senate Committee on Environment and Public Works has scheduled today's hearing concerning the Toxic Substances Control Act (TSCA).

The members of CSPA, GMA, and SDA are committed to manufacturing and marketing safe and innovative products that provide essential benefits, including important public health benefits, to consumers while protecting human health and the environment. Product safety is the foundation of consumer trust and the consumer products industry devotes substantial resources to achieving this goal. To that end, we support modernization of TSCA and continue to urge Congress to establish a stakeholder process to develop the most comprehensive chemicals management policy in the world. All stakeholders - Congress, regulators, downstream users, raw material suppliers, retailers, environmental, consumer and animal welfare and labor groups - should work together to develop sound public policy on this complex issue.

Among the issues we believe should be addressed in any effort to modernize TSCA include:

1) **Promote Innovation** – TSCA reform should boost confidence in government chemical management and promote even greater innovation by chemical manufacturers and users.

2) **Review Priority Chemicals** – EPA should establish a system to quickly identify and review "priority" chemicals based upon both hazard characteristics and exposures, including exposures to children.
3) **Provide Adequate Use, Exposure and Toxicity Information** – EPA should work with chemical manufacturers and users to ensure that EPA has timely and adequate information of chemical hazards, exposures and uses, including uses in children's products.
4) **Update the Safety Standard** – EPA should establish a risk-based methodology to determine whether a "priority" chemical is reasonably expected to be safe for its intended use. Safety determinations should consider the effects of exposure to children and other sensitive populations.
5) **Clarify Risk Management Tools** – EPA should have clearer risk-based authorities to specify risk management measures that will ensure that chemicals of concern are reasonably expected to be safe for their intended uses.
6) **Leverage and Integrate Chemical Reviews** – Policymakers should take steps to leverage the chemical management programs undertaken by other nations and to integrate the patchwork quilt of laws governing chemical management.
7) **Meet Deadlines** – Policymakers should provide EPA with adequate resources and clear authorities to establish and meet deadlines to carry-out agency work under a revised TSCA program.
8) **Use the Best Available Science** – Policymakers should ensure that EPA relies upon the best available science regardless of its source.

We have a unique opportunity to modernize chemical regulation the right way—protecting the public and the environment while retaining U.S. leadership in chemical innovation and we should seize that moment. As we engage with other stakeholders, EPA and the Congress, we should all keep in mind that innovation will be critical to the development of more sustainable products. CSPA, GMA and SDA appreciate the opportunity to submit these comments and look forward to working with you on this very important issue.

About CSPA
The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately $80 billion annually in the U.S. of hundreds of familiar consumer products that help household, institutional and industrial customers create cleaner and healthier environments. Our products include disinfectants that kill germs in homes, hospitals and restaurants; candles, fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used everyday. Through its product stewardship program Product Care®, scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety, sustainability and environmental impacts of their products. For more information, please visit www.cspa.org.

About GMA
The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth and helps ensure the safety and security of consumer packaged goods through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over $1 trillion in added value to the nation's economy. For more information, visit the GMA Web site at www.gmaonline.org.

About SDA
The Soap and Detergent Association, the Home of the U.S. Cleaning Products Industry®, represents the $30 billion U.S. cleaning products market. SDA members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. SDA and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. SDA's mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. For more information visit www.cleaning101.com.

Senator LAUTENBERG. It has been a very good hearing, and I thank all of you for your contributions.

Those of you who were stuck with the seats there by either commitment to your client, representative or otherwise, we are glad you are here, too.

Thank you all very much.

This meeting is adjourned.

[Whereupon, at 4:40 p.m. the committee and subcommittee were adjourned.]

[Additional statements submitted for the record follow:]

STATEMENT OF HON. MAX BAUCUS,
U.S. SENATOR FROM THE STATE OF MONTANA

I am very pleased that the committee is considering the effectiveness and status of the Toxic Substances Control Act. The Toxic Substances Control Act was adopted in 1976 and was intended to establish protective regulations to prevent harmful exposure to chemicals of various types. Today, I look forward to hearing the assessment from our witnesses as to the effectiveness of this statute at achieving its goals. Based on the testimony submitted to the committee, it is clear that there have been some difficulties with the implementation of TSCA. I am particularly struck by the issues surrounding the use of TSCA to regulate asbestos.

Montanans know about the harmful effects of asbestos. We know because of Libby. For those of you who don't know about Libby, Montana, it is a tragic story that evidences the devastating impact that asbestos exposure can have in one community.

Libby, Montana, is a beautiful little town in northwestern Montana. It is surrounded by millions of acres of Federal forest lands. It is a Superfund site where hundreds of people have been sickened and died because of the pervasive presence of asbestos spewed from the vermiculite mining and milling operations of W.R. Grace. For decades, the W.R. Grace operation belched thousands and thousands of pounds of asbestos contaminated dust into the air in and around Libby, coating the town and its inhabitants with the deadly substance. People used expanded vermiculite to fill their gardens, their driveways, the high school track, the little league field, and in their attics. Mineworkers brought the dust home with them on their clothing and contaminated their own families without knowing that this dust was poison. Asbestos was everywhere in Libby, for decades.

The type of asbestos in Libby is particularly deadly. The tremolite asbestos fibers found here quickly find their way into victims' lungs and stay there—essentially a time bomb waiting to strike. The impact on Libby has been severe. Today, we know that over 200 residents of Libby have died, and thousands are sickened with asbestos-related disease.

The experience in Libby is truly unique. It is, in fact, so unique that earlier this year EPA Administrator Jackson declared Libby to be a "public health emergency"—a distinction under the Superfund statute reserved for the most extreme cases, where the public health threat is so severe that special action is required to mitigate the immediate threat. EPA has never before used this authority, and the Agency indicates that there are currently no sites on the books that come close to the conditions at Libby.

There is no question that asbestos exposure leads to respiratory disease, mesothelioma, and ultimately death. No one knows this better than the people of Libby, Montana.

Yet, in spite of everything we know about the hazards of asbestos, in spite of a 10-year analysis and a 45,000-page record produced by EPA, the Agency was precluded from moving forward with an asbestos ban under a Court interpretation of TSCA. I am not an expert on every element of this analysis or every detail of the legal opinion in that case. However, I do know this—asbestos is deadly, no matter where it is used. The people of Libby, Montana, know this better than anyone. If TSCA, which was intended to give the Agency the authority to control toxic substances, cannot be effectively used to address even the obvious hazards posed by asbestos, it is certainly appropriate for this committee to review the statute to determine if changes are warranted. I do not have the answers as to what the appropriate course of action is, but we clearly need to re-look at the effectiveness of TSCA. I look forward to the testimony of our witnesses today and the committee's work on this topic.

STATEMENT OF HON. KIRSTEN GILLIBRAND,
U.S. SENATOR FROM THE STATE OF NEW YORK

Thank you, Chairman Lautenberg and Chairman Boxer, for holding this important hearing. The Toxic Substances Control Act (TSCA) was landmark legislation toward reducing toxic risk to public health and the environment when it was first signed into law in 1976.

Unfortunately, since its inception, the statute has failed to address its stated purpose because the Environmental Protection Agency (EPA) was never given the authority, resources and access to information needed to carry out the mission of truly regulating the chemicals in our environment. For decades now this committee has heard testimony from representatives of multiple Administrations and other stakeholders about the shortcomings of the law and its implementation.

In fact, 29 years ago, the General Accounting Office penned their initial report regarding TSCA titled "EPA Slow To Carry Out Its Responsibility To Control Harmful Chemicals." Three decades later, we have not progressed. As a mother and Senator representing the State of New York, TSCA is a particularly important issue to me and my constituents.

A short drive from my home in Upstate New York is the town of Fort Edward in Washington County. Apart from its importance as a focal point in the French and Indian Wars and the War of Independence, Fort Edward is also critically important to the history of the Toxic Substances Control Act. It is in Fort Edward where over 1.3 million pounds of polychlorinated biphenyl, better known as PCBs, were dumped into the Hudson River.

According to EPA studies, PCBs are a probable human carcinogen and also can cause a number of serious non-cancer health effects to human immune, reproductive, nervous and endocrine systems. It was the high levels of PCBs found in fish in the Hudson River that raised flags about the effects that this chemical has on human and environmental health and led to its banning in the original legislation.

Thirty years later, TSCA has only been able to examine and ban 5 chemicals out of the more than 80,000 currently in the marketplace. The vast majority of those chemicals have not even received the minimum level of scrutiny because of the lack of resources and access to critical information.

This summer, I authored an amendment as part of the Water Infrastructure Financing Act that calls for a comprehensive study of the presence of pharmaceuticals and personal care products in waters of the United States. This proposed study was born out of a number of investigations conducted by various agencies as well as a series of articles from the Associated Press that found traces of a number of chemicals and drugs in waters in my State of New York and across the country. The studies have shown troubling effects in wildlife, but we do not have comprehensive data as to the health effects on humans who rely on those waters.

We also do not have definitive information as to how the chemicals get into the water; are they from consumers, manufacturing, agricultural use?

In regard to our work on this important legislation, it is critical that we give regulators the authority, access to information and resources to prevent harmful chemicals from entering into our environment. Doing so will minimize risk to our environment and prevent health concerns in our communities.

Earlier this year, I cosponsored legislation with my colleagues Senator Feinstein and Senator Schumer that examines one chemical in particular, Bisphenol-A, better known as BPA. This chemical has gained a lot of attention lately because of recent scientific studies and possible links to breast cancer, obesity and neurological disorders. This fall, Administrator Jackson, you announced that BPA would be one of five chemicals included on an action list of chemicals of concern. My hope is that even with the current obstacles the EPA is facing under the current statute, that you will be able to proceed with this critical investigation.

As we consider ways to modernize TSCA, we must use the best science to dictate our efforts. We must learn from the failures of the past to ensure timely consideration and regulation of these chemicals. We must put forward the resources to ensure that regulators can do the work that Congress asks of them. We must work with industry to promote the development of new products that are both competitive in a global economy and safe for consumers.

I look forward to working with my subcommittee Chairman, Senator Lautenberg, and my fellow Senators as we develop the legislative text that will modernize this program and achieve the protections that the American people need.

Thank you.

[Additional material submitted for the record follows:]

TESTIMONY OF

PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE

AND

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

AND

THE HUMANE SOCIETY OF THE UNITED STATES, HUMANE SOCIETY INTERNATIONAL, HUMANE SOCIETY LEGISLATIVE FUND

BEFORE THE

US SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS AND ITS SUBCOMMITTEE ON SUPERFUND, TOXICS, AND ENVIRONMENTAL HEALTH

ON THE

TOXIC SUBSTANCES CONTROL ACT

DECEMBER 15, 2009

Kristie Sullivan, MPH
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave NW, Suite 400
Washington, DC 20016

Catherine Willett, PhD
People for the Ethical Treatment of Animals
500 Front Street
Norfolk, VA 23510

Martin Stephens, PhD
The Humane Society of the United States
2100 L Street, NW
Washington, DC 20037

Troy Seidle
Humane Society International
2100 L Street, NW
Washington, DC 20037

Sara Amundson
Humane Society Legislative Fund
519 C Street, NE
Washington, DC 20002

I. Introduction

While estimates of the number of chemicals in commerce differ, there could be environmental exposure to anywhere between 10,000 and 100,000 chemicals. Understanding the potential health and environmental risks posed by chemicals currently in the environment, while ensuring new chemicals are safe for use, presents a monumental challenge. For ethical, scientific, and practical reasons, this challenge cannot be met using toxicity test methods that use animals.

In order to effectively assess both existing and new industrial chemicals, we must reform the way in which toxicity testing is conducted, including the science used to evaluate chemicals. If carried out thoughtfully, reform of the Toxic Substances Control Act (TSCA) represents an unprecedented opportunity to implement an effective program of chemical assessment and management that is consistent with the National Academy of Sciences' recent landmark report presenting a vision and strategy for toxicity testing in the 21st Century (NRC, 2007). Without the committee's careful consideration of all stakeholders' concerns and subsequent careful drafting, TSCA reform could result in more ineffective chemical testing programs that waste time, money, and hundreds of thousands of animals while leaving human health and the environment unprotected.[1] Incorporation of the approach outlined in the NRC report is essential to creating a feasible and effective program. While some of the elements outlined in the report will require research and development before they can be implemented, a number of existing methods and approaches can be used now for prioritization.

The current TSCA Inventory contains approximately 80,000 chemicals; in order to review this number of chemicals over 10 years, the EPA would have to review approximately 6,000 – 8,000 chemicals each year (approximately 20 each day), at heavy expense to the taxpayer. Currently, the EPA's Office of Pollution, Prevention, and Toxics—the office that would be charged with implementing this legislation—reviews about 1000 pre-manufacture notices[2] each year – review of existing chemicals would be in addition to these PMN reviews.

Evaluation of this tremendous backlog of existing chemicals, as well as the generation of robust information regarding new chemicals, is simply not feasible under the current toxicity testing paradigm used by the EPA and other regulatory agencies. This paradigm is largely based on experiments on animals, particularly rodents, rabbits, and dogs, and uses methods that were developed as long ago as the 1930s and 40s - tests that are time-consuming, expensive, and in some cases use thousands of animals apiece. For example, a single two-generation reproductive toxicity study requires a minimum of two years, $380,000, and 2,600 animals. There are simply not enough laboratories in the world to conduct all the testing required in a reasonable time-frame. In addition, the current testing paradigm has a poor record of predicting effects in humans (Seidle and Stephens, 2009; Knight and Bailey 2006a, 2006b; Ennever and Lave 2003) and an even poorer record in leading to actual regulation of hazardous chemicals (Seidle 2006).

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[1] The High Production Volume Chemical Challenge Program is a recent example of a chemical testing program that has not resulted in better regulation of chemicals. For more information, please see the June 17, 1999 testimony by animal advocates before the Subcommittee on Energy and the Environment of the House Committee on Science (106th Congress, Serial No. 106-18).

[2] http://www.epa.gov/oppt/ar/2007-2008/reviewnewchem/index.htm

In light of these concerns, the Environmental Protection Agency (EPA) realized that the current toxicity testing paradigm is in urgent need of overhaul and requested the National Academy of Sciences' National Research Council (NRC) assess the current paradigm and recommend actions to improve it. The NRC Committee on Toxicity Testing and Assessment of Environmental Agents (NRC Committee)[3] set out to create a vision for the future of toxicity testing and a strategy that, once implemented, would improve the depth and breadth of toxicology and its usefulness as a predictive—and protective—science (Edwards and Preston 2008). *Toxicity Testing in the 21st Century: A Vision and Strategy* outlines such a vision, together with an initial roadmap for its implementation (NRC 2007). The NRC Committee envisions an iterative process of chemical characterization, toxicity testing, and dose-response and extrapolation modeling informed by population-based data and human exposure information. The report calls for the development of a suite of human-based *in vitro*[4] cell and tissue assays instead of whole-animal tests for hazard assessment and regulatory decision-making.

Not only would use of these new technologies increase the depth and breadth of information available about each chemical, they would dramatically decrease the time required to evaluate each substance. The result is that a vastly larger number of chemicals could be evaluated within a shorter period of time. This approach could also address currently intractable problems such as the toxic effects of chemical mixtures and nanoparticles, synergistic effects of chemicals, susceptibility of sensitive sub-populations, sensitivity at different life stages, gene-environment interactions, the need to test the effects of chemicals over wider dose ranges, and the effects of chemicals at very low, environmentally relevant doses (Gibb 2008). The conclusion of the report is that the reduced reliance on whole-animal testing leads to a more human-relevant and efficient toxicity testing paradigm, resulting in increased protections for people and the environment.

II. Short-Term Solutions

While the 2007 NRC report outlines a way forward that will take time to fully achieve, available methods and technologies can be applied to the prioritization of chemicals today (Andersen 2009). For example, *in vitro* or *in silico* models can be relied upon as a first "tier" in order to characterize the potential mechanisms of action of test chemicals. In another example, data from the EPA Office of Research and Development's ToxCast Program[5] has been used to create a prioritization scheme for detecting chemicals with the potential to interact detrimentally with the endocrine system.[6] Shaw et al. (2008) showed the feasibility of a similar process for prioritizing 50 different nanomaterials based on likely biological reactivity according to differences in material characteristics. Last year, scientists at the NIH Chemical Genomics Center (NCGC) published results of a mechanism-of-action study that used 26 assays in 13 different cell types to

[3] The Committee on Toxicity Testing and Assessment of Environmental Agents is an ad-hoc committee convened by the National Academies' National Research Council to create a vision and strategy for 21st-century toxicity testing at the request of the Environmental Protection Agency.

[4] *In vitro* refers to assays that take place in a culture dish or test tube.

[5] High-throughput systems capable of running hundreds of chemicals at many different doses through suites of different cell-based and biochemical assays are being used to generate information predictive of the modes of action of test chemicals, to create clusters of chemicals with similar mechanisms of action, and to prioritize chemicals for immediate investigation or regulation.

[6] Kavlock, Robert. Nov. 11, 2009. Presentation given at Johns Hopkins University School of Public Health, Center for Alternatives to Animal Testing, Chemical Information Day.

cluster 1,408 compounds given at 14 different concentrations according to mechanism of action. The results compared favorably with current information about the chemicals' toxic profiles, and provide support for such approaches (Huang et al. 2008).

Recent changes in chemical legislation in Europe, i.e. the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, has presented a similar challenge of scale (EC 2006). In an attempt to ensure that REACH is successful, European, American, and multi-national bodies such as the Organization for Economic Cooperation and Development (OECD), are working to further develop strategies to streamline toxicity testing and risk assessment. The REACH legislation also requires that animal tests be used only as a last resort, after all avenues to obtain the required information without animals (i.e. existing data, read-across from similar chemicals) have been exhausted.

In addition to the mandatory use of suitable non-animal testing methods, REACH includes:

- An emphasis on the acquisition and use of existing information
- Use of chemical categories with similar properties
- Use of weight-of-evidence approaches
- Incorporation of non-guideline test results in weight-of-evidence approaches
- Criteria for identifying situations where testing is not feasible
- Exemption of chemicals with no exposure potential

In addition to these sensible strategies, an international collaboration including the OECD is developing and standardizing computer algorithm-based models, known as Quantitative Structure Activity Relationship models (QSARs) for use in chemical assessment. These models can group and classify chemicals based on similar structure or activity profiles, help extend information about similar chemicals to substances with little data (known as bridging), and provide data for classification or risk assessment. Scientists and regulators influential to the REACH legislation are currently demonstrating how these models can—and must—be used in order to quickly assess chemical hazards in the scientific literature (Schaafsma et al. 2009; vanLeeuwen et al. 2009).

Incorporating these strategies into TSCA reform will allow the U.S. to take advantage of the experiences of other regions in regulating industrial chemicals and create the best and most protective policies.

III. Common-sense guidelines for chemical prioritization

A first step in implementing updated TSCA regulations will be setting priorities for assessment and regulatory action. We suggest the following guidelines when determining how to set priorities:

1. Review of TSCA inventory: It is important to get a true picture of the chemicals currently manufactured or imported within the U.S., and the current and near future use and exposure patterns, in order to evaluate and prioritize information needs.

2. Tabulate and review all existing data: Companies should submit to the EPA all unpublished studies for manufactured or imported chemicals relating to physical-chemical properties, environmental dispersal, toxicity, and human and environmental exposure. The EPA should also gather information from other governmental bodies, such as Health and Environment Canada and the European Chemicals Agency, and solicit any additional information from public sources.

3. Make regulatory determinations where possible: Using available data, make determinations of safe use or put necessary risk management controls in place where possible and warranted. Here, special emphasis should be placed on chemicals with known high exposure profiles or those with high potential to remain in the environment after an accidental release.

4. Group chemicals according to common modes of action or structural class: Assessing chemicals as members of scientifically-supported categories has several advantages, the strongest of which is that in some cases hazard information from one or more chemicals can be extrapolated to other members of the category lacking information. Methods mentioned in (5) can support the formation of categories, as can regulator or scientist experience.

5. Apply QSAR and high-throughput biological methods to prioritize chemicals and design integrated strategies for further testing, if warranted. For some chemicals, cellular and computation methods can be used to fill information needs; in other cases these methods can be used to detect priority chemicals and endpoints that require further study.

6. Determine and fulfill information needs according to exposure: Prioritization should be based on potential risk, including potential exposure. For example, chemicals that are produced within a verified closed system may not need extensive hazard information. In addition, a data "gap" is not necessarily a data "need," and the EPA should be given the flexibility to determine the information needed to make a regulatory decision without requiring a fixed list of data requirements that would apply comprehensively to all chemicals. Testing should be tailored to the chemical based on its toxicity profile and expected exposure. Testing beyond such a determination would waste time, money, and animal lives.

7. Prevent duplicative testing by providing incentives for data sharing. Companies should be required to form consortia and share data where appropriate, in order to prevent duplicative testing on the same chemical or category of chemicals.

8. Where appropriate, allow waivers for tests that are not practical to conduct or clearly redundant, such as inhalation testing of solid materials or aquatic testing for insoluble substances (Sandusky et al 2006).

IV. Ensure Implementation of New Technology

The next decade will see extensive development of new high-throughput and high-content cell, tissue, and computer-based toxicity testing methods. Any effective modernization of TSCA must allow for and encourage adoption of this evolving technology. By providing legislative support to this effort as it modernizes TSCA, Congress will also send a strong message: that more effective chemical regulation is dependent on more effective and humane testing methods. To do this, we urge the Congress to be mindful of the following considerations:

1. The principle of animal testing as a "last resort" should be a foundation of US policy.

2. Computational, cell and tissue-based methods can be used now to prioritize chemicals or groups of chemicals that are of primary concern. These methods can also be used to satisfy information needs for some chemicals. Further development and application of these methods for use in risk assessment should be encouraged in the new legislation.

3. New legislation should be flexible enough to allow the inclusion of new testing methods and Integrated Testing Strategies as they are developed, and should not prescribe a minimum data set/check-list of toxicity tests to which all substances must be subject.

4. New legislation should provide EPA with significant funding and organizational support, guidelines for an efficient and flexible peer review process, and clear benchmarks of success, to ensure rapid implementation of better testing methods.

5. New legislation should offer strong incentives for companies to fund, develop, and use new methods and testing strategies; and, as non-animal/alternative methods become available, require the use of such methods in place of animal tests.

V. Summary and Conclusion

As the NRC and EPA[7] both state, advances in computational and cellular technologies will allow more predictive and protective toxicological assessments of chemicals. While this vision is being progressively realized, existing methods and approaches can be used in addition to exposure variables, physical-chemical information, and existing knowledge to prioritize chemicals for regulation or further study.

Protecting human health and the environment is the critical goal of effective chemical regulation. In order to achieve this goal, it is necessary to reform chemical testing methods along with policy. The current toxicity-testing paradigm relies on animal testing and is slow, sometimes misleading, open to uncertainty and manipulation, and as a consequence of these factors, can not adequately protect human health. Prioritization of chemicals and endpoints to be tested, based on potential for hazard and exposure, is essential in order to avoid unmanageable bottlenecks that would further stymie environmental protections.

[7] See The U.S. Environmental Protection Agency's Strategic Plan for Evaluating the Toxicity of Chemicals, located at: http://www.epa.gov/spc/toxicitytesting/index.htm.

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