S. HRG. 111–1222

CURRENT SCIENCE ON PUBLIC EXPOSURES TO TOXIC CHEMICALS

HEARING

BEFORE THE

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

FEBRUARY 4, 2010

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CURRENT SCIENCE ON PUBLIC EXPOSURES TO TOXIC CHEMICALS

THURSDAY, FEBRUARY 4, 2010

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

The subcommittee met, pursuant to notice, at 10 a.m. in room 406, Dirksen Senate Office Building, Hon. Frank R. Lautenberg (chairman of the subcommittee) presiding.

Present: Senators Lautenberg, Inhofe, Udall, Vitter, Boxer, Klobuchar, and Whitehouse.

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

Senator LAUTENBERG. Welcome to our witnesses. We have a major matter of interest because we are really going to be working very hard to make sure that we are doing the best that we can to protect the lives and well-being of our human population. And I thank everyone for being here as we focus on protecting the health of our families by updating our chemical safety laws.

Now there is no question that chemicals are essential to our modern living. They are used in household cleaners to kill germs, they are used in medical equipment that saves lives, they even help fight global warming by creating insulation for homes, better components for wind turbines, and additives to make fuels cleaner.

But when we use these products the chemicals in them can end up in our bodies. So, in essence the American public has become a living, breathing repository for chemical substances. And when the chemicals used in flame retardants, plastics or rocket fuel show up in our children's bodies we have a potentially dangerous situation.

We can trace this problem back to current law that covers the safety of chemicals. That law, the Toxic Substances Control Act, or TSCA as it is known, fails to give EPA the tools it needs to protect against unsafe chemicals. In fact the Government Accountability Office has identified our current law as a high risk area of law.

In nearly 35 years TSCA has allowed EPA to test only 200 of the more than 80,000 chemicals in the products that we use every day. What is more, EPA has been able to ban only 5 substances on EPA's inventory of chemicals on the market.

With EPA unable to require adequate testing our children have become the test subjects. And we are seeing the results in a dra-

matic increase in childhood cancers, birth defects and hormonal problems across the population. Studies have found that as much as 5 percent of cancers, 5 percent of cancers, 10 percent of neural behavioral disorders, and 30 percent of asthma cases in children are associated with hazardous chemicals. Our children should not be used as guinea pigs. So, it is time to update the law and protect our children.

Led by a distinguished leader in Lisa Jackson—she is from New Jersey, I quickly mention—and Assistant Administrator Steve Owens, he is here with us today, the Environmental Protection Agency has taken steps to try to reduce the risks from chemicals. But they cannot protect our children with one hand tied behind their back.

And that is why I will soon introduce a bill that will overhaul our Nation's chemical laws. My Safe Chemicals Bill will have a simple goal: force chemical makers to prove that their products are safe before they end up in a store, in our homes, or in our bodies. We already regulate 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.

Everyone from the chemical manufacturers to businesses that use chemicals in their products to environmental, labor and health groups has called for a reform of our chemical laws. We cannot waste this opportunity.

I will be reaching out in the coming weeks to our colleagues, Democrats and Republicans alike, to support my Safe Chemicals Bill. It is a problem that affects all of us, and we should all be committed to working on this solution.

There is nothing more important in our lives than the health and well-being of our families, our children. There is a lot of susceptibility out there, and we are going to find out exactly what kind there is and what we can do to fight against it.

And I am pleased to have our colleague, the Ranking Member of the committee, Senator Inhofe.

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

Senator INHOFE. Thank you, my good friend Senator Lautenberg, for holding the hearing on the state of the science and human exposure of chemicals. We have talked about this for many years, and it is my understanding that this is the first of a series of hearings.

I am glad we are doing this. We have had nothing but global warming hearings for the last 2 years, and there are other issues that we need to get to. I say to my friend Steve Owens, we want to build some roads and some other things. So, I am glad that today we will hear the perspectives on scientific approaches for evaluating human exposure to chemicals.

In particular, I am interested in the discussion relating to biomonitoring, one of the scientific techniques used for assessing human exposure for natural and synthetic compounds in the environment. I believe that biomonitoring can be a useful tool in assessing the human chemical exposures, but it has its limits as it provides only information on exposure. It does not provide dosed information.

Simply put, the presence of a substance in the body at any level cannot be interpreted as being adverse. We go through this all the time. People say, oh, we cannot have any arsenic in water. And yet there is always arsenic in water. Everybody knows that. But the level is what we are concerned with. And you cannot start legislating these levels where the science is not there in terms of causing problems in human health.

I know in my State of Oklahoma we have so many people, Senator Lautenberg, in small communities, that we send those mandates out and we give them targets, I do not know if it is wastewater treatment or anything else, but it costs millions of dollars. You do not have a lot of the poor communities in New Jersey that we do in Oklahoma. And they just cannot do this. So, to me this panel is very important.

The most important thing in dealing with this is that we do it on sound science. And I just cannot tell you, we went through this thing with the IPCC, with the United Nations, for 10 years. I can remember 10 years ago, when I was the Chairman of this committee, when Republicans were the majority, and we looked at the false science. I can remember 4 years ago, Senator Lautenberg, I made a speech on the floor for about an hour, talking about the scientists who had come to me and said hey, this is cooked science.

Then 4 years later, right before Copenhagen, we find out in fact that is the case. ClimateGate came right before that and what happened yesterday and the day before, GlacierGate, AmazonGate, and all the rest of these things. What I am saying is it was cooked science, and this thing that we said some 4 years ago is exactly what happened.

So, I would hope that on this that we are very careful to make sure that we use sound science and do not overreact to something. I am glad that we have the witnesses that we have today, and I am looking forward to hearing their comments about what they are going to do, what their opinion is, in terms of the health effect that is out there and any health to our people.

That is what we are supposed to be doing up here, and that is what we are going to do, Senator Lautenberg.

[The prepared statement of Senator Inhofe follows:]

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

Thank you, Chairman Lautenberg, for holding this hearing on the state of the science of human exposures to chemicals. My understanding is that this is the first in a series of hearings leading up to a legislative debate on revision of the Toxic Substances Control Act (TSCA). I welcome the opportunity to discuss the strengths and weaknesses of the law and the science surrounding it.

Today we will hear perspectives on scientific approaches for evaluating human exposures to chemicals. In particular I am interested in the discussion related to biomonitoring—one of the scientific techniques used for assessing human exposures to natural and synthetic compounds in the environment.

I believe that biomonitoring can be a useful tool in assessing human chemical exposures. But biomonitoring has its limits as it provides only information on exposure; it does not provide dose information. Simply put the presence of a substance in the body at any level cannot be interpreted to mean that adverse effects will occur.

I hope the witnesses here today remain objective in their discussions of biomonitoring and avoid the temptation to rely on detection as a surrogate for risk. Misapplying biomonitoring data only serves to scare the public and in some cases advance political agendas. By invoking notions of "body burden" and "chemical tres-

pass" people who do not understand the limitations of biomonitoring are encouraged to reduce exposures to some substances that may increase rather than decrease their overall health risks. A perfect example is mothers refraining from breast feeding in order to avoid feeding their babies chemicals found, or that may be found, in breast milk. In almost all circumstances, the benefits of breast feeding exponentially outweigh any possible risks from the mere presence of a chemical in the milk. This same advice is given to nursing mothers by public health authorities.

For over 30 years TSCA has provided a scientifically sound framework for reporting, testing, tracking and restricting chemical substances and mixtures. As I have stated before I am open to the idea of modernizing the statute. But to the proponents of radical reform and supporters of the precautionary principle let me be very clear: my principles for any regulatory or statutory changes to TSCA must be based on the best available science, including risk assessment; must include cost-benefit considerations; must protect proprietary information; and must prioritize reviews for existing chemicals. Further, I will not support changes that encourage litigation, allow for activist enforcement, or that compel product substitution.

I look forward to hearing from the witnesses here today and to the upcoming debate on how best to modernize TSCA.

Senator LAUTENBERG. Thanks very much. I am particularly interested in this subject, as I am with anything that can protect our people and improve our general environment. My dad was 42 years old, worked in a mill, and he was a health enthusiast. He used to watch his diet, and in those days we called it workout in the gym, exercise. But he fell victim to cancer, as did his brother and as did their father, all three of them dying very young. My father was 43, and he was aware of the fact that there was danger in the mill, but he needed the job, and he stuck with it and paid a price for it. So that is deep in my thoughts.

Senator INHOFE. Senator Lautenberg, also in our State of Oklahoma, you know, you are familiar with the Tar Creek Superfund Site, the most devastating site in the Nation. We had people that went through the same thing that your father went through. These are lead and zinc mines. And we are to the point now where we can actually do something to preclude things like that from happening, and that is what we are talking about today.

Senator LAUTENBERG. Thank you.

Our colleague from New Mexico, Senator Udall.

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

Senator UDALL. Senator Lautenberg, thank you very much. I want to associate myself with your remarks. I think that you have really hit it on the head that we do not want to be experimenting with our young people, having them be guinea pigs in this experiment of putting more and more chemicals out into the environment and out in the ecosystems. So, I look forward to your piece of legislation that you are working on right now.

I am reminded by my very able staff that it was 50 years ago today, Senator Lautenberg, more or less in that range, Rachel Carson wrote the book A Silent Spring. It was such a powerful book, and it said so much about how we were treating the environment, how we were treating all of the living beings in the environment. And people at that point became galvanized, and they got behind the idea of Government protecting people in terms of these toxic and hazardous chemicals. And I think people probably believe today that the Government is weighing in and doing that on a regular basis.

Yet we have these national surveys, and I know there have been a lot of big national news stories, where if you take the blood of individuals in our society, there is a huge chemical, large number of chemicals, a chemical burden being carried by people. And that is something that worries me a lot.

I want our panels to go forward, so, at this point, I just want to thank you for working on this issue. And I agree with Senator Inhofe, our Ranking Member. Science is the key here. We should be taking the very best science.

But the Government should also be doing that work with the scientists, working with the universities, working with everybody out there that really knows the science. And then when we have the science, we put it into effect, and we protect the public. And I think that is the big gap that we have right now, would be my guess, if you ask many of the witnesses and the scientists around the country.

So, thank you for doing this. It is great to be here today with you, and I look forward to hearing from the panelists.

Senator LAUTENBERG. Thank you.

Senator Vitter, the Ranking Member of the subcommittee, we welcome your comments.

OPENING STATEMENT OF HON. DAVID VITTER, U.S. SENATOR FROM THE STATE OF LOUISIANA

Senator VITTER. Thank you very much, Mr. Chairman, and thank you for holding this hearing today.

The first thing I would like to do is simply ask unanimous consent that the written testimony of the National Petrochemical and Refiners Association and the Society of Chemical Manufacturers and Affiliates be submitted for the record.

Senator LAUTENBERG. Without objection.

[The referenced testimony follows:]

WRITTEN STATEMENT OF

NATIONAL PETROCHEMICAL & REFINERS ASSOCIATION (NPRA)

AS SUBMITTED TO THE

SUBCOMMITTEE ON SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH

Senate Committee on Environment and Public Works

on

"Current Science on Public Exposures to Toxic Chemicals"

February 4, 2010

Introduction

NPRA, the National Petrochemical & Refiners Association, appreciates the opportunity to submit written testimony for today's hearing examining the current scientific methods for determining the potential for exposure to certain substances. Our association includes more than 450 member businesses, including virtually all U.S. refiners and petrochemical manufacturers, their suppliers, and vendors. NPRA members supply consumers with a wide variety of products used daily in their homes and businesses, including fuels, lubricants, and chemicals that serve as building blocks for everything from plastics to clothing, medicine, and computers.

Background and Overview

NPRA considers the existing federal chemicals regulatory framework to be a strong foundation for the protection of consumer health and our environmental quality, while simultaneously allowing for the development of products that enhance our standard of living and safeguard all aspects of health, safety and the environment. NPRA and our members support a responsible update of the nation's chemicals risk management regulatory framework. Within that context, we understand the Subcommittee's interest in how the federal government examines the potential for exposure to certain substances.

1. Sound Science in Chemicals Management Policy

Scientific advances in key areas, such as analytical chemistry, genomics and predictive modeling are expected to eventually provide regulators with a new suite of tools with which to make informed regulatory decisions. Many refer to these breakthroughs as the "new science" and NPRA supports the exploration of how scientific breakthroughs can be used to develop regulatory tools that are based on sound, verifiable science. The unfortunate fact, however, is that sound science requires time. As exciting as the new science can seem, it *must always be held to the same level of scrutiny* as traditional scientific approaches. Traditional science should never be abandoned because of "new science," unless it can be *repeatedly* demonstrated that a newer approach achieves a more precise or accurate result than the traditional approach.

High degrees of scientific scrutiny are essential to distinguish between sound science and the latest "fad." Transparency and repeatability are the keys to sound science. Also included in NPRA's definition of sound science is the appropriate use of scientific discovery. The determination of the appropriate use of science requires peer validation from a wide variety of stakeholders in an open and transparent process. Anything short of a rigorous peer validation process runs the risk of accepting unfounded science as truth.

2. Risk Assessment in a Regulatory Setting

For chemicals there is a difference between the regulatory approach to risk evaluation and the academic approach. The objective of academic chemical risk assessment is to estimate with as much scientific certainty as possible the risk posed by a certain substance. The information requirements to reduce scientific uncertainty typically are burdensome and time-intensive. In contract, the purpose of regulatory risk assessment, particularly under the Toxic Substances Control Act (TSCA), is to use the results from the risk assessment process to protect human health and the environment in a reasonable and efficient manner. These two very different approaches have been viewed as being one and the same, which has led to confusion in public discussions regarding the implementation of TSCA.

Regulatory risk assessment must ensure protection of human health and the environment while reasonably guarding against politically-motivated and emotional decision-making, It must also be efficient to allow for the most effective use of scarce government resources. This requires an approach that is slightly different from traditional, academic risk assessment. While the goal of any risk assessment approach is to achieve as much scientific certainty as is practical, regulatory risk assessment should use a tiered and targeted approach that employs some measure of conservative assumption to maintain an appropriate level of protection.

The U.S. Environmental Protection Agency (EPA) realized decades ago, consistent with the findings of Congress, that it was not practical or logical to try to obtain extremely detailed information for all chemicals in commerce. For instance, chemicals used as intermediates or building blocks to make other chemicals should not be treated the same, from a risk perspective, as chemicals used in consumer products. Rather, EPA found that after an initial qualitative

analysis of how a chemical is used, and under what circumstances, risk assessors could quickly target certain areas for increased scrutiny, saving the Agency time and resources. In a similar manner, it would be wasteful and inconsiderate of animal welfare to expect a great deal of toxicity testing on each chemical in commerce. Instead, EPA begins with a semi-quantitative look at potential hazards through the comparison of the substance in question with other, known substances for which there are toxicity data.

After an initial determination of hazard and exposure potential, the Agency uses exposure information as the driver for new toxicity testing and hazard information as the driver for the level of detail on exposure. A closer look at each subsequent tier allows for increased scrutiny, yet minimizes the need to collect and process a great deal of information upfront without first establishing a need or purpose for that information. It is and should be an iterative process that employs conservative assumptions throughout.

When determining the potential public risk from certain chemicals, EPA should continue its well-founded, tiered and targeted approach. EPA should also continue to approach hazard and exposure assessments, the components that make up a full risk assessment, in a tiered and targeted manner.

3. Regulatory Exposure Assessment

In a regulatory setting, the potential for human exposure to a chemical is every bit as important to assess as the chemical's hazards. However, what is the appropriate level of detail in an exposure assessment that will enable a regulatory risk assessor to know if a chemical is being used safely? The correct answer will vary, according to how a substance is used and what is known about its hazards. Similar to the risk assessment approach, regulatory exposure assessment should be a tiered, targeted and iterative process.

The exposure assessment approach used by EPA is similar to approaches used around the world. In fact, under the Organization for Economic Cooperation and Development's Environment Programme, EPA works with scientists around the world to coordinate and, when possible, harmonize assessment approaches. Typically, the approach begins with qualitative descriptions

of how a chemical is used and the circumstances under which it is used. From there, regulators can easily discern general activity patterns associated with each use and focus on those that could result in the most significant degrees of exposure. EPA, similar to other regulatory authorities around the world, relies on conservative computer models to estimate potential exposures. The models employ somewhat unrealistic, but protective, assumptions and default values in the absence of specific environmental monitoring data. Many of the assumptions and values are the result of international consensus among scientists. Therefore, EPA only needs to know how a chemical is used to conservatively predict the extent to which a person or people could be exposed to it. The conservative default values and assumptions inherent in the exposure models allow an appropriate level of protection for human health and the environment, so the Agency does not have to sacrifice good information in the search for perfect information.

4. The Appropriate Use of Biomonitoring

Biomonitoring is an important and useful tool that should play a role in chemical risk prioritization; however, several fundamental principles must be considered in its application. First, due to the limitations of its data in determining sources of exposure, biomonitoring should not be considered indicative of, or the primary determinant of, a substance's potential to cause harm. Second, the Centers for Disease Control and Prevention (CDC) should be the focal point for selecting chemicals for biomonitoring, collecting biomonitoring information, and communicating results. Chemicals of anthropogenic origin identified to be present in human tissues and fluids as part of the CDC's biomonitoring program should be considered as one factor in the prioritization process. Trace amounts of chemicals found in the body may not be very helpful, however. In those cases, the biomonitoring data should be combined with other traditional exposure indicators. Third, any requirement for biomonitoring should have measurable public health goals as its fundamental foundation, and potential for human health risk should be the primary driver for the requirement of biomonitoring data. Finally, a substance that poses a high degree of risk to human health, or through its uses results in significant exposures, should be considered a priority candidate for biomonitoring.

NPRA supports the use of biomonitoring data to track levels of national priority chemicals, such as lead. While biomonitoring data cannot explain the origins of exposure, it can be a useful tool to determine trends in exposure.

Conclusion

NPRA and our members are committed to the protection of consumers and the environment and, to that end, are supportive of sound and sensible modifications to existing chemicals risk management regulations. As modifications to TSCA are discussed, we urge policymakers to take into account the important considerations we have raised with regard to exposure assessment and the application of biomonitoring data.

NPRA looks forward to discussions with Congress, EPA and other stakeholders on how to assess public exposures to chemicals.

February 3, 2010

The Honorable Barbara Boxer
Chair, Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510-6175

The Honorable James Inhofe
Ranking Member, Senate Committee on Environment and Public Works
456 Dirksen Senate Office Building
Washington, DC 20510-6175

Re: "Current Science on Public Exposures to Toxic Chemicals"

Dear Chairwoman Boxer and Ranking Member Inhofe:

On behalf of the Society of Chemical Manufacturers and Affiliates (SOCMA), I would like to share with you our perspective on the subject of your hearing this week: exposure to chemicals, with an emphasis on reforming the Toxic Substances Control Act (TSCA). Since 1921, SOCMA has served as the leading trade association representing the batch and custom chemical industry. SOCMA has over 300 member companies, which are typically small to medium-sized businesses, each with up to $100 million in annual sales. Our members make a $60 billion annual impact on the U.S. economy and contribute to the chemical industry's position as one of the nation's largest exporters.

Since the enactment of TSCA, technological advancements have greatly changed how we view chemicals management. We have seen the emergence of biotechnology and nanotechnology. Improvements in quantitative analytical chemistry have given us the ability to detect decreasingly low amounts of chemicals in the body, at the same time as there have been improvements in the detection of disease and illness. Equally important, media outlets have put increasing emphasis on reporting certain aspects of exposures to everyday chemicals and the internet has provided people with instant access to vast amounts of information. All of these factors have created a heightened awareness of – and fear about – chemical exposures, particularly among consumers and the general population.

SOCMA believes that the degree of this public concern about the health risks of chemical exposures is not justified by what we currently know. This is largely because most of the information people are provided does not accurately track the views of knowledgeable scientists. In a recent study by STATS and George Mason University's Center for Health and Risk Communication, nearly 1,000 surveyed toxicologists--scientists who study the adverse effects of

chemical or physical agents on living organisms--opined that recent media and nonprofit coverage of everyday chemical exposures vastly overstates their health risks. These scientists also overwhelmingly reject the notions that exposure to even the smallest amounts of harmful chemicals is necessarily dangerous or that the detection of any level of a chemical in your body by biomonitoring indicates some degree of health risk.

SOCMA agrees that we should act to fill the knowledge gaps that exist regarding chemical exposures and risks, and our members have been working hard to do so. Our industry has become increasingly involved in product stewardship, with a greater focus on chemical testing and basic research. Fortunately, these same efforts and new innovative techniques have also resulted in improvements in the physical sciences, an improved standard of living and, we believe, longer and healthier lives for everyone.

SOCMA supports efforts to update TSCA, which has had little Congressional oversight and not been fully implemented by EPA in its 30-year history. We also believe that reform will be most successful if it is fundamentally informed by science and a careful assessment of risk. TSCA reform must also be accomplished in a way that doesn't cripple a strategic American industry that is fighting recession and foreign competition. We believe this is possible, and we look forward to working with the Committee on this important task.

Sincerely,

William E. Allmond IV
Vice President, Government Relations & ChemStewards®

cc. Environment and Public Works Committee

Senator VITTER. Thank you.

Mr. Chairman, I want to echo several folks' words, including Senator Inhofe. You know, there is a lot of discussion about how do we balance ensuring human health and safety and a clean environment with competitiveness, et cetera. I think the answer is exactly what Senator Inhofe and others have been saying—sound science, complete focus on, complete reliance on, sound science above all else. In that spirit I want to quickly offer five points.

First, I believe EPA should redo their inventory of chemicals in commerce. There are not 80,000 chemicals in significant commerce as we often hear. The number is probably closer to one-fourth of that, and we need to home in on the true universe that we should be concerned about.

Second, a European Registration Evaluation and Authorization of Chemical Substances style program would likely kill innovation in the United States in my opinion and is a recipe for hamstringing small- and medium-sized manufacturers.

Third, to assume that REACH is the wave of the future is entirely premature and could actually impair human safety by preventing critical products, helpful products, from entering the marketplace.

Fourth, if the EPA decides to use any given study as a reason for limiting or terminating the use of a certain chemical the results of that study need to be repeatable and proven in further supporting studies.

And fifth, if the EPA is going to decide to utilize resources to re-review a chemical prior to the necessary review period I think that review, that re-review, should sure as heck be based on sound science and not some New York Times article that utilized politicized science from an environmental group attempting to scare the public. And I think that is exactly, unfortunately, what has happened with the herbicide atrozine.

I look forward to this discussion so that we do move forward with the complete focus on sound science.

Thank you, Mr. Chairman.

Senator LAUTENBERG. Thank you, Senator Vitter.

Now, we will hear from our panel, the first of whom will be Mr. Stephen Owens.

I would ask you to keep your remarks to 5 minutes or less. Our tolerance level is guided by the fact that we have a panel after you, and I know people are anxious to ask questions.

So, please, Mr. Owens.

STATEMENT OF STEPHEN OWENS, ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. OWENS. Thank you, Chairman Lautenberg, Ranking Member Inhofe and other members of the subcommittee. I want to thank you for the opportunity to be here and to discuss the need for reforming chemical risk management in this country.

As EPA Administrator Lisa Jackson testified before the full Environment and Public Works Committee last December the public does expect the Government to provide assurances that chemicals have been assessed with the best available science and that unac-

ceptable risks have been eliminated, and restoring confidence in our chemical management system is a top environmental priority for not only EPA but for the Obama administration.

The Toxic Substances Control Act, or TSCA as it is called, regulates chemicals in commerce. When TSCA was enacted in 1976, however, it grandfathered in the roughly 60,000 chemicals that existed at that time without any evaluation whatsoever. Manufacturers were not required to provide the data needed to adequately assess potential risks from these chemicals, and EPA was not given adequate authority to reevaluate existing chemicals as new concerns arose or as new scientific information became available.

And even for new chemicals manufacturers are not required to provide the data necessary to fully assess a chemical's risk without further action by EPA. And, even when EPA has adequate data on a chemical TSCA prevents us from taking quick and effective regulatory action.

Consequently, over the last 30 years, as you noted, Senator Lautenberg, EPA has been able to require testing on only around 200 of the nearly 84,000 chemicals currently listed on the TSCA inventory, and moreover to date only 5 chemicals have been regulated under TSCA's ban authority.

The Obama administration has articulated several principles for modernizing TSCA. 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.

Second, the responsibility for providing adequate health and safety data should rest on industry, and EPA should have the tools to obtain information from manufacturers without the delays and obstacles currently in place and without excessive claims of confidentiality.

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.

Fourth, EPA should have clear authority to review and act on priority chemicals in a timely manner with firm deadlines to maintain accountability.

Fifth, we must encourage innovation in green chemistry and support more sustainable chemicals and processes.

And finally implementation of the law should be adequately funded with manufacturers supporting the costs of agency implementation.

Because science has evolved substantially since TSCA was enacted 33 years ago we need to be able to take advantage of new approaches in modeling and testing methods that will assess risk more quickly and efficiently. With so many chemicals now being found in our bodies we need to better understand the implications of cumulative exposure to multiple chemicals. EPA's Office of Research and Development is developing computational tools that will help us address these questions and evaluate thousands of chemicals in less time and for less cost.

Because we know that legislation will take time Administrator Jackson has directed my office to use our current authority under

TSCA to the fullest extent possible to protect the American people and the environment.

As part of this effort in December we released action plans for several chemicals, phthalates, long-chain perfluorinated chemicals, polybrominated diphenyl ethers and short-chain chlorinated paraffins. We also are currently developing action plans on benzadine dyes and bisphenol A, otherwise known as BPA.

These chemicals were chosen for action by us on the basis of multiple factors including available hazard, exposure and use information, potential concern for children's health, use in consumer products, presence in human blood, persistent, bioaccumulative and toxic or PBT characteristics, toxicity, and their production volume. And we will use these criteria to select additional chemicals for future action plans as well.

We are moving forward to use the tools currently available to us to increase the public's access to chemical information as well. While there are certainly legitimate reasons why a company may sometimes need to claim confidentiality it is also clear that confidentiality claims have been made far too often by far too many companies in far too many ways. Indeed, of the roughly 84,000 chemicals included on the TSCA inventory the identity of more than 16,000 of these chemicals is currently classified as confidential. That is simply unacceptable.

To begin addressing this problem, last month we announced that companies will no longer be able to claim confidentiality for the identity of chemicals that present substantial health and environmental risks when those chemicals already are on the public portion of the TSCA inventory. Moreover, last summer we removed confidentiality for over 500 chemicals because the information claimed as confidential already had been made public elsewhere by companies.

Mr. Chairman, as we are taking action let me reemphasize our view that the current law simply is not sufficient to adequately protect the American people and the environment. It is time to bring TSCA into the 21st century.

Thank you again for the opportunity to be here, and I will be happy to answer any questions that you may have.

[The prepared statement of Mr. Owens follows:]

Testimony of Steve Owens
Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
before the
Subcommittee on Superfund, Toxics, and Environmental Health
Committee on Environment and Public Works
United States Senate
February 4, 2010

Chairman Lautenberg, Ranking Member Inhofe, and other members of the subcommittee, thank you for the opportunity to discuss exposure to toxic chemicals and the need for reform of this nation's chemicals management program.

As this Committee knows, EPA's mission is to protect human health and the environment. Ensuring that our citizens, and especially our children, are protected from exposure to unsafe levels of toxic chemicals and pollution or other environmental threats in their homes, schools, or communities is central to EPA's work. Simply put, protecting people from the adverse health effects that result from exposure to harmful chemicals is our job. As EPA Administrator Lisa Jackson recently testified before this committee, the public expects the government to provide assurance that chemicals which 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. Restoring confidence in our chemical management system is a top priority for EPA and a top environmental priority for the Obama Administration.

Chairman Boxer and Chairman Lautenberg, we stand ready to work with you and other Members of this committee to improve the safety of chemicals and restore the public's confidence in effective chemicals regulation. The public is rightly concerned that we are all being exposed to numerous chemicals without a clear understanding of the risks from those chemicals.

Administrator Jackson and I have both testified before Congress that EPA's authority is outdated and does not provide the tools to adequately protect human health and the environment. We believe there is a growing consensus that more needs to be done to improve our management of chemicals and reduce harmful exposures to chemicals.

Just this past December, the Centers for Disease Control, issued their most recent biomonitoring report on 212 chemicals, which reflects the levels of chemicals in our bodies. While this type of information does not provide a complete picture of environmental concerns and related health effects, it raises concern about exposure to harmful 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 at that time. 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.

As a result of the legal hurdles and procedural requirements TSCA places on EPA prior to collecting data, there are large, troubling gaps in the available data and state of knowledge on many widely used chemicals in commerce. Although there is a review process for new chemicals being introduced into commerce, chemical producers are not required to provide, without further action from EPA, the data necessary to fully assess a chemical's risks.

In the cases where EPA has adequate data on a chemical, and wants to protect the public against well-known risks to human health and the environment, there are legal hurdles that

prevent quick and effective regulatory action. Meanwhile, the public may be exposed to chemicals for which we have little understanding of the consequences.

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

The question before all of us is how we better identify chemical risks and take effective action to eliminate harmful chemical exposures. To begin with, we need better and more comprehensive information on chemicals. Due to the legal and procedural hurdles in TSCA, over the last 30 years, EPA has only been able to require testing on around 200 of the 84,000 chemicals on the TSCA Inventory. To date, only five existing chemicals have been regulated under TSCA's ban authority.

The Obama Administration's principles for how this law should be revised and modernized call for stronger and clearer authority for EPA to collect and act upon critical data regarding chemicals risks. To summarize those 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.

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 also provide business with the certainty 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 consideration of 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.

Over the past few decades, the United States has negotiated and signed international agreements that have the goal of protection of human health and the environment from toxic

chemicals, but has been unable to join these Conventions because of lack of domestic legislation to implement chemicals treaty commitments. The Obama Administration has identified the Rotterdam and Stockholm conventions as priority treaties for U. S. ratification. We believe that TSCA reform provides an opportunity for the consideration of implementing legislation for the Rotterdam and Stockholm conventions.

The science underlying our understanding of chemicals has evolved substantially since TSCA was enacted. Any standards we set must allow us to take advantage of new approaches in modeling and alternative testing methods that will give us the tools to better understand risks, more quickly and efficiently. Most importantly, we must look closely at the chemicals which may present unique health effects among sensitive populations, such as children. Data suggest that many commonly used chemicals can be found in our bloodstreams, and we need to better understand the implications of this cumulative exposure to multiple chemicals. Further we are taking advantage of advances in molecular biology and computer science that have the potential to transform chemical toxicity testing and provide the ability to rapidly screen environmental chemicals. EPA's Office of Research and Development is developing robust and flexible computational tools that will assist the Agency in evaluating thousands of chemicals. The goal of EPA's Computational Toxicology Research Program is to provide decision support tools for screening and assessing chemical exposure, hazard and risk, and to inform green chemical design. One such tool is ToxCast, a cost-effective approach for screening thousands of chemicals in less time and for less cost than animal studies. Bioactivity profiles and toxicity predictions from ToxCast are providing EPA regulatory programs with science-based information helpful in prioritizing chemicals for more detailed toxicological evaluations.

As legislative reform moves forward, Administrator Jackson has committed to enhancing the Agency's chemical management program, by utilizing our current authority under TSCA to the fullest extent possible to ensure that we do everything we can to protect the American people and the environment from dangerous chemicals. Fundamental reform is needed to fully

protect against chemical risks, but until then we will move forward aggressively under the existing law.

On December 30, as part of this effort, EPA posted an initial set of four action plans addressing phthalates, long-chain perfluorinated chemicals (PFCs), polybrominated diphenyl ethers (PBDEs), and short-chain chlorinated paraffins. We are also developing action plans on benzadine dyes and bisphenol-A (BPA), although those plans are not yet ready for public release. The action plans outline the concerns that the chemicals present and the actions the Agency intends to take to address those concerns, including for the first time, utilizing TSCA's authority to list chemicals of concern.

The chemicals selected for action plan development were chosen on the basis of multiple factors, including available hazard, exposure, and use information; potential concern for children's health; use in consumer products; presence in human blood; persistent, bioaccumulative and toxic characteristics; toxicity; and production volume. We plan to use these criteria for selecting additional chemicals for future action plans as well.
Last month, EPA also announced that several U. S. companies will undertake a three-year phaseout of decabromodiphenyl ether (DecaBDE), a substance that has been used as a flame retardant in consumer and other products. Studies have shown that DecaBDE persists in the environment, potentially causes cancer, and may impact brain function. DecaBDE also can degrade to more toxic chemicals that are frequently found in the environment and are hazardous to wildlife. EPA believes that the action by these companies is an appropriate and responsible step to protect human health and environment.

As I indicated earlier, increasing transparency needs to be part of the foundation of legislative reform but we are not waiting. We intend to use the tools currently available to us, to increase the public's access to chemical information. While we understand that there are, at times, legitimate reasons why a company may need to claim confidentiality, it is also clear that CBI claims are used too often, in too many areas. For example, under TSCA, companies are

required to submit health and safety information on substantial risk, and companies have frequently claimed the chemical name as CBI in these submissions. While the Agency has the information, the public version does not include the chemical name which obviously limits the value of that information. Indeed, of the roughly 84,000 chemicals included on the TSCA inventory, the identity of more than 16,000 of these chemicals is currently classified as confidential. That makes no sense.

To begin addressing this problem, earlier this month, we announced a policy shift to alert companies that we will reject confidentiality claims for chemicals that are on the public portion of the TSCA inventory. Moreover, this past July, in one of my first acts at the new Assistant Administrator, we took action to add 530 chemicals to the public portion of the TSCA Inventory which had previously been on the confidential portion because the CBI information had been made public in one form or another. Over the coming months, we intend to announce a number of actions that will further increase transparency and assure the safety of chemicals in this country.

While we have undertaken an effort to identify and take action on a number of chemicals that are commonly used in commerce and we are beginning to increase access to information, it is clear that increased regulatory and scientific attention needs to be focused. Simply put, the existing TSCA authorities are not adequate and there can be no substitute for meaningful reform of the underlying law. It is time to bring TSCA into the 21st century. EPA looks forward to working with this committee on this very important issue. I am now happy to answer questions.

Senator LAUTENBERG. Thank you very much, Mr. Owens.

Dr. Falk, we welcome your testimony.

STATEMENT OF HENRY FALK, M.D., MPH, ACTING DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION AND AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FALK. Thank you very much.

Good morning, Chairman Lautenberg, Senator Boxer, members of the subcommittee. My name is Henry Falk, and I am the Acting Director of the National Center for Environmental Health at the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry.

I am pleased to appear here today before the committee to discuss CDC's work in assessing people's exposure to chemicals. My testimony will focus on the Biomonitoring Program at CDC.

For at least three decades CDC has been assessing people's exposure to chemicals through biomonitoring, which is the direct measurement of chemicals or their metabolites in people, in their blood, urine and other tissues. It determines which chemicals and how much of them get into people after they have been exposed. CDC's Biomonitoring Program assesses the U.S. population's exposure to chemicals and conducts targeted studies to examine vulnerable populations.

CDC's Fourth National Report on Human Exposures to Environmental Chemicals was released in December 2009. Findings showed evidence of widespread exposure in the U.S. population to some commonly used commercial chemicals such as bisphenol A, BPA, the perfluorinated compound known as PFOA, and a type of fire retardant known as BDE-47. The report also noted continued progress in reducing children's exposure to lead.

The data in the exposure report provide unique exposure information to scientists, physicians and health officials to help identify and reduce or prevent exposures and potential health effects that may result from human exposure to chemicals.

Each year CDC's Environmental Health Laboratory works with States, other Federal agencies, academic institutions and international organizations on 50 to 70 studies that examine vulnerable populations, particularly newborns, children, pregnant women, and population groups or communities known or likely to have higher exposures.

For example one important current partnership is with the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. This partnership involves a pilot study of 525 pregnant women in which CDC is lending analytical and biomonitoring expertise. Scientists at CDC's Environmental Health Lab will measure chemicals in pregnant women's blood and urine and after delivery in the newborns' cord blood and mothers' breast milk. Cord blood is a promising way to assess prenatal exposure to certain chemicals. Urine, at times, is a better way to measure exposures to chemicals that pass through the body more quickly.

Biomonitoring is one important tool for identifying and preventing health problems. For example, biomonitoring has been a key tool in some landmark public health actions including the reduction of exposure to lead. CDC has been measuring lead since 1976. Lead is highly toxic, especially to young children, and can harm a child's brain, kidneys, bone marrow and other body systems. Our laboratory analysis showed that the American population's blood lead levels were declining in parallel with declining levels of lead in gasoline, providing critical support for the Environmental Protection Agency regulations that reduced lead in gasoline.

CDC results for the period from 1999 through 2004 show that only 1.4 percent of children age 1 to 5 had elevated blood lead levels. At one time there was actually 88 percent, in the late 1970s. This progress is a direct result of collaborative efforts by CDC, EPA, NIEHS and others.

In conclusion, biomonitoring provides solid human data that can assist in making important health decisions. Better exposure information means that we can make better decisions to protect the health of the public.

We are fully committed to continuing our work with other Federal agencies and partners to improve the uses and benefits of biomonitoring.

And with that, thank you very much.

[The prepared statement of Dr. Falk follows:]

Testimony before the Subcommittee on Superfund, Toxics and Environmental Health
Committee on
Environment and Public Works
United States Senate

Current Science on Public Exposures to Toxic Chemicals

Statement of

Henry Falk, MD, MPH
Acting Director,
National Center for Environmental Health,
Centers for Disease Control and Prevention; and
Agency for Toxic Substances and Disease Registry
U.S. Department of Health and Human Services

CDC
SAFER • HEALTHIER • PEOPLE™

For Release on Delivery
Expected at 10 a.m.
February 4, 2010

Introduction

Good morning Mr. Chairman and Members of the Subcommittee.

My name is Dr. Henry Falk, and I am the Acting Director of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC), and of the Agency for Toxic Substances and Disease Registry (ATSDR).

I am pleased to appear today before the Subcommittee to discuss CDC's work in assessing people's exposure to chemicals. My testimony will focus on the biomonitoring program at CDC, and public health uses of biomonitoring.

For approximately three decades, CDC has been using biomonitoring to assess human exposure to selected chemicals (both manmade and naturally occurring). Biomonitoring is the direct measurement of chemicals and naturally occurring compounds or their metabolites in people's blood, urine or tissue. It determines which chemicals—and how much of them—get into people after they have been exposed.

CDC's Biomonitoring Program

I will describe two aspects of CDC's biomonitoring program: assessment of the U.S. population's exposure to chemicals, and targeted studies to examine exposure in vulnerable populations.

How CDC assesses the U.S. population's exposure to chemicals: CDC's Environmental Health Laboratory measures chemicals or their metabolites in blood and urine samples from participants in the National Health and Nutrition

Examination Survey (NHANES). NHANES, which is conducted by CDC's National Center for Health Statistics, involves a complete physical exam, a detailed questionnaire that collects more than 1,000 pieces of information, and the collection of blood and urine samples. The survey, which is nationally representative of the U.S. population, has been conducted multiple times since the 1970s and became a continuous survey in 1999 with two-year survey cycles. With some exceptions, most urine measurements are done in participants ages 6 years and older, and most serum measurements are done in participants age 12 years and older. Thus, the exposure information it provides on young children is limited, mostly due to the difficulty in obtaining large enough blood and urine samples from them. Currently blood levels of lead, cadmium, and mercury are measured in children aged 1 year and older, and cotinine, which is a marker for environmental tobacco smoke exposure, is measured in children aged 3 years and older.

CDC scientists publish significant biomonitoring findings from NHANES in peer-reviewed publications, and then CDC periodically publishes a summary report, the National Report on Human Exposure to Environmental Chemicals. The Fourth Exposure Report was released in December 2009, and summarizes blood and urine levels for 212 chemicals, including levels for 75 chemicals which had never before been measured in a representative sample of the U.S. population. Findings show evidence of widespread exposure in the U.S. population to some commonly-used commercial chemicals such as bisphenol-A (BPA), the perfluorinated compound known as PFOA, and a type of fire retardant known as BDE-47. The Fourth Exposure Report also notes continued progress in reducing

children's exposure to lead.

The data in the Fourth Exposure Report provide unique exposure information that can be used by scientists, physicians, and health officials for a variety of public health purposes, such as to: determine which chemicals get into Americans' bodies and at what concentrations; determine what proportion of the population has levels above those associated with adverse health effects for chemicals with a known toxicity level; establish reference values that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure; track over time trends in levels of exposure of the population; assess the effectiveness of public health efforts to reduce exposure of Americans to specific chemicals; determine whether exposure levels are higher among minorities, children, women of childbearing age, or other special groups; and direct priorities for research on human health effects from exposure.

Chemicals analyzed from the NHANES samples and reported in the Fourth Report were selected based on known or hypothesized exposure in the U.S. population; scientific data on the health effects known or thought to result from some levels of exposure; the need to assess the efficacy of public health actions to reduce exposure to a chemical with known health effects; the availability of an analytical method that is accurate, precise, sensitive, and specific; the availability of adequate blood or urine samples from the NHANES survey; and the analytical cost to perform the analysis. Also, CDC has solicited suggestions for candidate chemicals from the public and other government agencies.

Targeted studies: Each year CDC's Environmental Health Laboratory works with states, other federal agencies, academic institutions and international organizations on 50-70 studies that examine vulnerable populations, particularly newborns, children, pregnant women and population groups or communities known or likely to have higher exposures. For example, one important current partnership is with the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. This partnership involves a pilot study of 525 pregnant women in which CDC is lending analytical and biomonitoring expertise. Scientists at CDC's Environmental Health Lab will measure chemicals in pregnant women's blood and urine and, after delivery, in the newborn's cord blood and mother's breast milk. Cord blood is a promising way to assess prenatal exposure to certain chemicals. However, cord blood is not the best way to measure exposures to chemicals that pass through the body more quickly; these generally are best measured in urine.

Public Health Uses

As distinguished from measurements in environmental samples, such as air, soil, water, food, and consumer products, biomonitoring measurements have the advantage of indicating the amount of a chemical that actually gets into people, rather than extrapolating from measurements of environmental media. Although biomonitoring is far ahead of the science of interpreting what exposures mean for health, biomonitoring data is valuable, and CDC uses it for a range of public health purposes, including to establish reference ranges in the population and to identify groups of people with higher levels of exposure than those typical for the

U.S. population. In addition, by tracking exposures in the U.S. population, we can detect trends in people over time, and assess whether a chemical is present in large numbers of people, or is disproportionately present in vulnerable subgroups, such as children. This information can be used by scientists and policy makers as one of the considerations in setting priorities for evaluating health impacts of chemicals. Biomonitoring thereby serves as one important tool in identifying and reducing or preventing exposures and potential health problems.

A National Research Council review of biomonitoring noted that it has been a key tool in some landmark public health actions (NRC, 2006). One example is lead. Our laboratory has been measuring lead in the NHANES blood samples since 1976. Many of the effects of lead can be benchmarked to blood lead concentrations. Lead is highly toxic, especially to young children, and can harm a child's brain, kidneys, bone marrow, and other body systems. It can cause decrements in cognitive ability and IQ and at very high levels can cause coma, convulsions, and death.[1] Our laboratory analysis of the NHANES samples, which showed that the American population's blood lead levels were declining in parallel with declining levels of lead in gasoline, provided critical support for the Environmental Protection Agency (EPA) regulations that reduced lead in gasoline (GAO, 2000). CDC and EPA have used this decline in blood lead levels over time to demonstrate that the removal of lead from gasoline had a dramatic impact on the levels of lead in the U.S. population. Today, the most common source of children's exposure to lead is from dust and soil derived from lead-based paints in older homes.[2] In the late 1970s, CDC used the NHANES data to document

that 88 percent of children had blood lead levels above 10 µg/dL, the current level of concern. Data from the Fourth Exposure Report demonstrate that collaborative public health efforts by CDC, EPA, NIEHS, the Department of Housing and Urban Development, and others reduced children's exposure to lead. For the period 1999–2004, only 1.4% of children aged 1 to 5 years had elevated blood lead levels.

Biomonitoring also can be used to monitor the effectiveness of interventions designed to reduce exposures. In the early 1990s, our laboratory analysis of cotinine data from NHANES showed that 88 percent of the nonsmoking population was exposed to secondhand tobacco smoke. This finding was used by state and local areas as a justification for restricting smoking in public places. Over the past 15 years, NHANES data have shown that exposure to secondhand smoke in nonsmokers has decreased about 70 percent, indicating that public health interventions to reduce exposure have been successful.

Conclusion

In conclusion, biomonitoring provides solid human data that can assist in making important health decisions. Better exposure information means that we can make better decisions to protect the health of the public.

CDC is fully committed to working with other federal agencies and partners to improve the uses and benefits of biomonitoring. Thank you Mr. Chairman and members of the Subcommittee. I look forward to answering any questions you may have.

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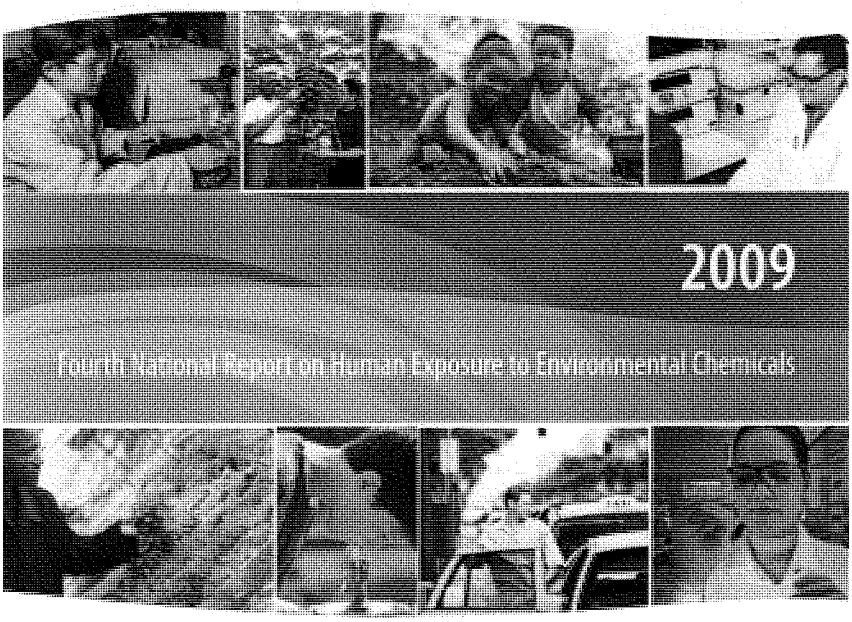
Fourth National Report on Human Exposure to Environmental Chemicals: http://www.cdc.gov/exposurereport/

NHANES Web Site: http://www.cdc.gov/nchs/nhanes.htm

[1] *Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards*. Washington, DC: President's Task Force on Environmental Health Risks and Safety Risks to Children; 2000.

[2] Lanphear BP, Roghmann KJ. Pathways of lead exposure in urban children. Environ Res. 1997;74(1):67-73

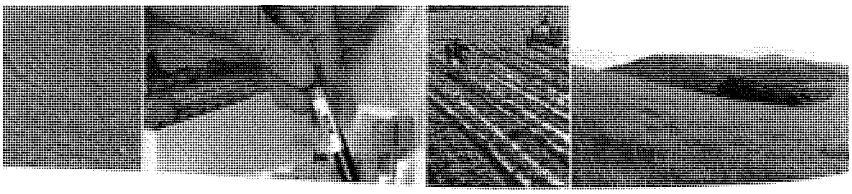


2009

Fourth National Report on Human Exposure to Environmental Chemicals

Executive Summary

Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Environmental Health



Background

The *National Report on Human Exposure to Environmental Chemicals (National Exposure Report)* is a series of ongoing assessments of the U.S. population's exposure to environmental chemicals by measuring chemicals in people's blood and urine, also called biomonitoring. The *Fourth National Report* on *Human Exposure to Environmental Chemicals* (*Fourth Report*) presents exposure data for 212 environmental chemicals for the civilian, noninstitutionalized U.S. population. This *Fourth Report* includes results from 2003–2004, as well as data from1999–2000 and 2001–2002 as reported in the *Second* and *Third National Report on Human Exposure to Environmental Chemicals.*

To obtain data for this *Fourth Report*, the Centers for Disease Control and Prevention (CDC)'s Environmental Health Laboratory at the National Center for Environmental Health measured chemicals or their metabolites in blood and urine from a random sample of participants from the National Health and Nutrition Examination Survey (NHANES). CDC's National Center for Health Statistics conducts NHANES, which is a series of surveys on the health status, health-related behaviors, and nutrition of the U.S. population. Since 1999, NHANES has been conducted in continuous two-year survey cycles.

For the *National Exposure Report*, an environmental chemical refers to a chemical compound or chemical element present in air, water, food, soil, dust, or other environmental media, such as consumer products. Blood and urine levels reflect the amount of the chemical that actually gets into the body from the environment. Either the chemical or its metabolite is measured. A metabolite is a substance produced when body tissues chemically alter the original compound.

The *Fourth Report* includes results for 75 chemicals measured for the first time in the U.S. population. These chemicals are in the following groups:

- acrylamide and glycidamide adducts;
- arsenic species and metabolites;
- environmental phenols, including bisphenol A and triclosan;
- perchlorate;
- perfluorinated chemicals;
- polybrominated diphenyl ethers;
- volatile organic compounds; and
- some additions to chemical groups previously measured.

A complete listing of the 75 new chemicals is given on page 10. A full listing of the chemicals included in the *Fourth Report* is available at http://www.cdc.gov/exposurereport/pdf/NER_Chemical_List.pdf.

Interpreting the Data

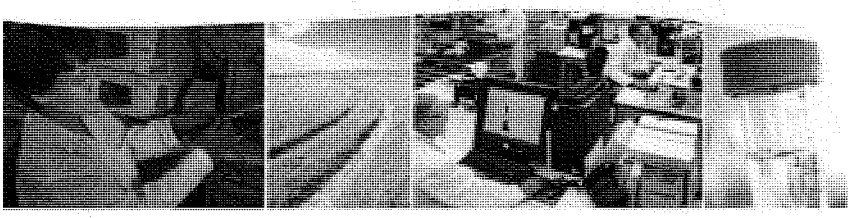
The presence of an environmental chemical in people's blood or urine does not mean that it will cause effects or disease. The toxicity of a chemical is related to its dose or concentration, in addition to a person's individual susceptibility. Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects. Research studies, separate from the *National Exposure Report*, are required to determine the levels of a chemical that may cause health effects and the levels that are not a significant health concern. For some chemicals, such as lead, research studies provide a good understanding of health risks associated with various blood levels. For most of the environmental chemicals included in the *Fourth Report*, more research is needed to determine whether exposure at the levels reported is a cause for health concern. CDC conducts and provides biomonitoring measurements for this type of research in collaboration with other agencies and institutions.

The *Fourth Report* presents data that provides estimates of exposure for the civilian, noninstitutionalized U.S. population. The current survey design does not permit CDC to estimate exposure on a state-by-state or city-by-city basis. For example, CDC cannot extract a subset of data and examine levels of blood lead that represent a state population.

Public Health Uses of *the Fourth Report*

The *Fourth Report* provides unique exposure information to scientists, physicians, and health officials to help prevent effects that may result from exposure to environmental chemicals. Specific public health uses of the exposure information in the *Fourth Report* are to:

- determine which chemicals get into Americans' bodies and at what concentrations;
- determine what proportion of the population has levels above those associated with adverse health effects for chemicals with a known toxicity level;
- establish reference values that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure;
- assess the effectiveness of public health efforts to reduce exposure of Americans to track levels over time;
- determine whether exposure levels are higher among minorities, children, women of childbearing age, or other special groups; and
- direct priorities for research on human health effects from exposure.



Key Highlights and Findings

First-Time Exposure Information for the U.S. Population Provided for 75 Chemicals

The *Fourth Report*, for the first time, provides population reference values in blood and urine, including 95th percentile levels, for 75 chemicals. The 95th percentile level means that 95% of the population has concentrations below that level. Public health officials use such reference values to determine whether groups of people are experiencing an exposure that is unusual compared with an exposure experienced by the rest of the population.

To provide scientists and public health officials these new data quickly, CDC published much of this exposure information on new chemicals in separate scientific peer-reviewed publications before the *Fourth Report* was released. Abstracts and links to full-text articles are available at http://www.cdc.gov/exposurereport/.

Widespread Exposure to Some Industrial Chemicals

Findings in the *Fourth Report* indicate widespread exposure to some commonly used industrial chemicals.

- Polybrominated diphenyl ethers are fire retardants used in certain manufactured products. These accumulate in the environment and in human fat tissue. One type of polybrominated diphenyl ether, BDE-47, was found in the serum of nearly all of the NHANES participants.
- Bisphenol A (BPA), a component of epoxy resins and polycarbonates, may have potential reproductive toxicity. General population exposure to BPA may occur through ingestion of foods in contact with BPA-containing materials. CDC scientists found bisphenol A in more than 90% of the urine samples representative of the U.S. population.
- Another example of widespread human exposure included several of the perfluorinated chemicals. One of these chemicals, perfluorooctanoic acid (PFOA), was a byproduct of the synthesis of other perfluorinated chemicals and was a synthesis aid in the manufacture of a commonly used polymer, polytetrafluoroethylene, which is used to create heat-resistant non-stick coatings in cookware. Most participants had measurable levels of this environmental contaminant.

Ongoing Progress in Reducing Blood Lead Levels in Children

Progress is being made in reducing children's blood lead levels. New data on blood lead levels in children aged 1 to 5 years enable estimates of the number of children with elevated levels (that is, levels greater than or equal to 10 micrograms per deciliter [µg/dL]). Figure 1 shows how the percentage of blood lead levels in children has declined since the late 1970s. For example, for the period 1999–2004, 1.4% of children aged 1 to 5 years had elevated blood lead levels, the smallest percentage of any of the prior survey periods.

These data document that public health efforts to reduce the number of children with elevated blood lead levels in the general population continue to be successful. However, the *Fourth Report* also notes that other data sources show that special populations of children at high risk for lead exposure (for example, children living in homes containing lead-based paint or lead-contaminated dust) have higher rates of elevated blood lead levels and remain a major public health concern.

First-Time Assessment of Acrylamide Exposure in the U.S. Population

Acrylamide is formed when foods containing carbohydrates are cooked at high temperatures (e.g., French fries) and as a byproduct of tobacco smoke. Most people are exposed to acrylamide through the diet and from smoking. Because acrylamide is a reactive chemical, it can bind to proteins. These reaction products are called adducts. CDC's Environmental Health Laboratory developed a new method to measure acrylamide and its metabolite, glycidamide, as adducts of hemoglobin, a major blood protein. This measure reflects the dose of acrylamide and glycidamide over the previous several months of intake. The data in the *Fourth Report* show that acrylamide exposure is extremely common in the U.S. population.

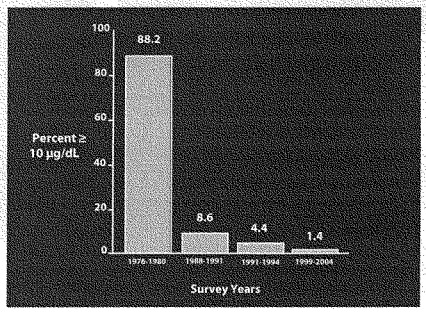


Figure 1. Percentage of children 1-5 years old in the U.S. population with elevated blood lead levels (≥ 10 µg/dL).[1]

[1] *Jones RL, Homa DM, Meyer PA, Brody DJ, Caldwell KL, Pirkle JL, Brown MJ. Trends in blood lead levels and blood lead testing among U.S. children aged 1 to 5 years, 1988–2004. Pediatrics 2009;123(3):e376-e385.*

First Available Exposure Data on Mercury in the U.S. Population

For the first time, the *Fourth Report* characterizes mercury exposure of the U.S. population aged 1 year and older. Previous *National Exposure Reports* presented mercury levels for children 1–5 years old and women 16–49 years old. Total blood mercury levels are primarily composed of one type of mercury, methyl mercury, which enters the body mainly from dietary seafood sources. Findings in the *Fourth Report* show that total blood mercury levels increase with age for all groups and begin to decline after the fifth decade of life. Compared to older women of childbearing age, younger women have higher birth rates and lower mercury levels (see Figure 2).

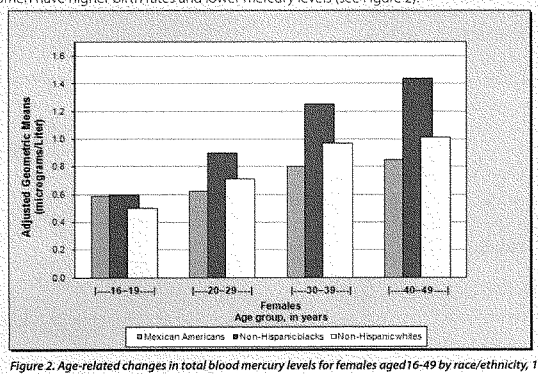


Figure 2. Age-related changes in total blood mercury levels for females aged 16-49 by race/ethnicity, 1999-2006.[2]

Eight Different Species and Metabolites of Arsenic Measured

By using special laboratory methods, CDC researchers measured total arsenic and seven other forms of arsenic in the urine of NHANES participants for the first time. Some of the forms of arsenic measured are metabolites of inorganic arsenic and others are less toxic species that are formed in the environment. By differentiating these types of arsenic exposure, the *Fourth Report* helps scientists understand which forms of arsenic are important to human health.

[2] *Caldwell KL, Mortensen ME, Jones RL, Caudill SP, Osterloh JD. Total blood mercury concentrations in the U.S. population: 1999-2006. Int J Hyg Environ Health 2009;212:588-598.*

Perchlorate and Thyroid Function

The chemical perchlorate is both naturally occurring and manmade and is used to manufacture fireworks, explosives, flares, and rocket propellant. For decades, scientists have known that large medical doses of perchlorate affect thyroid function. Low-level exposure to perchlorate from the environment has been under investigation by many scientists in recent years. The *Fourth Report* shows that all NHANES participants have detectable perchlorate in their urine and provides reference values for urinary perchlorate levels (see Table 1). This knowledge helps scientists target the levels of human exposure for future study.

Urinary Perchlorate

Geometric mean and selected percentiles of urine concentrations (in µg/L) for the U.S. population from the National Health and Nutrition Examination Survey.

	Survey years	Geometric mean (95% conf. interval)	Selected percentiles (95% confidence interval) 50th	75th	90th	95th	Sample size
Total	01-02	**3.54** (3.29-3.81)	**3.70** (3.50-4.00)	**6.30** (5.80-6.90)	**10.0** (9.10-11.0)	**14.0** (11.0-17.0)	2820
	03-04	**3.22** (2.93-3.55)	**3.30** (2.90-3.80)	**5.50** (5.00-6.40)	**9.50** (8.40-11.0)	**13.0** (12.0-15.0)	2522
Age group							
6-11 years	01-02	**4.93** (4.22-5.76)	**5.20** (4.40-6.40)	**8.10** (6.90-9.80)	**12.0** (9.30-19.0)	**19.0** (12.0-23.0)	374
	03-04	**4.32** (3.67-5.09)	**4.60** (4.00-5.20)	**7.90** (5.70-9.50)	**13.0** (8.81-16.0)	**16.0** (11.0-29.0)	314
12-19 years	01-02	**3.80** (3.44-4.20)	**4.40** (3.80-4.80)	**6.80** (6.30-7.30)	**10.0** (8.90-11.0)	**13.0** (11.0-17.0)	828
	03-04	**3.62** (3.19-4.12)	**3.80** (3.20-4.40)	**6.40** (5.50-7.10)	**9.80** (7.90-12.0)	**13.0** (10.0-18.0)	721
20 years and older	01-02	**3.35** (3.08-3.65)	**3.50** (3.20-3.70)	**5.90** (5.30-6.60)	**10.0** (8.70-11.0)	**13.0** (11.0-17.0)	1618
	03-04	**3.05** (2.75-3.38)	**3.20** (2.70-3.60)	**5.20** (4.70-6.10)	**9.10** (7.90-10.0)	**12.0** (11.0-14.0)	1487
Gender							
Males	01-02	**4.19** (3.93-4.46)	**4.40** (4.20-4.50)	**7.10** (6.40-7.90)	**11.0** (9.70-12.0)	**14.0** (11.0-19.0)	1335
	03-04	**3.75** (3.39-4.16)	**3.90** (3.40-4.40)	**6.40** (5.60-7.50)	**11.0** (9.20-12.0)	**14.0** (13.0-17.0)	1229
Females	01-02	**3.01** (2.74-3.31)	**3.10** (2.70-3.40)	**5.40** (5.00-6.00)	**9.20** (8.20-11.0)	**13.0** (11.0-17.0)	1485
	03-04	**2.79** (2.49-3.11)	**2.90** (2.50-3.20)	**4.90** (4.40-5.50)	**8.20** (6.90-9.84)	**11.0** (8.80-15.0)	1293
Race/ethnicity							
Mexican Americans	01-02	**4.02** (3.47-4.66)	**4.40** (3.70-5.00)	**7.10** (5.80-8.40)	**12.0** (9.40-13.0)	**14.0** (12.0-18.0)	708
	03-04	**3.76** (3.45-4.11)	**3.96** (3.50-4.40)	**6.20** (5.30-7.50)	**11.0** (9.10-12.0)	**15.0** (12.0-17.0)	617
Non-Hispanic blacks	01-02	**3.51** (3.07-4.03)	**3.70** (3.10-4.10)	**5.90** (5.10-7.00)	**9.20** (7.80-12.0)	**15.0** (11.0-20.0)	681
	03-04	**3.21** (2.90-3.56)	**3.20** (2.87-3.50)	**5.40** (4.60-6.30)	**8.60** (7.50-11.0)	**13.0** (9.30-17.0)	652
Non-Hispanic whites	01-02	**3.51** (3.18-3.88)	**3.70** (3.40-4.10)	**6.30** (5.70-7.10)	**10.0** (8.90-11.0)	**14.0** (11.0-18.0)	1228
	03-04	**3.26** (2.89-3.68)	**3.30** (2.80-4.00)	**5.60** (4.90-6.80)	**9.40** (8.10-11.0)	**13.0** (11.0-15.0)	1092

Limit of detection (LOD, see Data Analysis section in full *Report*) for Survey years 01-02 and 03-04 are 0.05 and 0.05. For the 2001-2002 Survey period, surplus samples were used, and data are unavailable at NHANES website.

***Table 1. Urinary Perchlorate as provided in the* Fourth Report.**

Reduced Exposure to Environmental Tobacco Smoke

Environmental tobacco smoke (ETS) has significant health effects on cardiovascular and respiratory disease. Cotinine is a metabolite of nicotine, and for nonsmokers, levels of cotinine in people's blood tracks exposure to ETS. In the past 15 years, data show that blood cotinine levels for nonsmokers in the U.S. population have decreased about 70%, indicating that public health interventions to reduce ETS exposure have been successful.

U.S. Population's Exposure to Volatile Organic Compounds

People are exposed every day to volatile chemicals in the air we breathe. The *Fourth Report* provides measurements on 33 of these hydrocarbon and halohydrocarbon-type chemicals. One example is the gasoline additive methyl *tert*-butyl ether (MTBE). Exposure to this chemical can occur through the air we breathe or from contaminated water sources. A high percentage of the NHANES participants representing the U.S. population showed detectable levels of MTBE.

Exposure to Cadmium

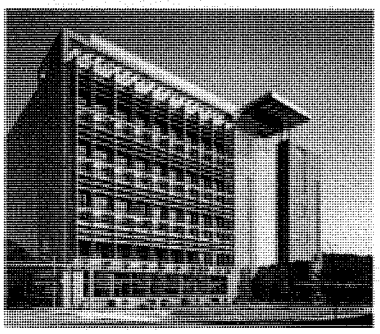
Recent research studies show that urine cadmium levels as low as 1 microgram per gram of creatinine in people may be associated with subtle markers of effects on the kidney and with an increased risk for low bone-mineral density. The *Fourth Report* shows that about 5% of the U.S. population aged 20 years and older has urinary cadmium levels at or near these levels. Cigarette smoking is the most likely source for these higher cadmium levels. These findings should promote further research on the public health consequences of cadmium in people.

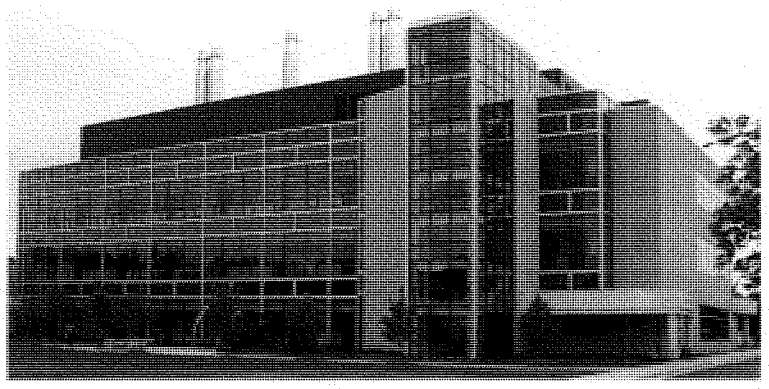
Selection of Chemicals for the *Fourth Report*

Plans for Future *National Exposure Reports*

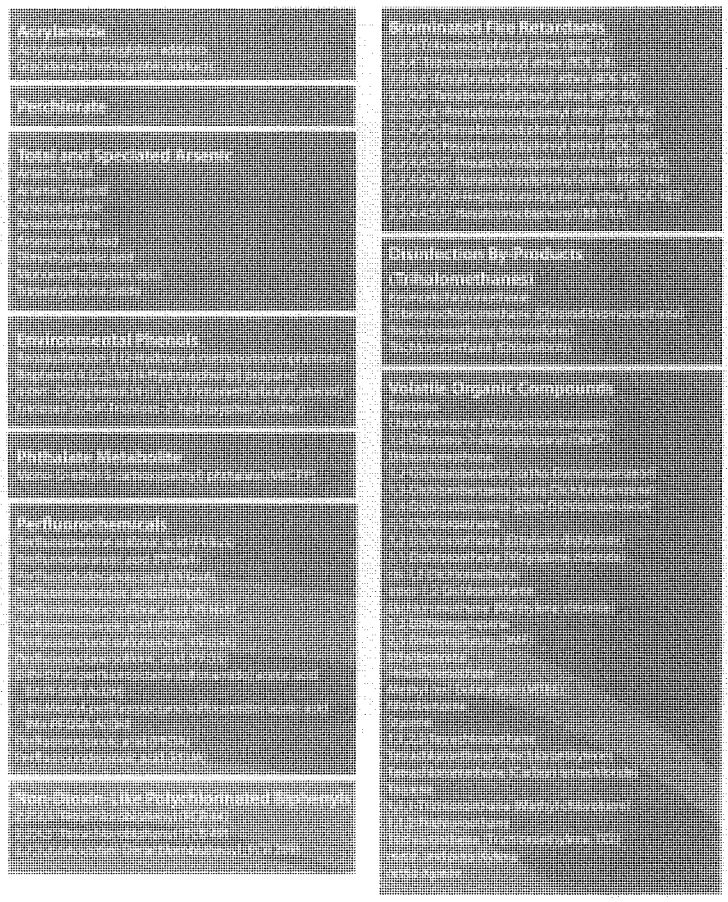
About CDC's Environmental Health Laboratory

By using advanced laboratory science and innovative techniques, CDC's Environmental Health Laboratory at the National Center for Environmental Health has been at the forefront of efforts to assess people's exposure to environmental chemicals. CDC's laboratory scientists have built on more than three decades of experience in measuring chemicals directly in people's blood or urine, a process known as biomonitoring. Biomonitoring measurements are the most health-relevant assessments of exposure because they measure the total amount of the chemical that actually gets into people from all environmental sources (e.g., air, soil, water, dust, or food). With a few exceptions, the concentration of the chemical in people provides the best exposure information for public health officials to evaluate the potential for adverse health effects.





New Chemicals in the *Fourth Report*



Centers for Disease Control and Prevention
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Website: http://www.cdc.gov/exposurereport

Dr. Henry Falk, CDC/ATSDR
Response to Questions for the Record
Senate Environment and Public Works Committee
Hearing on health impacts of toxic exposures
February 4, 2010

Senator Amy Klobuchar

1. One naturally occurring toxin, Radon, can easily find its way into people's homes and produce severe long term health problems. Aside from smoking, it's the leading cause of lung cancer in this country. From a public health perspective, are we doing enough to address the threat of radon?

The Environmental Protection Agency (EPA) is the lead federal agency for work on radon. They provide substantial information on their website, http://epa.gov/radon/.

CDC and ATSDR are supportive of EPA's work in this area. ATSDR has produced a fact sheet that provides answers to frequently asked health questions about radon, which can be found on ATSDR's website: http://www.atsdr.cdc.gov/tfacts145.html ATSDR is also currently updating the Toxicological Profile for Radon (published in 1990). The update will use newer epidemiological analyses to address risks from radon exposure to miners and the public. The updated of the Radon profile (which was published as a draft for public comment) will be revised based on public comments, and is expected to be released as final in mid 2011.

We also know that the radon decay product (polonium) is one of several known major contributing causes to lung cancer from smoking and that reduction in smoking reduces the synergistic effect of smoking and environmental radon on lung cancer.[1] [2]

2. The Government Accountability Office (GAO) has issued several reports on toxic substances policies in the last few years. Last year, GAO placed EPA's chemical management program on its "high risk" programs and found that chemical assessment poses a major management challenge. How is the EPA and how are other government agencies coordinating their risk assessments and health assessments?

Many of ATSDR's activities are possible only through partnerships with other federal, state, and local agencies. As an example, ATSDR conducts public health assessments to determine the health implications of environmental chemical exposures through, among other things, analysis of data provided by EPA or state partners. Public health assessments provide

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[1] HEALTH EFFECTS OF EXPOSURE TO RADON: BEIR VI, Committee on Health Risks of Exposure to Radon (BEIR VI), Board on Radiation Effects Research, Commission on Life Sciences, National Research Council, NATIONAL ACADEMY PRESS, Washington, D.C.,1999. Muggli ME, Ebbert JO, Robertson C, Hurt RD. Waking a Sleeping Giant: The Tobacco Industry's Response to the Polonium-210 Issue. *Am J Public Health.* 2008;98:1643–1650.

recommendations to prevent or reduce exposures. EPA may then be called upon to implement the recommendations, obtain additional samples, and/or clean up the chemical waste.
At most sites around the country where ATSDR is conducting a public health assessment, EPA is concurrently working to fulfill its mandates under Superfund. Generally, during the course of development of the public health assessment, there is ongoing dialogue between agency staff and with all other stakeholders. In most cases, the ATSDR public health assessment is provided to EPA for review and comment at an early stage of development; and at a second time when the public health assessment is released for public comment.

ATSDR and EPA chemical managers also collaborate on toxicologic profiles, EPA toxicologic reviews, and the exchange of scientific data and documents. ATSDR collaborates with EPA's Integrated Risk Information System (IRIS) program on producing toxicological profiles for hazardous substances found at National Priorities List (NPL) sites. ATSDR submits requests to EPA directly for comment about substances that are being are considered for tox profile development. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. To date, ATSDR has produced profiles covering more than 250 substances. http://www.atsdr.cdc.gov/toxpro2.html.
ATSDR participates in the interagency review of the IRIS toxicological assessments. Through our MOU with EPA/NCEA, we collaborate on substances of mutual interest by exchanging scientific data and documents. EPA also participates in the ATSDR MRL workgroup discussions and review of profiles. CDC's biomonitoring data is being used by EPA and other agencies to inform the risk analyses for mercury, TCDD, PFOA, perchlorate, triclosan, and other chemicals.

3. How can inter-agency coordination be improved?

ATSDR and CDC currently collaborate in many areas with many agencies, including with EPA and multiple agencies within the Department of Health and Human Services. For example, the ATSDR Computational Laboratory is currently collaborating with the FDA, EPA and NIH/ NCGC on 2 inter-agency projects, funded by FDA, which are related to high through-put screening of chemicals and drugs using computer modeling techniques. In addition, CDC/ATSDR and EPA collaborate with the National Institute of Environmental Health Sciences through the National Toxicology Program at NIH. NTP participates in the ATSDR MRL workgroup and review of the tox profiles. ATSDR also participates in the following committees with NIEHS: Tri-Agency Superfund Applied Research Committee (TASARC); Interagency Committee for Chemical Evaluation and Coordination (ICCEC); Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) NIEHS Committee; NTP Executive Committee Interagency Working Group (RG2) for the Report on Carcinogens (RoC); and Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) NIEHS Committee. ATSDR's involvement on these NIEHS committees allows the Agency to stay knowledgeable about the chemicals that are being considered for testing and provides the opportunity to suggest that certain chemicals be considered for testing.

And, CDC partners with other federal agencies, including NIH, FDA, and EPA, on studies that rely on biomonitoring data from the environmental health lab at CDC. These studies examine vulnerable populations, particularly newborns, children, pregnant women and population groups or communities known or likely to have higher exposures to chemicals. In one of those collaborations, with the Eunice Kennedy Shriver National Institute of Child Health and Human Development at NIH, the CDC lab will measure chemicals in pregnant women's blood and urine and, after delivery, in the newborn's cord blood and mother's breast milk. EPA and CDC/ATSDR also have senior leadership on the other's Boards of Scientific Counselors. CDC/ATSDR and EPA also both support The Pediatric Environmental Health Specialty Units (PEHSU), which are 12 regionally based sources of medical information and clinical advice on preventing or resolving environmental health threats (e.g., siting of schools, heavy medals, pesticides, mold, plastics and threats associated with disaster recovery) that influence children's health. EPA and CDC/ATSDR also collaborate on the prevention of lead poisoning, support for environmental justice, promotion of healthy homes, and examination of emerging environmental health concerns, such as hydraulic fracturing (serving on an EPA committee examining the impacts of fracturing on drinking water).. There are numerous other examples of good coordination.

EPA and HHS have an MOU that allows each to take advantage of ongoing, cross-institutional initiatives to develop and link environmental health information sources, namely the EPA National Environmental Information Exchange Network (NEIEN) and the CDC National Environmental Public Health Tracking Network (NEPHTN). The linkage of these two systems will utilize and enhance information technology tools to advance the analysis and dissemination of information obtained to various audiences. This joint effort between EPA and HHS also has the potential to increase environmental and health infrastructure and capacity at the local, state, and national level by coordinating and integrating electronic reporting of hazard, exposure, and health data. These collaborative efforts will also help define critical data gaps, accelerate research to develop, validate, and apply environmental and public health indicators to fill those gaps, and promote training and education opportunities, all of which will lead to further improvements in the linkage of networks. For example, research has shown that fine particulate matter ($PM_{2.5}$) in air is associated with several health outcomes. However, the coverage of monitoring data is incomplete because monitors are not present in many areas of the country and most monitors do not sample on a daily basis. EPA collaborated with CDC and state public health agencies in New York, Maine, and Wisconsin to evaluate different methods for generating air quality data that can provide uniform geographic and temporal coverage across the contiguous United States and be systematically and routinely available to link with public health surveillance data. The Public Health Air Surveillance Evaluation (PHASE) project focused on generating ozone and PM2.5 surface concentrations which were subsequently linked with asthma and cardiovascular disease data. Software was developed that is available to analyze the linked data. As a result of this effort, CDC entered into an interagency agreement with EPA to routinely develop modeled daily ozone and $PM_{2.5}$ concentration estimates. These data, as well as monitoring data, are currently available on CDC's Tracking Network for use by public health officials, researchers and the public.

On various levels, the National Environmental Information Exchange Network (Exchange Network) and CDC's Tracking Network have explored and established ways to converge with the goal of advancing the dissemination and analyses of environmental health information. Under the guidance of experts from CDC and EPA, several CDC state and municipal grantees completed an Interoperability project during 2006. This project demonstrated techniques for exchanging data between state health departments, CDC, and EPA's Central Data Exchange (CDX). As a result of the CDC/EPA Interoperability Pilot Project, CDC's Tracking Network has standardized the use of the Exchange Network as transport mechanism for environmental data. For example, some state health departments currently funded by the Tracking Program utilize Exchange Network systems and software to obtain environmental information from their respective state department of environmental quality.

Since 1985, EPA and ATSDR have had an MOU that provides guidance on each agency's responsibilities under CERCLA. The MOU established policies and procedures for conducting health activities related to releases of hazardous substances. It describes the coordination of the health based activities. ATSDR is responsible for evaluation of populations with current or potential exposures to waste sites (health consultations, health assessments), development of health advisories in instances of acute exposure, and the conduct of follow up on populations for evaluation of future health effects (epidemiologic studies, health registries, or pilot studies).

EPA is responsible for ranking sites for the NPL and conducting the remedial investigations, feasibility studies, and the design and implementation of remedial action plans. While EPA conducts the environmental sampling for site characterization, ATSDR may provide technical assistance for site characterization and removal actions by reviewing site sampling plans, recommending sampling to further characterize exposures, or analyzing the data and providing health consultations. At EPA's request, ATSDR may assist EPA in engaging communities.

At the site level, ATSDR and EPA staff work hard to coordinate their respective activities, and to engage with the community. Our staff meet regularly to discuss progress on public health assessments, and to plan coordinated updates and presentations for the public. Staff at ATSDR and EPA headquarters meet at least once annually to discuss and coordinate activities that affect all regions and all sites.

Additionally, ATSDR has senior staff embedded with EPA staff at all EPA regional offices and in Washington, D.C. One possibility for improving coordination between EPA and ATSDR could be for EPA to embed a senior EPA official at ATSDR headquarters, which when done in the past rendered significant benefits to both Agencies.

Senators James M. Inhofe and David Vitter

1. Potency is the dose of a substance required to produce a specific effect of given intensity. While some have suggested that the low levels of chemicals found in human tissues are of concern precisely because they are typically at such low doses and so may interact with receptor sites in cells, this ignores the concept of potency. What role does potency play in our understanding of biomonitoring information?

As indicated in the question, chemicals vary in their potency to produce a specified effect. Potency is a fundamental consideration in toxicology and risk assessment. The toxicity of a chemical is related to its dose or concentration, in addition to a person's individual susceptibility. The presence of an environmental chemical in people's blood or urine does not necessarily mean that it will cause effects or disease. Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects. For many chemicals we do not have enough information to know what the effects are at the levels found in humans.

CDC's *National Report on Human Exposure to Environmental Chemicals* describes the U.S. population's exposure to environmental chemicals and does not study the relationship of these chemicals to health effects. For many of the environmental chemicals presented in the *National Exposure Report*, separate scientific studies are needed to determine whether exposure at levels reported is a cause for health concern. Each year, CDC collaborates with research investigators in academia and other federal agencies on about 50 studies that use biomonitoring to examine exposure, best practices in biomonitoring, and associations with possible health effects.

2. Data collected by the Centers for Disease Control and Prevention (CDC), the U.S. public health research organization that conducts the national biomonitoring program, show that levels of many substances of interest---dioxins, PCBs, DDT, lead, and mercury-have been declining over time. In light of that data, please explain whether detections of chemicals in cord blood equate with bobies and children experiencing more exposures to chemicals at higher levels than in the past?

Cord blood is a promising way to assess prenatal exposure to certain chemicals. There have not been useful comparisons of cord blood levels over time. Adult levels have decreased over the last several decades for most of the chemicals mentioned in the question. Adult levels correspond to maternal levels and maternal levels determine cord blood levels. Therefore, it is likely that cord blood levels of these chemicals have also fallen over the same time period.

Senator LAUTENBERG. Thank you very much.
Mr. Stephenson.

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

Mr. STEPHENSON. Thank you, Mr. Chairman, Ranking Member Inhofe, who has gone, and members of the subcommittee. Thank you for the invitation to testify on our report to this committee on EPA's use of biomonitoring data.

To help EPA achieve its mission of protecting human health the Toxic Substances Control Act, or TSCA, authorizes it to regulate the manufacture, processing and distribution of chemicals. To do so it must first do chemical risk assessments to determine the extent of exposure to a chemical and assess how this exposure affects human health.

EPA uses such risk assessments to determine if it needs to take any risk management actions such as prohibiting or restricting the use of a chemical. As has been mentioned there are over 80,000 chemicals in the TSCA inventory, but about 6 of these are produced in significant volume today.

The growing availability of biomonitoring data has provided new insights into the general population's exposure to chemicals and can be a valuable new tool in EPA's ability to assess chemical risk. Recent advances in analytical methods have allowed scientists to measure more chemicals in smaller concentrations in blood and urine samples. Biomonitoring measurements are very relevant because they identify the amount of a chemical that actually gets into people from all environmental sources such as the air, soil, water, dust and food.

In one such example, CDC estimates that 90 percent of the population has detectable levels of BPA, a chemical widely used in plastic bottles and food and beverage cans. Some studies have linked this chemical to developmental problems. This data has raised concerns, fostering additional research by FDA on the health effects and led to a ban of the chemical in children's products in several States.

In our April 2009 report to the committee we found that EPA has been able to make only limited use of biomonitoring data to date. One reason is that relevant biomonitoring data exists for only about 212 of the over 6,000 significant volume chemicals that EPA must monitor. And even less data is available for children.

In addition, biomonitoring data alone indicates only the presence of the chemical in the body, not the source of exposure to the chemical or its effect on human health. Much more research is needed to understand if the levels measured in people pose a health concern.

We also found that while EPA has taken a number of useful steps to better understand and use biomonitoring data it has not developed a comprehensive strategy for research that takes into account its own efforts and those of the multiple other Federal agencies involved in biomonitoring research. EPA does have several important efforts underway, as have been mentioned, including research into the relationships between exposure to harmful chemi-

cals, the resulting concentration of those chemicals in human tissue, and the corresponding health effects.

However, without a plan to coordinate its efforts EPA has no means to track progress or determine the resources needed in specific areas of biomonitoring research. Moreover, there is not overarching national biomonitoring strategy to coordinate initiatives across the Federal Government. As a result biomonitoring data indicating widespread exposure to dangerous chemicals such as flame retardants may go unaddressed, according to the National Academy of Sciences.

Our report recommended that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring data and work with the Executive Office of the President to establish an interagency task force to coordinate and leverage limited resources across the many Federal Government agencies involved in biomonitoring research including NIH, CDC, FDA, OSHA and USDA.

Finally, as with many areas of TSCA we found that EPA's authority to collect biomonitoring data from companies is untested by the courts and may be limited. We recommended that EPA clarify to authorities, provide better guidance to industry and seek additional authorities from Congress if necessary in this area.

EPA attempted to test its authority in a 2005 action against DuPont regarding the chemical PFOA in Teflon. DuPont had biomonitoring data on PFOA but argued that it was not reportable under section 8 of TSCA because the data indicated only the presence of the chemical and not the health effects. DuPont settled this and other claims for $16.5 million without admission that it was required to submit the data. As a result the court never ruled on EPA's authorities.

In conclusion, Mr. Chairman, we believe that biomonitoring data offers great potential as a tool in assessing the risk of dangerous chemicals, but a coordinated national strategy is needed to facilitate to realization of this potential.

Mr. Chairman, that concludes this summary of my statement, and I will be pleased to answer questions at the appropriate time.

[The prepared statement of Mr. Stephenson follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Superfund, Toxics and Environmental Health, Committee on Environment and Public Works, U.S. Senate

For Release on Delivery
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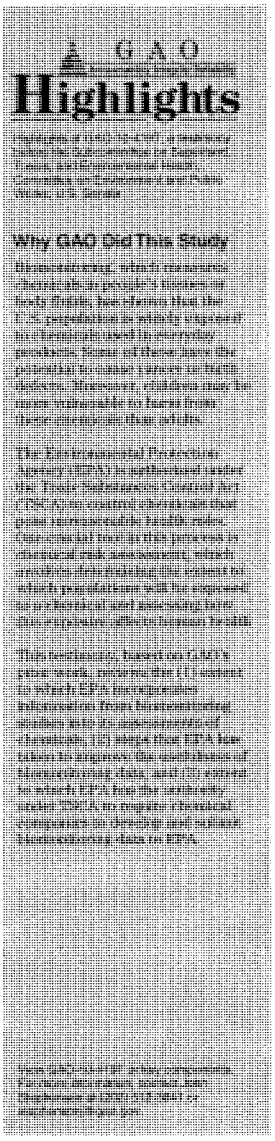
BIOMONITORING

EPA Could Make Better Use of Biomonitoring Data

Statement of John Stephenson, Director
Natural Resources and Environment

GAO-10-419T



GAO

Highlights

Why GAO Did This Study

February 4, 2009

BIOMONITORING

EPA Could Make Better Use of Biomonitoring Data

What GAO Found

EPA has made limited use of biomonitoring data in its assessments of risks posed by commercial chemicals. One reason is that biomonitoring data relevant to the entire U.S. population exist for only 212 chemicals. In addition, biomonitoring data alone indicate only that a person was somehow exposed to a chemical, not the source of the exposure or its effect on the person's health. For most of the chemicals studied under current biomonitoring programs, more data on chemical effects are needed to understand if the levels measured in people pose a health concern, but EPA's authorities to require chemical companies to develop such data is limited. However, in September 2009, the EPA Administrator set forth goals for updated legislation to give EPA additional authorities to obtain data on chemicals.

While EPA has initiated several research programs to make biomonitoring more useful to its risk assessment process, it has not developed a comprehensive strategy for this research that takes into account its own research efforts and those of the multiple federal agencies and other organizations involved in biomonitoring research. EPA does have several important biomonitoring research efforts, including research into the relationships between exposure to harmful chemicals, the resulting concentration of those chemicals in human tissue, and the corresponding health effects. However, without a plan to coordinate its research efforts, EPA has no means to track progress or assess the resources needed specifically for biomonitoring research. Furthermore, according to the National Academy of Sciences, the lack of a coordinated national research strategy has allowed widespread chemical exposures to go undetected, such as exposures to flame retardants. While EPA agreed with GAO's recommendation that EPA develop a comprehensive research strategy, the agency has not yet done so.

EPA has not determined the extent of its authority to obtain biomonitoring data under TSCA, and this authority is untested and may be limited. The TSCA section that authorizes EPA to require companies to develop data focuses on health and environmental effects of chemicals. However, biomonitoring data indicate only the presence of a chemical in the body, not its impact on health. It may be easier for EPA to obtain biomonitoring data under other TSCA sections, which allow EPA to collect existing information on chemicals. For example, TSCA obligates chemical companies to report information that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment. EPA asserts that biomonitoring data are reportable if a chemical is known to have serious toxic effects and biomonitoring data indicates a level of exposure previously unknown to EPA. EPA took action against a chemical company under this authority in 2004. However, the action was settled without an admission of liability by the company, so EPA's authority to obtain biomonitoring data remains untested. GAO's 2009 report recommended that EPA clarify this authority, but it has not yet done so. The agency did not disagree, but commented that a case-by-case explanation of its authority might be more useful than a global assessment.

Mr. Chairman, Ranking Member, and Members of the Subcommittee:

I am pleased to appear here today to discuss EPA's use of biomonitoring data. Biomonitoring, which measures chemicals in people's tissues or body fluids, has shown that the U.S. population is widely exposed to chemicals used in everyday products. Some of these have the potential to cause cancer or birth defects. Moreover, children may be more vulnerable to harm from these chemicals than adults because their biological functions are still developing and their size and behavior may expose them to proportionately higher doses.

The mission of the Environmental Protection Agency (EPA) is to protect human health and the environment. To help EPA achieve this objective, the Toxic Substances Control Act (TSCA) authorizes it to regulate the manufacture, processing, and distribution of chemicals. A crucial tool in this regulatory process is chemical risk assessment, which involves determining the extent to which populations will be exposed to a chemical and assessing how this exposure affects human health. EPA uses such risk assessments to determine if it needs to take any risk management actions, such as prohibiting or restricting the manufacture, processing, or distribution of a chemical.

A recent proliferation of biomonitoring data has provided new insights into the general population's exposure to chemicals. Biomonitoring studies for certain chemicals, such as lead, have been ongoing for decades, but recent advances in analytic methods have allowed scientists to measure more chemicals in smaller concentrations. This is a promising development. According to the Centers for Disease Control and Prevention (CDC), "biomonitoring measurements are the most health-relevant assessments of exposure because they measure the amount of the chemical that actually gets into people from all environmental sources, such as the air, soil, water, dust, or food combined." The CDC conducts the most comprehensive biomonitoring program in the country, and in December 2009 it published the fourth in a series of reports on the concentrations of certain chemicals or their by-products in a representative sample of the U.S. population. For example, the CDC reported that 90 percent of the people tested had detectable levels of Bisphenol A (BPA). BPA is an industrial chemical that has been present in many hard plastic bottles and metal-based food and beverage cans since the 1960s. On the basis of results from recent studies using novel approaches to test for subtle effects, the Food and Drug Administration announced in January of this year that it and the National Toxicology Program at the National Institutes of Health (NIH) have some concern

about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.

My testimony today is based on our prior work on federal biomonitoring efforts and discusses EPA's use of current biomonitoring studies, EPA's biomonitoring research strategy, and EPA's authorities under TSCA to obtain biomonitoring data.[1] Specifically, my statement addresses (1) the extent to which EPA incorporates information from biomonitoring studies into its assessments of chemicals, (2) steps that EPA has taken to improve the usefulness of biomonitoring data, and (3) the extent to which EPA has the authority under TSCA to require chemical companies to develop and submit biomonitoring data to EPA. Our prior work was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Biomonitoring—one technique for assessing people's exposure to chemicals—involves measuring the concentration of chemicals or their by-products in human specimens, such as blood or urine. While, biomonitoring has been used to monitor chemical exposures for decades, more recently, advances in analytic methods have allowed scientists to measure more chemicals, in smaller concentrations, using smaller samples of blood or urine. As a result, biomonitoring has become more widely used for a variety of applications, including public health research and measuring the impact of certain environmental regulations, such as the decline in blood lead levels following declining levels of gasoline lead.

CDC conducts the most comprehensive biomonitoring program in the country under its National Biomonitoring Program and published the first, second, third and fourth National Report on Human Exposure to Environmental Chemicals—in 2001, 2003, 2005, and 2009, respectively—which reported the concentrations of certain chemicals or their by-products in the blood or urine of a representative sample of the U.S. population. For each of these reports, the CDC has increased the number

[1]GAO, *Biomonitoring: EPA Needs to Coordinate Its Research Strategy and Clarify Its Authority toObtain Biomonitoring Data*, GAO-09-353, (Washington, D.C.: Apr. 30, 2009).

of chemicals studied—from 27 in the first report, to 116 in the second, to 148 in the third, and to 212 in the fourth. Each report is cumulative (containing all the results from previous reports). These reports provide the most comprehensive assessment to date of the exposure of the U.S. population to chemicals in our environment including such chemicals as acrylamide, arsenic, BPA, triclosan, and perchlorate. These reports have provided a window into the U.S. population's exposure to chemicals, and the CDC continues to develop new methods for collecting data on additional chemical exposures with each report.

For decades, government regulators have used risk assessment to understand the health implications of commercial chemicals. Researchers use this process to estimate how much harm, if any, can be expected from exposure to a given contaminant or mixture of contaminants and to help regulators determine whether the risk is significant enough to require banning or regulating the chemical or other corrective action. Biomonitoring research is difficult to integrate into this risk assessment process, since estimates of human exposure to chemicals have historically been based on the concentration of these chemicals in environmental media and on information about how people are exposed. Biomonitoring data, however, provide a measure of internal dose that is the result of exposure to all environmental media and depend on how the human body processes and excretes the chemical.

EPA Has Made Limited Use of Biomonitoring Data in Assessing Risks Posed by Chemicals

EPA has made limited use of biomonitoring data in its assessments of risks posed by chemicals. As we previously reported,[2] one major reason for the agency's limited use of such data is that, to date, there are no biomonitoring data for most commercial chemicals. The most comprehensive biomonitoring effort providing data relevant to the entire U.S. population includes only 212 chemicals, whereas EPA is currently focusing its chemical assessment and management efforts on the more than 6,000 chemicals that companies produce in quantities of more than 25,000 pounds per year at one site.[3] Current biomonitoring efforts also provide little information on children. Large-scale biomonitoring studies generally omit children because it is difficult to collect biomonitoring data

[2]GAO-09-353.

[3]Companies must report on most chemicals covered by TSCA that they produce above this 25,000-pound threshold during every fifth year. EPA's estimate of more than 6,000 is based on data chemical companies submitted during the 2005 calendar year.

from them. For example, some parents are concerned about the invasiveness of taking blood samples from their children, and certain other fluids, such as umbilical cord blood or breast milk, are available only in small quantities and only at certain times. Thus, when samples are available from children, they may not be large enough to analyze.

A second reason we reported for the agency's limited use of biomonitoring data is that EPA often lacks the additional information needed to make biomonitoring studies useful in its risk assessment process. In this regard, biomonitoring provides information only on the level of a chemical in a person's body but not the health impact. The detectable presence of a chemical in a person's blood or urine does not necessarily mean that the chemical causes harm. While exposure to larger amounts of a chemical may cause an adverse health impact, a smaller amount may be of no health consequence. In addition, biomonitoring data alone do not indicate the source, route, or timing of the exposure, making it difficult to identify the appropriate risk management strategies. For most of the chemicals studied under current biomonitoring programs, more data on chemical effects are needed to understand whether the levels measured in people pose a health concern, but EPA's ability to require chemical companies to develop such data is limited. As a result, EPA has made few changes to its chemical risk assessments or safeguards in response to the recent proliferation of biomonitoring data. For most chemicals, EPA would need additional data on the following to incorporate biomonitoring into risk assessment: health effects; the sources, routes, and timing of exposure; and the fate of a chemical in the human body. However, as we have discussed in prior reports, EPA will face difficulty in using its authorities under TSCA to require chemical companies to develop health and safety information on the chemicals. In January 2009, we added transforming EPA's process for assessing and controlling toxic chemicals to our list of high-risk areas warranting attention by Congress and the executive branch.[4] Subsequently, the EPA Administrator set forth goals for updated legislation that would give EPA the mechanisms and authorities to promptly assess and regulate chemicals.

EPA has used some biomonitoring data in chemical risk assessment and management, but only when additional studies have provided insight on the health implications of the biomonitoring data. For example, EPA was able to use biomonitoring data on methylmercury—a neurotoxin that

[4]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009).

accumulates in fish—because studies have drawn a link between the level of this toxin in human blood and adverse neurological effects in children. EPA also used both biomonitoring and traditional risk assessment information to take action on certain perfluorinated chemicals. These chemicals are used in the manufacture of consumer and industrial products, including nonstick cookware coatings; waterproof clothing; and oil-, stain-, and grease-resistant surface treatments.

EPA Has Taken Steps to Improve the Usefulness of Biomonitoring Data but Lacks a Comprehensive Research Strategy

EPA has several biomonitoring research projects under way, but the agency has no system in place to track progress or assess the resources needed specifically for biomonitoring research. For example, EPA awarded grants that are intended to advance the knowledge of children's exposure to pesticides through the use of biomonitoring and of the potential adverse effects of these exposures. The grants issued went to projects that, among other things, investigated the development of less invasive biomarker than blood samples—such as analyses of saliva or hair samples—to measures of early brain development. Furthermore, EPA has studied the presence of an herbicide in 135 homes with preschool-age children by analyzing soil, air, carpet, dust, food, and urine as well as samples taken from subject's hands. The study shed important light on how best to collect urine samples that reflect external dose of the herbicide and how to develop models that simulate how the body processes specific chemicals. Nonetheless, EPA does not separately track spending or staff time devoted to biomonitoring research. Instead, it places individual biomonitoring research projects within its larger Human Health Research Strategy. While this strategy includes some goals relevant to biomonitoring, EPA has not systematically identified and prioritized the data gaps that prevent it from using biomonitoring data. Nor has it systematically identified the resources needed to reach biomonitoring research goals or the chemicals that need the most additional biomonitoring-related research.

Also, EPA has not coordinated its biomonitoring research with that of the many agencies and other groups involved in biomonitoring research, which could impair its ability to address the significant data gaps in this field of research. In addition to the CDC and EPA, several other federal agencies have been involved in biomonitoring research, including the U.S. Department of Health and Human Service's Agency for Toxic Substances and Disease Registry, entities within the U.S. Department of Health and Human Service's NIH, and the U.S. Department of Labor's Occupational Safety and Health Administration. Several states have also initiated biomonitoring programs to examine state and local health concerns, such

as arsenic in local water supplies or populations with high fish consumption that may increase mercury exposure. Furthermore, some chemical companies have for decades monitored their workforce for chemical exposure, and chemical industry associations have funded biomonitoring research. Finally, some environmental organizations have conducted biomonitoring studies of small groups of adults and children, including one study on infants.

As we previously reported, a national biomonitoring research plan could help better coordinate research and link data needs with collection efforts.[5] EPA has suggested chemicals for future inclusion in the CDC's National Biomonitoring Program but has not gone any further toward formulating an overall strategy to address data gaps and ensure the progress of biomonitoring research. We have previously noted that to begin addressing the need for biomonitoring research, federal agencies will need to strategically coordinate their efforts and leverage their limited resources.[6] Similarly, the National Academies of Science found that the lack of a coordinated research strategy allowed widespread exposures to go undetected, including exposure to flame retardants known as polybrominated diphenyl ethers—chemicals which may cause liver damage, among other things, according to some toxicological studies. The academy noted that a coordinated research strategy would require input from various agencies involved in biomonitoring and supporting disciplines. In addition to EPA, these agencies include the CDC, NIH, the Food and Drug Administration, and the U.S. Department of Agriculture. Such coordination could strengthen efforts to identify and possibly regulate the sources of the exposure detected by biomonitoring, since the most common sources—that is, food, environmental contamination, and consumer products—are under the jurisdiction of different agencies.

We have recommended that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments.[7] However, though EPA agreed with our recommendation, the agency still lacks such a comprehensive strategy to guide its own research efforts. In addition, we recommended that EPA establish an interagency

[5]GAO-09-353.

[6]GAO, *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans*, GAO/HEHS-00-80 (Washington, D.C.: May 2, 2000).

[7]GAO-09-353.

task force that would coordinate federal biomonitoring research efforts across agencies and leverage available resources. If EPA determines that further authority is necessary, we stated that it should request that the Executive Office of the President establish an interagency task force to coordinate such efforts. Nonetheless, EPA has not established such an interagency task force to coordinate federal biomonitoring research, nor has it informed us that it has requested the Executive Office of the President do so.

EPA's Authority to Obtain Biomonitoring Data under TSCA Is Untested and May Be Limited

EPA has not determined the extent of its authority to obtain biomonitoring data under TSCA, and this authority is generally untested and may be limited. Several provisions of TSCA are potentially relevant. For example, under section 4 of TSCA EPA can require chemical companies to test chemicals for their effects on health or the environment.[8] However, biomonitoring data indicate only the presence of a chemical in a person's body and not its impact on the person's health. EPA told us that biomonitoring data may demonstrate chemical characteristics that would be relevant to a chemical's effects on health or the environment and that the agency could theoretically require that biomonitoring be used as a methodology for developing such data. EPA's specific authority to obtain biomonitoring data in this way is untested, however, and EPA is only generally authorized to require the development of such data after meeting certain threshold risk requirements that are difficult, expensive, and time-consuming.[9] EPA may also be able to indirectly require the development of biomonitoring data using the leverage it has under section 5(e) of TSCA, though it has not yet attempted to do so.[10] Under certain circumstances, EPA can use this section to seek an injunction to limit or prohibit the

[8]15 U.S.C. § 2603(a) (2006).

[9]To require testing, EPA must determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment, and that testing is necessary to develop such data. The agency must also make one of two additional findings. The first is that a chemical may present an unreasonable risk of injury to human health or the environment. The second is that a chemical is or will be produced in substantial quantities, and that either (1) there is or may be significant or substantial human exposure to the chemical or (2) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities.

[10]15 U.S.C. § 2604(e) (2006).

manufacture of a chemical.[11] As an alternative, EPA sometimes issues a consent order that subjects manufacture to certain conditions, including testing, which could include biomonitoring. While EPA may not be explicitly authorized to require the development of such test data under this section, chemical companies have an incentive to provide the requested test data to avoid a more sweeping ban on a chemical's manufacture. EPA has not indicated whether it will use section 5(e) consent orders to require companies to submit biomonitoring data.

Other TSCA provisions allow EPA to collect existing information on chemicals that a company already has, knows about, or could reasonably ascertain.[12] For example, section 8(e) requires chemical companies to report to EPA any information they have obtained that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment.[13] EPA asserts that biomonitoring data are reportable as demonstrating a substantial risk if the chemical in question is known to have serious toxic effects and the biomonitoring data indicate a level of exposure previously unknown to EPA. Industry has asked for more guidance on this point, but EPA has not yet revised its guidance. Confusion over the scope of EPA's authority to collect biomonitoring data under section 8 (e) is highlighted by the history leading up to an EPA action against the chemical company E. I. du Pont de Nemours and Company (DuPont). Until 2000, DuPont used the chemical PFOA to make Teflon®. In 1981, DuPont took blood from several female workers and two of their babies. The levels of PFOA in the babies' blood showed that PFOA had crossed the placental barrier. DuPont also tested the blood of twelve community members, 11 of whom had elevated levels

[11] Under section 5(e), when a company proposes to begin manufacturing a new chemical or to introduce an existing chemical for a significant new use, EPA may determine (1) that the available information is not sufficient to permit a reasoned evaluation of the health and environmental effects of that chemical and (2) that in the absence of such information, the manufacture of the chemical may meet certain risk or exposure thresholds. If the agency does so, the Administrator can issue a proposed order limiting or prohibiting the manufacture of the chemical. If a chemical company objects to such an order, the matter becomes one for the courts. If a court agrees with the Administrator, it will issue an injunction to the chemical company to limit or prohibit manufacture of the chemical. If and when the chemical company submits data to EPA sufficient for the Administrator to make a reasoned determination about the chemical's health and environmental effects, which may include test data, the injunction can be dissolved. Thus, an injunction would provide an incentive for the chemical company to develop testing data.

[12] 15 U.S.C. §§ 2604(a), 2604(b), 2607(a), 2607(d), 2607(e) (2006).

[13] 15 U.S.C. § 2607(e) (2006).

of PFOA in their blood. DuPont did not report either set of results to EPA. After EPA received the results from a third party, DuPont argued that the information was not reportable under TSCA because the mere presence of PFOA in blood did not itself support the conclusion that exposure to PFOA posed any health risks. EPA subsequently filed two actions against DuPont for violating section 8(e) of TSCA by failing to report the biomonitoring data, among other claims. DuPont settled the claims but did not admit that it should have reported the data. However, based on the data it had received, EPA conducted a subsequent risk assessment, which contributed to a finding that PFOA was "likely to be carcinogenic to humans." In turn, this finding contributed to an agreement by DuPont and others to phase out the use of PFOA by 2015. However, EPA's authority to obtain biomonitoring data under section 8(e) of TSCA remains untested in court.

Given the uncertainties regarding TSCA authorities, we have recommended that EPA should determine the extent of its legal authority to require companies to develop and submit biomonitoring data under TSCA. We also recommended that EPA request additional authority from Congress if it determines that such authority is necessary. If EPA determines that no further authority is necessary, we recommended that it develop formal written policies explaining the circumstances under which companies are required to submit biomonitoring data. However, EPA has not yet attempted a comprehensive review of its authority to require the companies to develop and submit biomonitoring data. The agency did not disagree with our recommendation, but commented that a case-by-case explanation of its authority might be more useful than a global assessment. However, we continue to believe that an analysis of EPA's legal authority to obtain biomonitoring data is critical.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of this Subcommittee may have.

GAO Contact and Staff Acknowledgements

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, Antoinette Capaccio, Ed Kratzer, and Ben Shouse.

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Enclosure

GAO Responses to Questions for the Record
Biomonitoring: EPA Could Make Better Use of Biomonitoring Data
February 4, 2010
John Stephenson, Director, Natural Resources and Environment

GAO Response to Questions from Senator James M. Inhofe and Senator Honorable David Vitter

1. 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 courts, 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.

2. Does GAO consider the exemptions in federal law for confidential business information, whether under FOIA or TSCA, to be legitimate exercises of legal authority? Please elaborate on your answer.

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 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.

3. Your comments before this Committee state that GAO believes that "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 GAO's rationale for looking so unfavorably on cost-benefit considerations and criticizing minimizing burdens on the private sector.

Enclosure

GAO Responses to Questions for the Record
Biomonitoring: EPA Could Make Better Use of Biomonitoring Data
February 4, 2010
John Stephenson, Director, Natural Resources and Environment

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.
Ms. Birnbaum, welcome.

STATEMENT OF LINDA 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

Ms. BIRNBAUM. Mr. Chairman and distinguished members of the subcommittee, as Director of the NIEHS and the National Toxicology Program I am pleased to appear before you today to present testimony on recent science related to exposure assessment. This is all about understanding the environmental agents we are exposed to and then determining if these environmental exposures cause health problems for you and for me.

From the days when readings from a single outdoor monitor was used to measure air pollution exposure for everyone in a city to the future when a badge is pinned on a shirt we will be able to give exposure readings of dozens of air pollutants for a single person. Our ability to measure personal exposure continues to improve significantly.

While our technical capacity to measure exposures continues to improve we still have a ways to go in our general understanding of exposure in the United States. This is especially true for our most vulnerable populations like the unborn, infants and young children, and those living in poverty and disadvantaged communities.

Biomonitoring, or the measurement of chemicals and their metabolites in blood, urine or other body fluids, has provided critical information on human exposure to toxic environmental agents. At NIEHS, we use biomonitoring to add precision to the measurements of exposures in our studies of specific human populations and to guide further research and understanding.

For example findings of high levels of tungsten in the urine of residents of Churchill County, Nevada, the site of a childhood leukemia cluster, prompted my National Toxicology Program to initiate studies on tungsten, which have been followed by additional studies in collaboration with NIOSH for levels of tungsten in workers.

NTP studies of the chemicals paraben, triclosan and oxybenzone were similarly prompted by CDC findings of widespread exposure. Other biomonitoring studies revealed unexpected rising levels of the polybrominated flame retardants in women of child bearing age and PFOA in residents near chemical plants, leading to intensive toxicological and epidemiological investigations and some changes in the use of these chemicals.

Sometimes, biomonitoring is initiated for chemicals known to be toxic in order to better understand risk for an affected population. Substances like DEHP and other phthalates, certain heavy metals in pesticides, and other toxic substances fall into this category.

Biomonitoring can also demonstrate the effectiveness of regulatory controls. An NIEHS study of infants in New York City documented lower cord blood levels of the harmful pesticides diazanon and chlorperifos after EPA implemented a ban on residential uses.

And the good news is that the adverse effects we had seen in the infants no longer occurred when the levels of diazanon and chlorperifos dropped.

Looking to the future, the NIEHS is developing 21st century methods of assessing exposures. For example, the NIEHS leads the Exposure Biology Program of the trans-NIH Genes, Environment and Health Initiative and is funding 32 research projects focusing on the development of innovative technologies to measure environmental exposures, diet, physical activities and psychosocial stress. The program also supports the development of biosensors to monitor the body's biological responses to environmental exposures.

The NIEHS is even supporting the development of a robot capable of mimicking a child's floor activities so that we can measure exposures to young children more accurately. Other activities include the use of computerized geographical tracking systems like GPS to improve exposure modeling and using nanotechnology and biosensors to improve the detection of chemicals.

Devices under development include a biosensor for detecting formaldehyde in air; I should have said that is a microsensor, nanobiosensors for probing chemical exposures and their effects on individual cells, wearable nanosensors, very small, 4 by 4, for monitoring diesel and gasoline exhaust, and low cost portable sensors for measuring metals such as arsenic and mercury at hazardous waste sites.

In summary we are committed to advancing the science of exposure assessment to meet emerging public health challenges. We look forward to the increased contributions of exposure scientists as we work to understand the role of the environment in the etiology of disease.

I would be happy to answer any questions.

[The prepared statement of Ms. Birnbaum follows:]

Testimony
Before the Subcommittee on Superfund, Toxics and Environmental Health
Committee on Environment and Public Works
United States Senate

Statement for hearing entitled, "Current Science on Public Exposures to Toxic Chemicals"

Statement of
Linda 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

For Release on Delivery
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February 4, 2010

Mr. Chairman and distinguished members of the Subcommittee, I am pleased to appear before you today to present testimony on recent science related to exposure assessment.

Since human disease sometimes results from the interactions of our genetic susceptibilities and our environmental exposures,[1] having reliable data on exposure is essential to planning for and carrying out research on how environmental exposures initiate or promote disease.

From the days when one outdoor monitor in a city would be used to measure air pollution for a study to backpack monitors to badges pinned on a shirt, our ability to measure exposure continues to improve significantly.

In this statement, I shall describe some examples of research where exposure in the U.S. population or a vulnerable subgroup drove or changed the research agenda, some studies exploring the initiation or promotion of disease related to environmental exposures and the efforts made by researchers to use the best possible exposure data, and some of the technologies to assess exposures under development by the National Institute of Environmental Health Sciences (NIEHS), which is part of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services (HHS).

The importance of biomonitoring cannot be underestimated. It can tell us three things: whether exposure to humans is actually occurring; at what levels; and how widespread the exposure is in the population. Sometimes the information is new; other times it confirms something we already suspected based on what we know about how a manmade or naturally occurring compound is used and where it is found in the environment. And occasionally, we are surprised by the results.

Findings from biomonitoring studies often trigger new research, either toxicology or population-based studies to investigate potential adverse health outcomes. One example is the surprising finding by HHS's Centers for Disease Control and Prevention (CDC) in 2002 of high levels of tungsten in urine of residents of Churchill County, Nevada, the site of a childhood leukemia cluster. Since we do not know enough about tungsten to understand whether this is a health risk, this discovery prompted the National Toxicology Program (NTP) to initiate studies on tungsten. More recently, CDC national blood and urine data showing widespread U.S. population exposure to parabens, triclosan and oxybenzone were an important factor in the decision to conduct additional toxicology studies for these compounds. What biomonitoring cannot tell us is the source of the exposure. For example, bisphenol A exposure is widespread in the population as evidenced by urinary levels in biomonitoring studies. We suspect that much of the bisphenol A exposure is coming from food and beverage containers. The findings from a small CDC study that premature infants in neonatal intensive care units (NICUs) had substantial levels of bisphenol A in urine indicated other sources of exposure. In a recently published study, the authors suspect the source was the presence of bisphenol A in polyvinyl chloride-containing medical devices used in NICUs.[2] Since premature infants represent a uniquely sensitive

[1] The World Health Organization defines exposure as the contact between an agent and a target. The target may be an individual or a population; it can be an organ, a tissue, or a cell. The agent of exposure can be a biological, physical, or psychosocial stressor.

[2] Exposure to Bisphenol A and Other Phenols in Neonatal Intensive Care Unit Premature Infants. Environ Health Perspect 117:639–644 (2009).

subpopulation, additional research is being carried out to understand the health risks of such exposures. Many if not all of the substances in CDC's biomonitoring program are included because of evidence that they pose potential human health hazards. For example, DEHP and other phthalates were included in CDC's first National Exposure Report because of known adverse developmental and reproductive effects in rodents, as identified in NTP and other toxicological studies. The same is true for heavy metals, certain pesticides, polycyclic aromatic hydrocarbons (PAHs), etc. As new hazards are identified from toxicological research, these compounds become good candidates for inclusion in national biomonitoring studies, e.g., brominated flame retardants. Once biomonitoring studies show us the range and nature of exposures occurring in the general U.S. population, the cycle continues as additional toxicological and epidemiological research is triggered to increase our knowledge on specific adverse health risks.

The Agricultural Health Study is a cohort study of 57,000 licensed pesticide applicators and 32,000 of their spouses in Iowa and North Carolina. NIEHS scientists, in collaboration with colleagues from NIH's National Cancer Institute (NCI), the Environmental Protection Agency (EPA) and CDC's National Institute for Occupational Safety and Health (NIOSH), have carried out biomonitoring studies of subgroups of pesticide applicators using specific chemicals and have used these data to validate and refine their questionnaire-based exposure algorithms for the much larger study population. In other studies conducted within the cohort, researchers have collected house/farm dust and biological samples to assess exposure to pesticides, endotoxins, and metals as well as gene variants that may affect risk of specific health outcomes.

In preparation for studies to assess health-related risks to mothers and their offspring, NIEHS researchers are assessing the validity of using blood and urine samples at a single time during pregnancy. They are assessing the agreement between measures from samples taken at three points during pregnancy to determine if a single sample is reliable enough to assess risk related to phthalates, pesticides, bisphenol A, and perfluorooctanoic acid (PFOA).

An example of biomonitoring where surprising results triggered additional research occurred in one of the NIEHS/NCI Breast Cancer and Environment Centers studies. Researchers found unexpectedly high levels of PFOA in girls in one school district. The source of the exposure could not be determined. The researchers worked with their community partners who had been involved in the program from the beginning to survey families about how they wanted to receive study results. In response to the survey, the researchers and the community partners produced a newsletter to provide updates to the families. The researchers have since received a second grant to identify possible sources and health effects of PFOA.

Sometimes an event changes an exposure in a population allowing a "before" and "after" comparison. In a study of infants born before the EPA's regulatory actions to phase out residential use of chlorpyrifos and diazinon, the association between birth weight and length and cord blood levels of these insecticides was highly significant. Among infants born after January

2001, exposure levels were substantially lower and no association with fetal growth was apparent.[3]

Concern about widespread exposure in the U.S. population often guides the NIEHS research agenda. In 1974, NIEHS launched a classic study in six cities to explore the associations between air pollution produced by fossil fuels and respiratory health in large cohorts of adults and children which provided a wealth of information. Collaboration with EPA led to expansion of this study to include more cities and confirmed the negative effects of air pollution on human health. In 1978, the NTP tested yellow paint on pencils; there was no evidence of carcinogenicity in rats or mice.[4] In a 2009 study of the effects of PAHs on children's IQ in New York City (Washington Heights, Harlem, and the South Bronx), the mothers' exposure as measured during their pregnancies by wearing backpack monitors was associated with a decrease in IQ among the more exposed children. The extent of this effect was similar to that of low-level lead exposure.[5]

By 2015, the use of engineered nanomaterials (ENMs) and nano-enabled devices is expected to exceed $3 trillion, resulting in exposures with possible unknown consequences to health and the environment. A key first step in understanding risk is to develop ways to measure exposures. NIEHS is supporting studies with funding from the American Recovery and Reinvestment Act of 2009 (ARRA) to conduct real-time, on-site measurement of exposures with a suite of instruments to characterize ENMs during different phases of the production process. The next step is to understand their interactions with biological systems and the resulting health risks. Again using ARRA funding, NIEHS is supporting studies on ENM-induced inflammatory and oxidative stress responses in multiple cell culture systems with the goal of finding biomarkers of response. This information will provide cell-specific and ENM-specific toxicity profiles. Other studies are looking at the fundamental interactions of ENMs at the cellular and molecular levels. ARRA funding is also supporting studies using animals to determine organ specific health effects and to evaluate human health risks of ENMs. Studies planned include research on the following:

- The effect of inhaled ENMs on the respiratory tract, brain, liver, and other organs;
- Whether inhaled cadmium nanoparticles can cross the placenta and influence fetal stability and development; and
- Pulmonary effects of ENMs to understand whether they modify the effects of other agents (e.g., drugs, vaccines) while having minimal effects on their own, enhance allergen sensitization, or alter innate immunity.

NIEHS is also supporting research on nanotechnologies to improve environmental monitoring. Detection devices under development include:

- a microsensor for detecting formaldehyde in air
- nanobiosensors for probing chemical exposures and their effects on individual cells

[3] Prenatal insecticide exposures and birth weight and length among an urban minority cohort. Environ Health Perspect 112:1125-1132 (2004).
[4] Bioassay of diarylanide yellow for possible carcinogenicity CAS No. 6358-85-6. National Cancer Institute Carcinogenesis Technical Report Series No. 30 (1978) http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr030.pdf - 2234.3KB
[5] Prenatal airborne polycyclic aromatic hydrocarbon exposure and child IQ at age 5 years. Pediatrics 124:e195-e202 (2009).

- wearable nanosensors (approximately 4"x4") for real-time monitoring of diesel and gasoline exhaust
- Low-cost, portable sensors for measuring metals such as arsenic and mercury at hazardous waste sites.

Investigators studying the interplay of genetic and environmental factors in the risk for Parkinson's disease have developed a new model to estimate residential exposure of individuals to pesticide drift from nearby farms. The exposure model uses a geographic information system that combines data on home addresses, land use, and pesticide applications. By measuring the proximity of residences to the fields where pesticides were applied, this model allows estimation of exposures that occur with drift from application sites and/or travel through soil to water wells. One of their studies showed that residential exposure to a combination of the herbicide paraquat and the fungicide maneb increases the risk of Parkinson's disease.[6] Another study revealed that estimated pesticide exposures from drift and from well water contamination combined to increase risk of Parkinson's disease.[7]

An investigator in California is using ARRA funding to improve exposure modeling in a study of birth outcomes related to exposure to pollution from traffic. Using real-time global positioning system (GPS) tracking and detailed activity questionnaires to determine locations more accurately, the model will assess pregnant women's exposure to traffic-related air pollution with greater precision.

In the NIEHS Sister Study of 51,000 women whose sisters have breast cancer, researchers have collected urine, blood, toenail, and dust samples to provide a snapshot of environmental exposures at the time of enrollment in the study. The study will assess exposure to pesticides, other hormonally active compounds such as bisphenol A and phthalates, toxic metals, trace metals, vitamin D, specific micronutrients, and hormones. Samples will also be used to measure gene variants that may be related to disease risk. The study design will allow researchers to assess the associations between breast cancer and other diseases with these markers of exposure, nutrition and health status. Ultimately these data will be used in studies of gene-environment interactions. These data will also be used in conjunction with self-reported questionnaire data to develop questionnaire-based exposure measures and to validate both questionnaire-based methods and the use of single biological samples. Lastly, these data will support mechanistic studies of specific pathways leading to breast cancer risk and to develop markers for early detection or for predicting progression of disease.

Determining actual levels of exposure for use in research, risk assessment, and risk management is an ongoing challenge, and NIEHS is actively pursuing many research approaches to help solve this problem and thus promote more accurate science and better decision making. For example, the NIEHS is supporting development and testing of a robot called PIPER[8] capable of mimicking children's floor activities while collecting better estimates of young children's

[6] Parkinson's Disease and residential exposure to maneb and paraquat from agricultural applications in the central valley of California. Am J Epidemio 169(8):919-926 (2009)
[7] Well-water consumption and Parkinson's Disease in rural California. Environ Health Perspect 117:1912-1918 (2009).
[8] Pretoddler Inhalable Particulate Environmental Robotic

exposure to indoor air pollutants (particulate matter, pesticides, allergens, endotoxins and airborne fungi). A study of asthma and indoor environmental contaminants is currently underway to test PIPER in the homes of 200 children. The study will compare measurements of particulates obtained by PIPER with those from standard adult height monitoring stations and examine their association with asthma symptoms.

The NIEHS has the lead for the Exposure Biology Program of the trans-NIH Genes, Environment and Health Initiative. The Program is funding 32 projects focusing on the development of innovative technologies to measure environmental exposures, diet, physical activities, psychosocial stress, and others factors that contribute to disease development. In addition to developing new measures of exposure, the program also supports the development of markers of biological response and DNA damage, as well as the development of biosensors based on monitoring biological responses. A critical aspect is the integration of these technologies to enable a more accurate understanding of exposure. For example, the combination of physical activity measurements with particulate matter exposure allows for an improved estimate of individual dose. With the additional inclusion of GPS analysis, this information can potentially be used to identify the sources of these exposures and guide the development of interventions to improve public health.

In summary, understanding the connection between our health and our environment, with its mixture of chemicals, diet and lifestyle stressors, is no less complex than understanding the intricacies of the human genome. At NIEHS, we remain committed to helping the field of exposure science evolve to meet emerging public health challenges. We look forward to the increased contributions of exposure scientists as we work to understand the role of environment in the etiology of disease.

Mr. Chairman and members of the Subcommittee, I am pleased to present testimony on this important issue and would be happy to answer any questions.

Questions for the Record to Dr. Birnbaum

Senate Committee on Environment and Public Works

Hearing on TSCA - February 4, 2010

Senator Sanders:

1. It has come to my attention in a recent ScienceNews article (Raloff, Janet. 2009. "Concerned About BPA: Check Your Receipts." *ScienceNews*, October 7.):
    a. "Some—but not all—cash register and credit-card receipts can be rich sources of exposure to BPA [bisphenol A], a hormone-mimicking pollutant." What is your knowledge on how much BPA can transfer from receipt papers through the skin?

       Answer: Transfer of BPA through skin has been shown to occur at a very slow rate when applied as a liquid or cream. Since BPA from cash register and credit-card receipts will not be in a solution and exposure will be brief, dermal absorption is expected to be very low[1].

    b. As a follow-up, how much BPA gets into the bloodstream, and which other organs can it reach within the body?

       Answer: A laboratory study indicated that 0.02%, 0.105%, and 0.7% of the applied dose penetrated through skin at 2, 5, and 10 hours following exposure[2]. BPA is rapidly metabolized to BPA glucuronide in humans. The metabolite does not have hormonal activity; therefore, glucuronidation is considered to be a detoxification reaction. BPA glucuronide is rapidly excreted in the urine with a terminal half-life of less than six hours[3]. Although glucuronidation is rapid and extensive, a very small fraction of the total BPA circulating in the blood remains in the parent unmetabolized form. It is possible that the relative level of BPA would be slightly higher in infants than adults.

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[1] Kaddar N, Harthé C, Déchaud H, Mappus E, Pugeat M. Cutaneous penetration of bisphenol A in pig skin. J Toxicol Environ Health A. 2008; 71(8):471-3.

[2] Ibid

[3] Völkel W, Colnot T, Csanády GA, Filser JG, Dekant W. Metabolism and kinetics of bisphenol a in humans at low doses following oral administration. Chem Res Toxicol. 2002 Oct;15(10):1281-7.

Senator Klobuchar:

1. One naturally occurring toxin, Radon, can easily find its way into people's homes and produce severe long term health problems. Aside from smoking, it's the leading cause of lung cancer in this country. From a public health perspective, are we doing enough to address the threat of radon?

   Answer: Over the years, EPA and a number of state governments have sponsored a variety of programs to educate the public about radon and to reduce exposure in the indoor environment. For example, EPA has established a voluntary program to promote radon awareness, testing and reduction. The program sets an action level of 4 picocuries per liter (pCi/l) of air for indoor radon. The action level is not the maximum safe level for radon in the home. Instead it is the point at which the cost to the homeowner for fixing the problem is warranted by the risk from radon. Since there is no known safe level of radon, there may always be some risk; however, the risk can be reduced by lowering the radon level in a home. There are several proven methods to reduce radon in a home with the cost for most homes about the same as other common home repairs. [4] The following EPA web site (http://www.epa.gov/radon/pubs/citguide.html) provides details on how to test for radon and how to reduce levels if they are found. In addition to working with homeowners, EPA is working with home builders and building code organizations. The goals are to help newly constructed homes be more radon resistant and to encourage radon testing when existing homes are sold.

   The 1988 Indoor Radon Abatement Act authorizes EPA to provide grants to states to support testing and reducing radon in homes. With various non-governmental and public health organizations EPA promotes awareness and reduction of indoor radon. Partners include the American Lung Association, the National Environmental Health Association, the American Society of Home Inspectors, and the National Safety Council. The Radon Publications page provides a list of EPA-sponsored publications in English and Spanish.

   EPA has also proposed a standard for the maximum amount of radon that may be found in drinking from community water systems using ground water. EPA's proposal for public health standards for radon in drinking water provided two options to States and community water systems for reducing radon health risks in both drinking water and indoor air quality, a unique multimedia framework authorized in the 1996 Amendments to the Safe Drinking Water Act. Information about the proposed rule and information relating to the status of the rule can be found at http://water.epa.gov/lawsregs/rulesregs/sdwa/radon/regulations.cfm. Another link that offers a plethora of information on radon is http://wwww.epa.gov/radon/index.html.

[4] EPA web site http://www.epa.gov/radon/pubs/citguide.html.

2. The Government Accountability Office (GAO) has issued several reports on toxic substances policies in the last few years. Last year, GAO placed EPA's chemical management program on its "high risk" programs and found that chemical assessment poses a major management challenge. How is the EPA and how are other government agencies coordinating their risk assessments and health assessments?

   Answer: EPA interacts with other government agencies concerning risk assessments and health assessments. Department of Health and Human Services (HHS) scientists participate in a number of interdepartmental activities that seek to coordinate risk assessments. For example, EPA's Integrated Risk Information System (IRIS) program interacts with other federal agency scientists at two points in the process for developing IRIS health assessment documents. Prior to public release and external peer review, EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other federal agencies and White House offices for an Interagency Science Consultation. Following peer review and prior to posting the final assessment on the IRIS database, EPA leads an Interagency Science Discussion where EPA provides other agencies and White House offices with the final draft of the IRIS Summary and Toxicological Review and appendix describing the disposition of the peer review and public comments.

   Furthermore, the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of the Centers for Disease Control and Prevention within HHS, advises EPA on public health questions related to hazardous substances in the environment. ATSDR also prepares public health assessments and health consultations evaluating public health impacts of specific hazardous waste sites or spills; the environmental data evaluated in these reports is often collected and analyzed by EPA. Additionally, EPA's National Center for Environmental Assessment has a Memorandum of Understanding in place with ATSDR for collaboration of the development of human health assessment documents on environmental contaminants of common interest to both agencies. The MOU, in place for several years, has served to increase cooperation and coordination and mitigate duplication of efforts thereby more effectively using federal resources.

   EPA also uses research data from other federal agencies in developing risk assessments and health assessments. Studies conducted by agencies, including the National Toxicology Program (NTP), the National Institute for Environmental Health Sciences' (NIEHS) , U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA), National Oceanic and Atmospheric Administration (NOAA), and U.S. Geological Survey (USGS) provide information used by EPA in evaluating potential or real environmental health threats and developing rules [e.g., Maximum Contaminant Levels (MCLs)], guidelines [e.g., reference doses (RfDs), reference concentrations (RfCs), Maximum Contaminant Level Goals (MCLGs)] for risk and health assessments.

3. How can interagency coordination be improved?

Answer: NIEHS and other environmental health science agencies have a long history of coordination through the NTP, jointly funded research projects, professional organizations such as the Society of Toxicology, and an ongoing series of workshops and conferences. In addition, we are actively pursuing better ways to coordinate and share information necessary for good environmental health decision-making. Interagency coordination could be improved through the following general activities:

- Developing and nurturing existing and additional partnerships to facilitate new critical studies based on existing cohorts that may be of cross-cutting interest. Many organizations and agencies have access to long-standing study populations that are relevant to issues other than those they were originally assembled to address. In many cases, other organizations or agencies will have questions or concerns in environmental health sciences that might be answered most effectively by using an existing study population.

  Likewise, we recognize the need for coordination across multiple agencies to share access to new study populations and/or their data. This coordination will include enhancing the stability/accessibility of databases, repositories, and registries through interagency partnerships. These types of partnerships could also provide more opportunities to study unique populations through twin registries, occupational cohorts, and large cohorts that cannot be assembled by a single agency.

- Improved collaboration with federal agency partners to enhance communication and translation of research results into effective means to protect public health. Outreach efforts and engagement of key partners will help to ensure funding the best and most relevant science and to ensure that a meaningful impact is being made on the nation's health.

Senators Inhofe and Vitter:

1. I agree with your point that biomonitoring is research, and can be useful to point the way to where more research is needed. Would you agree that biomonitoring alone won't tell us how to improve public health and could lead us down the wrong prioritization path?

   Answer: Biomonitoring alone, in the absence of other information such as source information or toxicity levels, will not by itself tell us how to improve public health. However, the benefits of knowing about our body burdens can be very helpful in determining appropriate priorities for research and other public health activities. For example, biomonitoring data is very useful in evaluating sites where exposures are ongoing or believed to be ongoing. It provides risk assessors with current exposure information. To improve public health it is also necessary to consider the hazard (toxicity) associated with compounds identified through biomonitoring.

2. Your testimony cites examples where biomonitoring is known to be a good biomarker of exposure. But, we do not know if something picked up in biomonitoring is a good marker of exposure unless we have considerable amounts of other information already. We have this additional information for pesticides because pesticides are intended to do harm to a target species, so, under FIFRA, the manufacturers provide more premarket data. However, producing this additional data cost the manufacturers and consumers upwards of $20M per active ingredient – wouldn't you agree that requiring that level of data for every chemical detected in biomonitoring is not practical or necessary to protect human health?

   Answer: It is important to make a distinction between markers of exposure and actual biological effects. A biomonitoring measurement is a marker of exposure by definition. As mentioned above, it will not necessarily by itself tell us how big the dose was, or where it came from, or what level of health risk it represents. What it will tell us is what our bodies are carrying, and that information can lead us to make informed choices about how to prioritize any further information that may be needed. Other factors such as cost and benefit would be a part of any final decision to gather more information.

Senator LAUTENBERG. I would like to thank each of you for your testimony.

As an observation, I am sorry that our colleague is not here because there is challenge as to what the number of chemicals is out there, and it is not said that all 80,000 of these chemicals are used on a regular basis. The number is quite a bit smaller. But that does not mean that these do not have an effect when in use and that we ought to be on guard.

I have been joined by the Chairman of the committee, and if you are interested, Senator Boxer.

Senator BOXER. I would just like to put my opening statement in the record. I will wait my turn for questions. Thank you.

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

Senator LAUTENBERG. Thank you.

Dr. Falk, of the more than 200 chemicals that were found in people's bodies, how many of these were known or are suspected to cause cancer or birth defects or other health problems?

Dr. FALK. Of the 212 that were tested in the Fourth Exposure Report I believe that six are known carcinogens. They would be arsenic, benzene, beryllium, cadmium, environmental tobacco smoke and tetrachlorodibenzodioxen. They are categorized in that fashion. And there are a number that are characterized as possible or probably. So, yes, there are some included in there that would be considered carcinogens.

Senator LAUTENBERG. Yes. Dr. Birnbaum, the mere presence of a chemical in the body does not necessarily mean that it is harmful. But cannot some of the chemicals cause harm to the sensitive populations in even very small amounts?

Ms. BIRNBAUM. I think the question you are raising is a major one. The presence of a chemical does not in and of itself mean that there is a problem. It depends on the amount of the chemical. And not only how much of the chemical is present but the inherent susceptibility of the person in whom that chemical resides and the issue that I think Mr. Owens referred to of the cumulative exposure.

We are not exposed to one chemical at a time. CDC has measured 212 different chemicals in our bodies. There are others that they have not yet begun to measure. And we really do not have a good handle on what happens when we have this multiplicity of chemicals in our bodies.

Senator LAUTENBERG. Yes.

Mr. Owens, there are thousands of chemicals in use every day, and EPA has to determine which of these to study and act on first. Do you feel that chemicals found in Americans' bodies ought to be prioritized for testing to determine whether the chemicals are safe in order to try and get some kind of a hold on this? Because otherwise there is so much out there that has been neglected and so much out there that is cause for alarm. What do you think about a prioritization of toxicity with the chemicals?

Mr. OWENS. Senator Lautenberg, we absolutely believe that there clearly are chemicals, clearly the entire 84,000 or whatever the actual number is of chemicals that are in widespread use in com-

merce. It would not be rated as the first order of business by the agency to look at chemicals.

But the list of criteria that I laid out for what we used to develop our action plans, including a variety of things, both the PBT and the toxicity characteristics of production and early on exposure in children and the presence of chemicals in the blood, are certainly a good criteria, we believe, to use to begin that prioritization process to address the chemicals that represent what we believe would be the greatest risk to not only the population as a whole but especially to vulnerable populations like children.

Senator LAUTENBERG. Yes. Mr. Stephenson, in your report you say that biomonitoring data alone indicate only that a person was somehow exposed to a chemical, but it does not have the source of the exposure nor its effect on the person's health. Can we identify the quantity of exposure, level of risk or the danger that a person is facing?

Mr. STEPHENSON. Yes. That is why we are suggesting that additional research is needed on both ends to determine where the person likely obtained the exposure and what the resulting health effects might be with those quantities of that exposure and for that, for the duration that they may be in the body. That is where the research is not strong enough yet to support chemical regulation.

Senator LAUTENBERG. Mr. Owens, the goal of my upcoming Safe Chemicals Bill is to give EPA the tools that it needs to keep dangerous chemicals out of our bodies. What changes need to be made to existing law for EPA to fulfill its mission of protecting public health and the environment from unsafe chemicals?

Mr. OWENS. How much time have we got?

[Laughter.]

Senator LAUTENBERG. Well, we have got enough time to listen.

Mr. OWENS. Senator, as I mentioned, the Obama administration, and these are Administration principles, not just EPA principles, have laid out a set of principles that identify some of the major items that we believe need to be addressed. And any updating and reform of the Toxic Substances Control Act, including setting a risk-based safety standard that is based on sound science so that the safety determinations are based solely on risk, the need to give EPA greater authority to obtain information from chemical manufacturers and shifting the burden from EPA to chemical manufacturers to produce that data and provide it to EPA, placing restrictions on the use of confidentiality when they submit data to EPA, giving us greater authority to make information public, as well as providing an adequate funding source for the agency so that when the program, assuming a reform occurs, ensuring that there is adequate funding in order to do the job that Congress would task us to do. So, a lot of different things would need to be done.

Senator LAUTENBERG. I am struck particularly by the reminder that resource has to accompany our legislation. Thank you for that.

Senator Udall.

Senator UDALL. Thank you, Mr. Chairman.

The European Union has recently enacted a comprehensive chemical rule system that many of the world's large chemical companies will comply with. Does this mean that the European environmental regulators will have better information about exposures

to their populations than we will have here in the U.S.? Any of you that would like to answer.

Mr. OWENS. Senator, if I may take a crack at that. I think the answer is, certainly for the time being, yes. And in fact, in our conversations with representatives of industry many of them are saying to us that they think that EPA ought to have the authority to get more information from them because in fact they are providing it, or will be providing it already, to the European Union through the REACH program.

We are handcuffed at EPA because of the obstacles that TSCA puts on our ability to obtain information from industry. As I mentioned in my statement the manufacturers of these chemicals are not required to provide information to us, and if we take steps to ask if they would provide the information to us we have to make a number of very difficult showings as are outlined in the law before we can even get that information from them.

So, the short answer is yes. But we are hopeful that in the long run we will be able to address that gap.

Senator UDALL. And all those hurdles you talked about that are put in place under TSCA that we are unable to get information, I assume that they are, the European Union regulatory system is getting directly to those issues, they are getting that information and that they have it and they have it available?

Mr. OWENS. Yes, Senator, that is correct.

Senator UDALL. Would any of you, please——

Mr. STEPHENSON. Senator, may I make a comment on that?

Senator UDALL. Yes.

Mr. STEPHENSON. The rub against REACH is that it does provide much more data on chemicals from the industry and does shift the burden, appropriately, I think, to the industry to prove its chemicals are safe rather than EPA to prove they are dangerous. But the problem is it is kind of one size fits all now. So, the problem is small chemical manufacturers may have to subscribe to the same information requirements that larger chemical manufacturers would.

So, we would combine what REACH does with some sort of risk analysis of a given chemical, sort of like the Canadian program does right now, so that it is not one size fits all, and the burden of information provided by the industry is more based on the risk of the chemical that they produce.

Senator UDALL. Thank you. That is a good comment.

Dr. Falk or Ms. Birnbaum, do you have any thoughts on this area?

Ms. BIRNBAUM. I can make a brief comment which is I think that REACH will provide a great deal of additional information on the potential toxicity of chemicals. I do not believe that REACH will require biomonitoring in the population because the focus of REACH is to get information before chemicals begin to be used.

Senator UDALL. Now, Dr. Birnbaum, you said in your testimony, you said—and I think I have got this right but please tell me—we do not have a good handle on the impact of the multiplicity of chemicals in one's body. How do we—and this is for the whole panel—how do we get a good handle on that? What are the things

that need to be done to get a good handle on the chemicals that we are all carrying around as a result of modern exposure?

Ms. BIRNBAUM. I think this is a major research question, and we are beginning to try to develop ways to approach it. It has been done for small groups of chemicals. For example, the dioxin-like chemicals are looked at in toto as a group. People are beginning to look at all the chemicals that might have estrogen active activity, for example, that kind of hormonal activity and say, can we look at them as a group.

We are going to have to begin to look at groups of chemicals, and then we are going to have to begin to look at the totality of the groups. And we are beginning to design approaches that we can actually ask that question in not only experimental animal or cell culture and then animal studies but also begin to ask the question in epidemiological studies.

For example, we are finding effects, for example, on thyroid hormones from many, many, many different kinds of chemicals. And we need to understand if you have exposure to PFOA and if you have exposure to PCBs and if you have exposure, for example, to perchlorate, if all these things are going on, how much more likely is that going to be to impact your thyroid hormone system than exposure to one at a time?

So, it is really still a research question but one which is very high priority and we are beginning to look at.

Senator UDALL. Thank you.

Dr. FALK. Senator Udall, if I might reply to that.

We have made a very extensive effort at CDC to actually organize this biomonitoring effort and develop it over the years. So, many years ago we would do individual analysis for specific chemicals. And approximately 8 or 9 years ago we began to do these biannual reports, National Exposure Reports, in which we assemble information on an ever increasing number of chemicals. So, we are up to 212 now. Undoubtedly, with advance of technology the numbers that we will be able to do in these roughly every 2-year reports will increase.

So, there has been in a sense a logistical effort to organize this effort fully, the advance of the science and technology to actually be able to do more chemicals and the commitment to actually do this in a way that advances the science on the biomonitoring.

Senator UDALL. Thank you.

Ms. BIRNBAUM. I would like to make——

Senator UDALL. I have run out of time——

Ms. BIRNBAUM. OK.

Senator LAUTENBERG. Senator Boxer, we are pleased to have the Chairman of the Environment and Public Works Committee with us.

Senator BOXER. Thank you. Senator Lautenberg, first of all, I want to say how pleased I am at your leadership in this crucial issue. And I am very grateful to you. You have really run this subcommittee with an active agenda, and we are looking at the ways to protect our kids and our families, and I am on your team, you know that.

I just wanted to make an announcement to the colleagues that are here that after the first vote at 12:30, we are going to meet off

the Senate floor to mark up some non-controversial GSA, courthouses and such. So, if I could remind you to do that.

And then if you want to start my time.

I would say that we have a responsibility to America's families to ensure that the chemicals in the environment and the products they use have been scientifically tested and that they and their children are not put at risk. We do not have such a system. And it is a dangerous world out there for our kids. That is how I feel about it.

The committee has the opportunity to strengthen our Nation's toxics laws to ensure that evaluations on the safety of chemicals are made based on science and public health and that all people, especially the most vulnerable, are protected. That is part of my statement. But I want to get to some questions. And then I will run out of time, and Mr. Chairman, with your permission I would like to be able to submit these questions to our witnesses.

Senator LAUTENBERG. Without objection.

Senator BOXER. The first one would be for Mr. Owens. Does the Toxic Substances Control Act give the EPA strong authority to fully understand potential health risks from chemicals and to prevent potentially dangerous chemical exposures from products purchased by consumers and used in the workplace? In other words, are you satisfied with the law as it is?

Mr. OWENS. No, Senator, we are not.

Senator BOXER. OK. And that is why this is so crucial and Senator Lautenberg has taken the lead on making sure that this law is adjusted so that you can protect our people.

Director Birnbaum, could you please describe the current state of science regarding health concerns over low level exposures to some chemicals in pregnant women, infants and children? In other words, there is an argument made by some of our colleagues who do not share our views on this that they are such small levels that they do not matter. But my view is, just from what I know about life and science, is that a pregnant woman is in great danger here for the child that she is bringing into the world. And I wonder whether that child is in great danger. So, could you discuss that?

Ms. BIRNBAUM. I think there is growing evidence that developmental exposure can in fact have long lasting health consequences. And what we mean by low level has to be defined, and I think the important way to define it is what we actually find in people.

And in fact, there are an increasing number of studies that demonstrate that the levels, these low levels that have been found in people in our animal studies are showing adverse effects on the developing animals, and in fact there are a growing number of human studies that are looking for associations in the studies where in fact we find that the low levels that are present in people are being associated with adverse impacts on their infants or as the children grow.

Senator BOXER. So at this point I have to cut you off because I do not have a lot of time, but at this point we do not know of any safe level for a pregnant woman and the child she is bearing?

Ms. BIRNBAUM. I think for many chemicals we just do not have the information about how low is low enough.

Senator BOXER. OK.

And Mr. Owens, I guess, Assistant Administrator Owens, some advocate, and I think this is where we are headed with Senator Lautenberg's rewrite of this law, some advocate changing the law to require the chemical industry to prove their chemicals are safe before they are put into products.

Now, it seems to me that is logical. Do you think that is logical to say if there is going to be a chemical introduced, prove to us it is safe before we say fine?

Mr. OWENS. Well, yes, Senator, we do. In fact one of the Administration's principles is that there be a risk-based safety standard that products, I mean chemicals, would have to meet before they can go into commerce, and then if it is determined not be safe there would be risk management actions taken that include a variety of considerations that I mentioned. But yes, Senator.

Senator BOXER. Thank you.

Director Falk, Acting Director Falk, the CDC recently issued its Fourth National Biomonitoring Report. Can you describe the range of different chemicals this report covers, and do the findings show widespread exposure in children and adults to arrays of different types of chemicals or only to a narrow range of substances?

Dr. FALK. The Fourth National Exposure Report actually covers more chemicals that we have ever looked at before. And in particular there are a number of substances that we have not measured in the past that appear to have widespread presence.

Senator BOXER. Did you mention those?

Dr. FALK. Yes. For example, bisphenol A, the polybrominated diphenyl ethers, PFOA, acrylamite, perchlorate, paraffins, benzophenones, triclosan, there is a whole series of new chemicals that we are measuring that we were not measuring 5, 10, 15 years ago.

Senator BOXER. Because they are showing up much more now?

Dr. FALK. Because they are showing up, and we are concerned about them and measure them. And also because of the science advances, and we are now able to measure more of these in the kinds of samples that we have.

So, yes, we are doing more chemicals, we are seeing their presence more, and for the chemicals that I mentioned just a moment ago most of them are present in most of the people. There are detectable levels in most people. So, that presents clearly an important area for all of us to evaluate in terms of what its potential impact is.

Senator BOXER. Well, Mr. Chairman, I will close with this. There are two things, I think, that your hearings you have held here just cry out to me. One is we need to change the way we look at chemicals, which is to make sure they are safe before they get out there, and suddenly they are all in all of us, and we do not know what is safe and what is not safe. And the numbers of chemicals, as you point out, that are untested is just, it has just gotten away from us, and we have got to get a handle on it. That is No. 1.

And No. 2, I think the public is going to cry out for us to take action the way we did, and Senator Klobuchar really deserves so much credit, just saying we are not going to allow certain toxins in toys, we are not going to allow them, you know, in plastics, and

so on and so forth, because that is the immediacy. The public is not going to allow it.

I have a bill for the EPA to set a standard for perchlorate. We had better do that. We know it is out there, everywhere, and you mentioned it. And we know in California it is out there. So, we need to set a standard. And we have to move.

So, to me it is a two track situation—how we go about controlling these chemicals in the first place, and then once they are out and they are ubiquitous, if they are dangerous we had better move.

And I want to say this. We have such a great committee. I am so proud of the members here. And I have to say Senator Lautenberg just plugging away at this, Senator Klobuchar heading a new subcommittee that deals with the safety of kids, and of course Senator Udall is here who is in on all of this and is pushing so hard.

So, you know, I need to leave to go to another meeting, but I just want to thank everybody here and just say to my subcommittee Chairs, just please do your work because I am behind you every inch of the way.

Senator LAUTENBERG. Thank you.

Senator Klobuchar.

Senator KLOBUCHAR. Well, thank you very much, Senator Lautenberg. Thank you, Chairman Boxer, for your leadership. And thank you, Senator Lautenberg.

We know it is important to update this law. It has been 30 years, and think of how the world has changed and the products we are getting from other countries. So, I want to thank our witnesses for their testimony.

When you talk about all these numbers as you have to do as we are setting the science here I think sometimes we forget what this really means in our communities. For me, I got interested in this when a little boy named Darnell Brown, who was 4 years old, swallowed a little charm he got with a pair of Reebok tennis shoes that his mom got. He didn't die from choking or from having his airway blocked. He died because the lead in that charm went into his bloodstream over a period of days. And when they tested the charm, it was 100 percent lead, and it led to one of, I think, the biggest fines ever against a company for what had happened there.

Now we have a new chemical to fear with children's jewelry. We passed, as Chairman Boxer mentioned, the Consumer Products Safety Act. And Dr. Falk, you mentioned cadmium and that you had found it to be one of six toxic chemicals. Can you elaborate on that?

Senator Schumer, Senator Gillibrand and I and a few others have a bill to ban this. I have talked to the head of the Consumer Products Safety Commission, Commissioner Tennenbaum, about what powers they have. And I do not expect you to go into that. But if you could give us some of the science and what you have seen with this chemical.

Dr. FALK. As you know, we have faced in the last number of years many consumer products which have, particularly, lead, cadmium and a number of heavy metals which pose dangers to children. And this is a lengthening list of products. So, we consider this very important.

Senator KLOBUCHAR. Is this cadmium thing something, a chemical that you had seen before in——

Dr. FALK. Yes. Cadmium has appeared in the biomonitoring reports as elevated a number of times. It is a clear concern in terms of health, in terms of kidneys and other diseases——

Senator KLOBUCHAR. Do you know what the toxic effects would be on kids?

Dr. FALK. I do not want to actually comment on this specific instance.

Senator KLOBUCHAR. I understand.

Dr. FALK. But of course children are very vulnerable to a variety of heavy metals, cadmium, lead and others. And I think, you know, we would very much want to limit the exposures to children of these chemicals.

Senator KLOBUCHAR. OK.

Dr. Birnbaum.

Ms. BIRNBAUM. I would just like to mention that we are funding a half-million dollar study right now to look at the impacts of cadmium exposure in children, especially focusing on cardiovascular risk. Most of the studies with cadmium previously have all looked at adults. We now know that cadmium is not only a carcinogen and a kidney toxicant and a reproductive toxicant, but it also is an endocrine disrupter, and we believe that is important to understand. So, we funded work to look at the role of cadmium and the impacts it will have long term of children's health.

Senator KLOBUCHAR. Right. And I will say, I think, for us, we banned lead, and we will put a trace level allowable, and now this new thing comes from China. So, we are very concerned about it and want to act quickly. I do think, unlike with the lead situation, the Consumer Products Safety Commission is acting quickly. A number of the retailers have taken these pieces of jewelry off their shelves, and we go from there.

Just a second question. Formaldehyde. Senator Crapo and I have a bill that has vast bipartisan support and has already gone through this committee because of wood products and what we have seen there. Again, not American wood products. Our timber producers have agreed to a voluntary standard. I know there is some research going on with formaldehyde. Does anyone want to respond to that?

Mr. Owens first.

Mr. OWENS. I'll just take a real quick crack at that. Senator, we are looking very closely at formaldehyde emissions from pressed wood products. My office, as well as the Office of Research and Development of the EPA, is looking at the emissions that come from those products, and we will be working toward trying to set a safety standard for that, a regulatory standard for that, as we get more information back based on that risk evaluation.

Senator KLOBUCHAR. Thank you.

First Dr. Falk, and then Dr. Birnbaum.

Dr. FALK. As you know, just about 2 years ago we did a study of 519 trailers to document the formaldehyde levels in them post-Katrina. And as part of that effort, we have been developing a longitudinal study to follow children who were exposed to formaldehyde in those trailers. So, that is in the process of being estab-

lished, and that, hopefully, will add more information on the health effects in children.

Senator KLOBUCHAR. Yes. I think that is why the Senators from Louisiana are supportive of this bill. And they know we need to move quickly.

Dr. Birnbaum.

Ms. BIRNBAUM. We know that children are often subject to higher exposure just because they have a more rapid respiration rate than adults. So, we are concerned that children do have higher exposure, and you know, we have been talking to CDC about the study they are doing.

I did want to mention that in our recent evaluation on the report on carcinogens, which is a congressionally mandated report, where we list chemicals as being known carcinogens or reasonably anticipate it to be a carcinogen; the expert peer panel which reviewed all the data came out with the conclusion that formaldehyde is a known human carcinogen.

Senator KLOBUCHAR. Very good. I have some additional questions on radon and carbon monoxide, also specific to the reauthorization that I will submit for the record. So, thank you very much for your time.

Senator LAUTENBERG. Thank you very much, Senator Klobuchar.

As you can see, there is a very active interest in the testimony that each of you has given, and thank you for it. It is very thoughtful and very helpful in our decisionmaking here.

With that, we will bring up the next panel, which includes Molly Jones Gray, Ken Cook, Charles McKay and Tracey Woodruff. Thank you for being here with us. Your testimony is so important because while we do not necessarily want to believe the worst, what we want to do is protect again even the least.

And why we have doubters who challenge whether or not there are 80,000 chemicals out there or what have you, the fact of the matter is that I know that you heard what the former panelists said, and it makes us—and I speak for myself and I think my colleagues—it makes us more determined to continue to wade through the opposition to even listen, to even accept, certain levels of conditioning that we have to get through. So we welcome you.

Molly Jones Gray, we welcome you. We know you are from Seattle, Washington, and you are going to tell us something about chemicals that were present in your body during a pregnancy. I would ask you to start by giving us your testimony. It is limited to 5 minutes, but I am a little bit of a patient fellow.

STATEMENT OF MOLLY JONES GRAY, PARTICIPANT IN A BIOMONITORING STUDY

Ms. GRAY. Thank you so much for having me. It is a great pleasure to be here today. My name is Molly Jones Gray, and I come before you today as a concerned mother.

I recently participated in a study by Washington Toxics Coalition called Earliest Exposures. This was a study designed to find out what our developing fetuses are exposed to during pregnancy.

The study tested for phthalates, mercury, BPA, PFCs, often referred to as Teflon chemicals, and a flame retardant. Many of these substances are known to have adverse health effects. Of the ones

tested I had higher than the national average for many. Of all the pregnant women tested I had the highest rates of mercury.

During the 5 years preceding the study I had struggled with fertility and repeated miscarriages. And as I searched for an answer to why, why I was having such a hard time carrying a baby to term, I discovered the connection between our environment, our toxic exposures and our health, particularly our reproductive health.

So, at that time I made reasonable changes in my life to reduce my exposure. I consumed mostly organic foods, I ate seafood only on the low mercury seafood list, I used personal care products without phthalates, and I avoided plastics, both cooking and storing my foods in plastics.

So you can see when I first heard of the study, I was extremely interested in participating because I wanted to see, do my best intentions make a difference? And the answer I received was incredibly disheartening. I was shocked to see that my levels were as high as they were. This made me realize that the fight to avoid toxins is so much larger than just one person. These chemicals have become so ubiquitous in our environment that as clean as I tried to be, it was not enough to protect my little baby boy.

Mothers-to-be, such as myself at the time, can make many choices to ensure a healthy pregnancy. We can take prenatal vitamins, we can eat a healthy diet, we can avoid cigarettes and alcohol, we can exercise. But of all the choices that we are able to make, we do not have a choice in this one. We cannot protect our babies from the powerful influence of toxic chemicals on their developing bodies.

So now that my son is 7 months old and people hear my results they often ask me if my son is healthy. And my answer is, as far as I know, he is. He is a vitally healthy wonderful little boy. And pretty cute, too. He wanted to be here today, but this whole time difference he could not quite understand, and he is sleeping away in the hotel now.

But what most alarms me now is that of the unknown. We have no idea what the long-term health implications of these results are. And I do not want my son or anyone's children to be our scientific experiment. Developing babies are uniquely vulnerable.

Something is terribly wrong when I, as an educated consumer, am unable to protect my vulnerable baby. I, and all families, I feel, should be able to walk into a store and buy whatever products they need without wondering if the products that they are bringing home are putting their families' health at risk.

Since participating in the study I have learned that companies can put chemicals into products without ever testing whether they harm our health. I think we need to change these laws.

So, on behalf of my son Paxton and all other children I am asking for your help, help in lowering our body burden from these toxic chemicals that come between us and our health. In order to do that, I think policymakers should take immediate steps to eliminate the use of persistent toxic chemicals, the ones that build up in our body over time and are passed on to the future generations. I believe legislation should reduce the use of chemicals that have known serious health effects and ensure that only the safest of

chemicals are used in our everyday products. And finally I think we need standards to protect our vulnerable populations such as pregnant women and their developing babies.

So, in conclusion, I believe that babies deserve to grow in a healthy environment, both in utero and out. Instead, babies are born every day already exposed to chemicals that have known serious health effects. Safe until proven harmful is not good enough for me or my baby.

And throughout the hearing today I have repeatedly heard that science is the key. So, I think that my role here today is to tell you that until we have that science, children such as my own, my Paxton, and all the other children are being affected by these laws.

It will take time to rid out population of this burden on our bodies. We need to start now. This is not my story alone. This is the story of all of our children, our grandchildren and future generations.

I appreciate this opportunity to tell my story. Thank you.

[The prepared statement of Ms. Gray follows:]

Testimony of Molly Jones Gray,
To the Senate Environment and Public Work's Committee
February 4th 2010

It is my pleasure to be here. My name is Molly Jones Gray. I come here before you today as a concerned mother. I recently participated as one of the women in a Washington Toxics Coalition study called "Earliest Exposures." This was a study of pregnant women to investigate what toxins our developing fetuses were exposed to during pregnancy.

Earliest Exposures- A research study by WA Toxics Coalition
The study tested for phthalates, mercury, PFC "Teflon chemicals", flame-retardants, and BPA. Many of these substances are known to cause adverse health effects such as reproductive problems, cancer, hormone disruption, and impaired neurodevelopment. My results were higher than the national average in many of the substances tested. In fact, I had the highest mercury of all the pregnant women tested.

During the five years preceding the study, I struggled with fertility and repeated miscarriages. As I searched for an answer to why I was having such a hard time bringing a child to term, I discovered the connection between our external environment, chemical exposures and their effect on our health, particularly reproductive systems. At that time, I made reasonable changes in my life to reduce my exposure to toxic chemicals from all routes of entry- air, food, drink, and skin. I did my very best to eat organic food, low mercury seafood and use personal care products without phthalates and fragrances.

Personal Reflection on My Test Results
When I first heard of the study about chemicals in pregnancy, I was extremely interested in participating. I wanted to see if my best intentions made a difference. The answer I received was incredibly disheartening. I was shocked that my levels were as high as they were. I learned that this fight to avoid toxins is larger than one person alone! These chemicals are ubiquitous in the environment and as clean as I tried to be, it was not enough to protect my baby boy.

Mother's- to- be can make many choices to ensure a healthy baby- we can take prenatal vitamins, exercise, avoid cigarettes and alcohol, and eat healthy diets. I am disappointed that with all of the choices we are able to make we do not have a choice to protect our children from the powerful influence of toxic chemicals on their developing bodies.

Now that my son is 7 months old, people often ask me if my son is healthy. My answer to that is as far as I know he is a healthy happy boy. My concerns are of the unknown. We have no idea what the long-term health implications of these

results are and I do not want my precious son or other children to be our scientific experiment.

Changes Needed to Protect All Children
Developing babies are uniquely vulnerable to insult as they are developing at a rapid pace. Toxic exposures at crucial points in development could affect the wellbeing for a lifetime. In addition, fetuses have been found to have immature detoxification pathways. They cannot clear toxins as well as adults.

Something is wrong when I, as an educated consumer, am unable to protect my baby from toxic chemicals. I and all other parents should be able to walk into stores and buy what we need without winding up with products that put our families' health at risk. Now that I've learned that companies can put chemicals into products without ever testing for whether they harm our health, I think we need to change our laws.

On behalf on my son Paxton and all other children, I am asking for your help to lower our body burdens of chemicals that come between our health and us.

In order to do that I am asking Congress to take immediate steps to eliminate the use of persistent toxic chemicals — those that build up in our bodies or are passed on to the next generation. Legislation should also reduce the use of chemicals that have known serious health effects and ensure that only the safest chemicals are created and used in everyday products. Finally, we need standards that protect our most vulnerable populations like pregnant women and developing fetuses.

Conclusion
I am disappointed that toxic chemicals like the ones found in my body in pregnancy are in our environment, our personal care products, our clothes, our furniture, our baby toys, and our food. Babies deserve to grow and develop in a healthy environment, in utero and out. But babies are born everyday already exposed to toxins linked to serious health problems. Safe until proven harmful is not good enough for my baby or me. I want our country to value the lives of its children the same way I value and love my son. It will take time to rid our population of this burden on our bodies- we need to start now. This is not my story alone—this is the story of all of our children, grandchildren and future generations. Thank you for this opportunity to tell my story.

Senator LAUTENBERG. Thank you very much. I am very pleased that you could sit face-to-face with some of the doubters and talk about the apprehension and the struggle that you went through to conceive and to carry. But I am sure, as you have said, that not only is our child smart and all those things, but he is cute as well. We take your word for that. And thank you.

Now, please, Dr. McKay, we invite your testimony. You are from the Hartford Hospital. That is Hartford, Connecticut, is it?

Dr. MCKAY. Yes, it is.

Senator LAUTENBERG. OK. Please.

STATEMENT OF CHARLES MCKAY, M.D., FACMT, FACEP, ABIM, DIVISION OF TOXICOLOGY, DEPARTMENT OF EMERGENCY MEDICINE, HARTFORD HOSPITAL, HARTFORD, CONNECTICUT

Dr. MCKAY. Thank you, Chairman Lautenberg, and the rest of the committee and guests.

I am coming to you today as a physician trained and certified in Internal Medicine, Medical Toxicology and Emergency Medicine and with a role to convey the information that is provided from biomonitoring data to patients and the public as well as to other professionals.

I want to just comment that the comments I have are—I am a member of the Board of the American College of Medical Toxicology, but the comments here are my own and do not necessarily reflect the opinions of the Board of Directors or all of the members of ACMT.

I do have material that I have provided for the written record that does come from the College as well as me.

I would just mention that admission to the American College of Medical Toxicology is to advance quality care of poisoned patients and public health through physicians who specialize in consultative, emergency, environmental, forensic and occupational toxicology. And as a part of that role we do have an important mission to try and translate the information that comes from studies.

I am not going to belabor the benefits of biomonitoring because I think that has already been adequately covered by the members of the first panel. But I also would like to mention some of the potential risks of taking biomonitoring information and miscommunicating that to the public.

As a medical toxicologist I have to, on a daily basis, deal with people who have a concern that they have been poisoned or that their children have been poisoned because of the identification of chemicals from one study or another. And I have developed a way of responding that is, I hope, appropriately cautious while at the same time reassuring to people regarding both the response and adaptability of our bodies but also the difficulty of taking a given exposure, or exposures to mixtures, and then defining a response with any degree of surety.

I would just list out for the committee several criteria that I think is very important as we try to communicate biomonitoring data.

No. 1 would be that identifying a substance as being a public health concern is not the same as stating that it is causing indi-

vidual harm. Biomonitoring data can help greatly here to try and identify the degree of exposure of individuals and how that does fit in with the population. Decisions about exposure need to incorporate information about at-risk populations and in particular whether the people that are expressing those concerns are actually members of that population as well as the benefits gained by use of the product or availability and potential adverse effects associated with the alternatives.

Biomonitoring data alone does not answer all of these questions. But common sense certainly should play an important role. And I think members of the committee as well as the panel have mentioned some of those issues.

In particular, I would like to comment on Dr. Falk's mention that we have nearly 2 percent of the population with measurable amounts of lead that exceed what are our current level of concern, whereas when most of us were growing up as children that was 90 percent. So, it is difficult as we approach zero on some chemicals to understand how there is a claim of continued, ongoing health risks from those when we were exposed to so much more as children. Or maybe it just actually identifies the degree of brain damage that we have as old adults.

Claims of association of a medical condition, therefore, with historic exposures to some substances do need to be evaluated in the face of current exposures. So, for those elements and items that we have decreasing exposure to, then we need to recognize that that is true. Those that are increasing or have particular issues with biopersistence, that is where we need to focus our efforts.

My point, though, is just that biomonitoring is not going to get rid of all of the potential confounders with our data that we are able to obtain. It is a very useful tool for documenting human exposure to environmental chemicals of concern, tracking trends in exposure, and prioritizing chemicals of most concern for possible regulation, restriction or substitution, consistent often with green chemistry principles that are being enunciated around the country.

I would just mention that there is a role to be played by the State public health laboratories in actually rolling out some of these issues, and they should be funded for that purpose because that is what they are there for.

I thank the committee for this opportunity to present my views as a practicing medical toxicologist and educator, and I would be happy to take any questions.

[The prepared statement of Dr. McKay follows:]

January 30, 2010

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Re. Hearing: Current Science on Public Exposures to Toxic Chemicals
Scope: Examination of recent science analyzing public exposures to toxic chemicals

Senate Committee: Environment and Public Works
Subcommittee on Superfund, Toxics and Environmental Health

Chairwoman Boxer, Chairman Lautenberg, Ranking Member Inhofe, esteemed Members of the Committee, and guests:

Thank you for the opportunity and honor of presenting testimony to this subcommittee on the "current science on public exposures to toxic chemicals." I trust that this hearing on health exposures and biomonitoring will be useful, and an important component to the process of improving public health through the intended reform of the Toxic Substances Control Act of 1976 (TCSA).

Biomonitoring is a tool with clear benefits. The ability to actually measure the amount of any given chemical in the body is an important step beyond – or test of – modeling assumptions. The ability to identify lower and lower concentrations of an increasing number of substances has allowed us to recognize potential problems much earlier than in the past and has provided the impetus to act before harm occurs. The use of biomonitoring for research to investigate potential new interactions on multiple fronts is an important new area for investigation. Many of the witnesses before this committee have discussed these points in the past. I want to focus my remarks on the impact of biomonitoring on medical care and public perceptions, particularly in the area of risk communication. I leave my written comments to be read into the record, along with associated references. I am happy to respond to any questions from the committee.

Personal Background:
I am a physician, trained and board-certified in Internal Medicine, Emergency Medicine, Medical Toxicology, with additional experience in Pathology, Occupational Health, and laboratory interpretation. I have been an attending physician in Connecticut for 22 years. I am the Medical Director of Occupational Health Services for Hartford Hospital and the Connecticut Children's Medical Center. I am the Associate Medical Director of the Connecticut Poison Control Center (CPCC), one of about 60 regional poison centers certified by the American Association of Poison Control Centers. The CPCC receives more than 30,000 calls every year from the public and medical personnel regarding possible or known toxic exposures. I am an Associate Professor at the University of Connecticut School of Medicine, and the Director of the Medical Toxicology training program at UConn, one of about 24 such programs in the country. In that role and as an educator, I am responsible for training some of the next generation of medical providers. I am a consultant to the Connecticut Department of Public Health and was a member of the Environmental Health Public Tracking Program Planning Committee. I participate in our state's biopreparedness activities. I also serve as a reviewer for 6 peer-reviewed medical journals, and am a member of the Editorial Board of the Journal of Medical Toxicology. I am a member of the Scientific Advisory Council of the Environmental Health Research Foundation, at whose invitation I agreed to testify today. I am a member of the Board of Directors of the American College of Medical Toxicology (ACMT), which is the member organization representing most of the 500 board-certified Medical Toxicologists in the country. In that capacity, I serve on the Practice Committee and am the National Director of a network between ACMT and the Agency for Toxic Substances and Disease Registry (ATSDR) of the Centers for Disease Control and Prevention (CDC). The purpose of this network is to provide the regional expertise of physician medical toxicologists to the regional ATSDR representatives and their public health partners in order to address concerns about human exposure to chemicals in the environment (either naturally-occurring or arising from human activity).

My comments are my own, and do not necessarily reflect opinions of the ACMT, its Board of Directors, or its members. I have attached for the written record an editorial published in our on-line journal (Appendix A), and a position statement of the College (Appendix B) relevant to some of the issues discussed today.

The mission of the American College of Medical Toxicology is to advance quality care of poisoned patients and public health through physicians who specialize in consultative, emergency, environmental, forensic, and occupational toxicology. Previous contracts and cooperative agreements with ATSDR have allowed ACMT to present material on chemicals as potential terrorist weapons (Toxic Industrial Chemicals and Toxic Industrial Materials) to more than 6000 public health, prehospital and medical personnel, emergency planners, and military personnel; and material on the health effects of clandestine methamphetamine laboratories to more than 1100, as well as recurring conferences at regional and national meetings.

Potential Benefits of Biomonitoring:
Medical Toxicology is a medical subspecialty focusing on the diagnosis, management and prevention of poisoning and other adverse human health effects due to medications, occupational and environmental toxins, and biological agents.

Biomonitoring is an important tool for use in toxicology. In the current setting of unwarranted or uncertain fear about "all things chemical", it can also be used to focus or alleviate concerns. Specifically, a robust biomonitoring program can be used to a greater or lesser extent to:

- Identify the concentration of chemicals actually taken up by the human body and the metabolic fate of those chemicals;
- Improve the accuracy or test the validity of assumptions in physiologically-based pharmacokinetic modeling or regulatory models;
- Identify susceptible populations or particular at-risk groups (e.g. genetic polymorphisms) for chemical toxicity;
- Track trends of exposure over time and in the setting of various interventions;
- Validate reference ranges for chemical exposure;
- Inform discussions regarding levels of exposure consistent with no adverse effects (thresholds);
- Provide a framework in which to evaluate individuals' concerns about chemical exposure.

Need for Support of Currently Existing Mechanisms to Conduct Biomonitoring:
While the viewpoints and worldview of the multiple participants in the 2006 National Research Council's (NRC) report on "Human Biomonitoring for Environmental Chemicals" (http://www.nap.edu/catalog.php?record_id=11700) may differ, their recommendations identify not only potential benefits and research utility, but also the shortcomings and the practical difficulties of using biomonitoring to answer questions about environmental exposures and human health.

These difficulties are to be expected, given the different dosing scenarios, genetic polymorphisms, and impact of other diseases and confounders on an individual's or population's response to any single or mixture of substances. As reform of TSCA is considered, please bear in mind the recommendations of this group, as well as the need for funding to reach the goals espoused by this committee. The NRC's recommendations include the need for:

- Coordinated strategy for population biomonitoring based on potential for exposure and public-health concerns;
- Development of biomonitoring-based hazard and exposure assessments and public-health; surveillance to interpret the risks posed by low-level exposure to environmental chemicals, enhancing where possible existing efforts by adding biomonitoring in order to improve interpretation;
- Focus on strategies for reporting results of biomonitoring studies;
- Review of bioethical issues inherent to biomonitoring efforts;

These are in fact the ultimate goal of such efforts as the recurring National Health and Nutrition Evaluation Survey (NHANES) and the goal of the Environmental Public Health Tracking

programs at the state and regional levels. Unfortunately, funding for state-based biomonitoring efforts, building on years of public health activities and medical concerns at the state, regional, and national levels, has been cut drastically, resulting – for example – in a 67% decrease in allocated funding this year and a reduction from a possible 33 states to only 3 states funded. The National Association of Public Health Laboratories (APHL) has issued a document identifying the priority needs of the state laboratories and emphasizing the need for coordinated funding of existing infrastructure to improve and regionalize what is now a fragmented system (http://www.aphl.org/policy/priorities/Documents/HillDayFactSheets2009.pdf). Utilizing improved capabilities and capacity developed through biopreparedness efforts over the last 8 years, it is very possible to utilize the expertise and resources of state-based public health laboratories for biomonitoring projects of public health importance. I was able to attend the National Biomonitoring Planning Conference held by the APHL in Atlanta last fall (http://www.aphl.org/aphlprograms/eh/Documents/NBMSummary2009.pdf). This meeting of state and federal laboratorians generated the framework for a 5 year plan to generate a data- and expertise-sharing biomonitoring program. However, this can only occur through funding and education of qualified personnel to make use of purchased equipment.

Limitations of Biomonitoring:

It is important to recognize the limitations of biomonitoring. Biomonitoring is a tool. It is not an answer. It does not, in and of itself, eliminate potential confounders or alternative explanations for identified associations between chemical exposure and disease. As perhaps needs reiterating, the identification of a substance confirms its presence; it does not indicate whether that substance is causing harm or benefit. Any environmental chemical will be present to some extent in those who ingest, inhale or otherwise are exposed to it. Thus, the statements that have been made in this committee and other venues that "neurotoxins", "endocrine disruptors", or other "harmful chemicals" are present in our (and our childrens') bodies is meaningless, without specific relationship to dose, exposure timing, and comparison to appropriate control populations. While it is frequently stated that "scientists have developed a more refined understanding of how some chemicals can cause and contribute to serious illness", it is also true that our ability to measure substances at very low concentrations has outstripped our ability to determine causation. In other words, scientists are able to identify spurious associations with environmental chemicals, while having difficulty accounting for confounders, thus proffering disease causations that do not, in fact, exist.

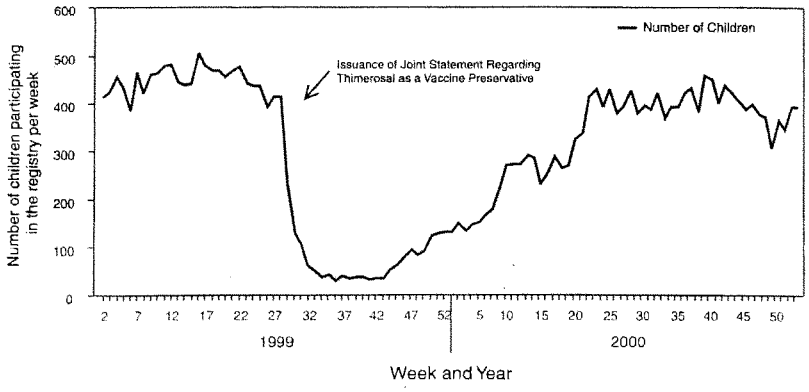
The Precautionary Principle (United Nations, 1992)

Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent degradation.

Unfortunately, biomonitoring can be – and has been – abused as a tool. The practical problem with overstating exposure-disease associations is seen every day by medical professionals who evaluate people who are fearful of being "poisoned" by the latest chemical touted in a study as the cause of the same disease blamed on another compound the month before. Unfortunately, there are also a number of practitioners who prey on such patients, offering therapies that are not

indicated for conditions the patient does not have. On a weekly, if not more frequent basis, I am contacted by patients or media desiring assistance in interpretation or personal application of data reported in the scientific literature or obtained from ill-considered or inappropriately-performed laboratory testing. This does not just affect the small portion of the population with fixed delusions. It potentially impacts every woman considering pregnancy, every parent wondering about their children's health, and every worker and employer. The incessant drumbeat that environmental chemicals are the source of all ills is hyperbole that should fall in the face of the evidence supported by biomonitoring.

FIGURE 2. Number of children who received first dose of Hepatitis B vaccine ≤5 days after birth — United States, 1999–2000



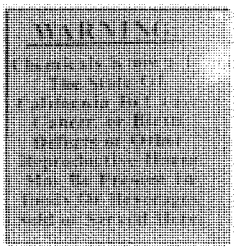
When the message is not communicated clearly or correctly, we end up with inappropriate response and harm, rather than the prevention of harm. This is demonstrated in the drop in vaccinations (figure above) and neonatal deaths from Hepatitis B secondary to unfounded concerns about thimerosal-preserved multi-dose vials of vaccine.

Similarly, increases in unvaccinated measles cases and persistently lower rates of vaccination are attributed to the unethical and dishonest study published in The Lancet by Wakefield et al., based on 12 patients.

Practical Risk Communication Issues Concerning Exposure to Chemicals in the Environment:

How do I as a practicing toxicologist provide a scientific, understandable, and appropriate message to my patients and other concerned parties, both professionals and lay public? I have used the following criteria in my evaluation of the literature and communication with others. I would respectfully suggest that these be considered when communicating biomonitoring data to

Americans, whether at the patient-physician, scientist-peer-review literature, policy or regulatory levels.



- Identifying a substance as being of public health concern is not the same as stating it is causing individual harm. Appropriately obtained or extrapolated biomonitoring data can be used to gauge an individual's exposure compared to population norms.

- Decisions about exposure need to incorporate information about at-risk populations (and whether an individual is a member of such a group), as well as the benefits gained by use of the product or availability and potential adverse effects associated with alternatives. Biomonitoring data alone does not answer this question, but common sense should play an important role.

- Claims of association of a medical condition with historic exposures to some substance need to be evaluated in the face of current exposures. Biomonitoring data that identifies decreasing – or increasing – population exposure to chemical compounds should be incorporated into all research publications touting disease associations and should be required by editors prior to acceptance for publication.

- Using a study population to data dredge for associations is reasonable for hypothesis generation. A statistical association generated post-hoc from multiple comparisons is shaky ground from which to draw conclusions, particularly when the conclusions fly in the face of existing information or known facts, or do not take into account reasonable confounders.

- It is intellectually dishonest to claim that effects of chemical exposure are so small as to be clinically unrecognizable, then attribute major clinical effects to these same exposures.

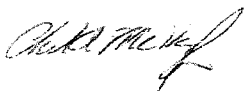
My point is that spurious associations and contradictory positions on regulation of chemicals in our environment are not going to be resolved solely by the use of biomonitoring. However, appropriate focus on those substances or exposures of most concern can be greatly influenced by the results of carefully considered, appropriately conducted and correctly interpreted biomonitoring studies.

As a practicing physician toxicologist, it is my responsibility to interpret the basic science, animal and human exposure data for people who are concerned about their risk, and to educate physicians and others who provide care for patients or information for people. Those who co-opt the biomonitoring process for their own advancement and political aims do a disservice to the entire medical and lay community with generalizations about "chemicals", "cancer", "neurotoxins", "endocrine disruptors", and other terms that are used without specific and detailed reference to dose, effect, and risk/benefit considerations, applied to both the products in use and their alternatives.

Biomonitoring is a very useful tool for documenting human exposure to environmental chemicals of concern, tracking trends in exposure, and prioritizing chemicals of most concern for possible regulation, restriction or substitution, consistent with "green chemistry" principles. Chemicals with declining prevalence or concentration in the population, as demonstrated by biomonitoring, should be treated as the historical success or cautionary stories they provide in terms of public health improvement or lack thereof. Attention and funding should be focused on those compounds that display biopersistence, bioaccumulation, biotransformation, or that generate sentinel signals from high-dose exposure (e.g. occupational) or high-risk populations (e.g. fetal/neonate); and for which concern for significant public health effects exist.

I thank the committee for this opportunity to present the views of a practicing medical toxicologist and educator on the important issues of biomonitoring, public health, and risk communication.

Sincerely,



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CDC EPHT: http://www.cdc.gov/nceh/tracking/trackbiomon.htm

CDC Funding 2009 Biomonitoring grants http://www.cdc.gov/biomonitoring/state_grants.htm

CDC. Fire Deaths and Injuries: Fact Sheet.
http://www.cdc.gov/HomeandRecreationalSafety/Fire-Prevention/fires-factsheet.html

CDC National Exposure Report: (chemicals in 4th report): http://www.cdc.gov/exposurereport/pdf/NER_Chemical_List.pdf [212 chemicals, including 75 being checked (retrospectively – 2003-4; 1999-2000, 2001-2) for the fist time]

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APPENDIX A: Internet Journal of Medical Toxicology Editorial

A Call To Arms For Medical Toxicologists: The Dose, Not The Detection, Makes The Poison
Internet Journal of Medical Toxicology 2003; 6(1):1 (archived)
http://www.acmt.net/cgi/page.cgi?aid=1543&_id=52&zine=show

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Introduction

Over the last several decades, the analytic capability to measure very small concentrations of an increasingly vast array of chemical structures has increased dramatically. Analytic chemists can now measure certain purported toxicants at a fraction of a part per trillion.[1] To give some idea of this level of detection, the proverbial "drop in a bucket" would be measuring things at the parts per million range; parts per trillion is equivalent to a "drop in a lake"!

Unfortunately, our ability to determine what to do with this data has not progressed as fast as the analytic technology. Although a tenet of toxicology is that "the dose makes the poison", many people inappropriately fear that the very detection of a substance must equate with toxicity. As medical toxicologists, we focus on the patient's symptoms and signs and their association with exposure and delivered dose. However, many of us are faced with patients coming from other practitioners with laboratory data from a multi-element panel indicating toxicity by mercury, arsenic, or other heavy metals or excesses or deficiencies of a wide array of trace elements or hydrocarbons (so-called environmental pollutants). These laboratory tests are often presented as *de facto* evidence of toxicity or "systemic imbalance or insufficiency" without any evidence of excessive dose or exposure. Furthermore these test results are then considered the cause of a variety of poorly characterized or general symptoms. Unfortunately, "environmental ecologists" and other practitioners[2] often use these test results, which we consider clinically irrelevant, as support for a variety of scientifically unproven or clinically non-indicated treatments.

We define esoteric testing to be uncommonly performed laboratory analyses for trace elements, environmental contaminants, or endogenous enzymes obtained from samples of blood, urine, hair or other body tissue. These tests or matrices generally lack a published reporting of validated reference ranges or suffer from significant procedural difficulties. While a large number of potentially valid analytes or methods may fall into this broad definition, the widespread use of certain testing panels and laboratories by certain groups of practitioners present obvious examples of aberrant practices with which we are all familiar. (the so-called "know it when you see it" definition of quackery).

We present the following composite case and a rationale for a proposed set of criteria to assist physicians in the decision to perform esoteric testing and in the interpretation and application of results already obtained.

Case Example

A 52 year old woman presents to the toxicology clinic complaining of generalized fatigue, difficulty with memory, and anxiety. There is a history of some weight loss over the last few months and difficulty sleeping. The patient is an ex-smoker and consumes occasional ethanol. A general physical exam is unremarkable, as is a neurological and mini-mental status exam. During

further questioning, as the toxicologist formulates a wide differential (including a number of non-toxicologic diagnoses), the patient declares, "My other doctors found I was out of balance and have too much mercury in my system. I want to know if I should have my dental fillings removed because I don't feel much better after chelation." With further discussion, it becomes clear that the patient has been to a number of practitioners, some of whom have used "alternative practices" such as kinesiology to determine she has an excess of heavy metal contamination, while others have given courses of dimercaptopropane sulphonate (DMPS) followed by urinary mercury collection and hair mercury analysis.

Discussion

While poisoning by a wide variety of naturally-occurring heavy metals or industrial contaminants is well-described, the "low-level" toxicity of mercury, arsenic, and other heavy metals is more problematic. Even for elements, such as mercury, where it is generally accepted that hair analysis is a valid analytic technique[3], proper collection, analysis and interpretation is still necessary. Furthermore, the distinction between public health concerns and individual toxicity is very important. For example, it is generally accepted that mercury contamination of the environment has contributed to an increase in the mercury concentration in marine animals. All states have health advisories regarding the consumption of fresh-water fish because of concerns about mercury (and PCB) contamination. Yet these advisories are focused on the possible risk for neurotoxicity for the unborn child of a pregnant woman. While various studies have raised questions about subtle population neurodevelopmental effects from amounts of mercury 10-100 times that of the average American diet (resulting in maternal hair mercury measurements far above what is commonly reported as abnormal by hair analysis laboratories), even these authors state that none of their subjects demonstrated clinical mercury poisoning.[4] Can we reassure the vast majority of patients with vague symptoms and abnormal heavy metal screens without glossing over the patient who is truly poisoned? We believe such a balance is possible and should be one component of the medical toxicologists' practice. On an individual basis, we can educate practitioners and the general populace in our area regarding some of the cautions to take with available laboratory testing. Each of the following points deserves careful consideration:

1) The decision to perform laboratory testing should be based on a differential diagnosis, rather than indiscriminate testing.

It is often tempting to run a large battery of tests on patients with poorly characterized or complex presentations. Patients who carry diagnoses such as chronic fatigue syndrome, multiple chemical sensitivity, fibromyalgia are especially prone to this type of testing, since these "conditions" are essentially symptom complexes and have no known organic or toxic etiology. Also, patients with chronic, progressive or incurable disorders such as multiple sclerosis and autism may be tested for toxicants. Some physicians will order trace mineral analyses searching for a cause of these syndromes, but many unscrupulous practitioners order these tests to "prove" to patients the need for chelation or other unnecessary, and potentially dangerous, "treatments". Unfortunately, this reliance on analytic testing is often misplaced. By pure chance, the statistical likelihood of finding a test result outside a population norm will increase as the number of tests increases. In the absence of good clinical correlation, these results are usually meaningless, but can cause a good deal of confusion and concern in both patient and physician.[5] As mentioned above, the dose determines toxicity. In addition, most toxicants produce a characteristic pattern of effects; this

specificity of effect should be carefully sought in the history and physical exam, which then should guide testing patterns.

2) Critical methodological steps regarding specimen collection and laboratory analysis must be heeded.
All of these tests measure very small amounts of chemical compounds. As such, even low-level contamination of collection materials or procedures can result in false positive reports. This problem is well described with lead biomonitoring, where elevated capillary blood measurements from fingerstick testing must be confirmed with a venous sample because skin contamination with lead may result in falsely elevated blood levels. This can also occur with heavy metal testing of hair, due to external contamination by metals found in hair treatments, public water supplies or air pollution.[6] Similar problems arise with blood or urine collections.[7] In addition, dietary restrictions are necessary when analyzing body burden of heavy metals or trace elements to prevent false elevations from such agents as dietary supplements or seafood. As an example, the presence of largely non-toxic arsenobetaine and arsenocholine - "fish arsenic" - from seafood interferes with the assessment of arsenic exposure.[8] Although a further testing refinement (i.e. speciation of arsenic type) can be used for this element if there are concerns about the patient's dietary contribution, few laboratories provide this expensive service. Furthermore, this would not distinguish the contribution of arsenosugars that are present in marine algal products (often present in supplements).[9] Finally, many labs will analyze a urine specimen collected for six hours after a chelation challenge, and then compare this result with a norm based on a non-challenged collection. This result will almost always be higher than the non-challenged test but does not reflect an abnormal body burden of the presumed toxicant.[10,11,12] As an example, normal subjects may excrete several fold more mercury post-chelation than in their own pre-chelation test.[12] The results then are "flagged" as abnormal when in fact the testing has done little more than document a normal response to the chelator.

3) Laboratory tests should have well-validated reference ranges. These are lacking for many esoteric tests.
Population norms are often not standardized or are based on small numbers. In fact, some of these laboratories have developed their own reference ranges that are much lower than widely accepted ranges such as that published for hair mercury by the National Centers for Environmental Health of the CDC. This represents their belief that these toxins are more poisonous than mainstream medical science believes. The end result is many patients' results will be flagged as abnormal. In addition, accuracy is very poor for some analyses, such as hair testing by popular laboratories.[13] Many of these laboratories claim Clinical Laboratory Improvement Amendments (CLIA) certification, a federal standard for certain analytic tests, yet no such certification specifically exists for hair mineral analyses. Proficiency testing standards for hair testing do not exist, and individual labs devise their own verification methods and criteria for accuracy. Analytic laboratories should demonstrate some validity of testing, both internal (precision) and compared to standards (accuracy). Even when this is done,[14] information regarding measurements in a target population, such as those with known clinical effects from excesses or deficiencies of the given analyte, should be included.

4) Exceedance of a reference value does not necessarily imply that a patient is poisoned.

Interpretation of laboratory tests is best done in the clinical setting. Often additional clinical, epidemiological and laboratory data are necessary to establish a scientific basis for linking an elevated lab value with the presence or future risk of an adverse health outcome. In fact, for some elements and enzymes, the biologic or physiologic human health effects are not well characterized. As with the heavy metals, the effects of gross deficiencies (e.g. selenium)[15] or excesses (e.g. manganese)[16] are well described, while the effects of smaller variations from a population norm are less clear. Indeed, the experiences of certain unusual populations, such as two-three fold increases in serum manganese in patients receiving total parenteral nutrition, suggest no clinical adverse effects from these excesses.[17,18] Again, laboratories will often report determinations, usually in hair or red blood cells, compared to an unvalidated population norm, rather than as correlated with health or disease. Laboratories should provide normal ranges based on validated control populations. It is inappropriate for a laboratory to provide treatment recommendations. This is particularly true when the laboratory is associated with industries that distribute or otherwise promote treatments for the purported intoxications or deficiencies they claim to document.

Summary

In general, testing for heavy metals, nutritional elements present at extremely low concentrations, or so-called environmental contaminants, should only be obtained in the following situations and with the indicated precautions:

- A properly performed clinical history and physical exam suggests the lack or excess of these chemicals or minerals/metals.
- Proper patient preparation may include dietary avoidance of food and supplements that contain the substance of interest for several days prior to the sample collection.
- The use of collections after chelation is usually unwarranted.
- If post-chelation collections are used, the range of normals must be adjusted accordingly, and the results must be interpreted with extreme caution.
- Collection should be done through a certified laboratory that is experienced in the collection and handling of these specimens to avoid contamination.
- Analysis should be at a reputable laboratory that provides data on their normative population, including the selection and number of controls, and validation of their analytic procedures.
- The laboratory should not provide treatment recommendations or sell therapy to the patient.

Conclusion

There are many factors to consider before ordering a large array of esoteric laboratory tests and a number of important considerations in the interpretation of these tests. The current popularity of broad trace element or pollutant screening with subsequent "detoxification" treatment, is often inappropriate. At this time, many of these tests are best utilized as research tools, such as the current population evaluations by the National Center for Environmental Health of the Centers for Disease Control and Prevention.[19] Application of these test results to individual patients is fraught with problems. Current concerns about environmental-related illness have been misappropriated by a number of practitioners to vindicate non-indicated treatments. A large portion of our toxicology clinic population is convinced their symptoms are due to poisoning, when neither their symptom complex nor laboratory testing justify such a conclusion. It is our

contention that medical toxicologists should be at the forefront in the discussion regarding the appropriateness of toxicologic testing and its interpretation. In addition, we should be active in protecting patients from the misapplication of these tests.

Addendum

The proceedings of an ATSDR panel on hair analysis have been published recently. The reference is: Harkins DK, Susten AS. Hair Analysis: Exploring the State of the Science. Environ Health Persp 2003;111:576-578.

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APPENDIX B: American College of Medical Toxicology Position Statement

Post-Chelator Challenge Urinary Metal Testing
by Nathan Charlton, MD and Kevin L. Wallace, MD FACMT, posted on 10:35 AM, July 27, 2009
http://www.acmt.net/cgi/page.cgi?aid=2999&_id=52&zine=show

Heavy metals, such as lead and mercury, are ubiquitous in the environment [1-4]. Exposure in human populations is constantly occurring, and detectable levels of lead and mercury are commonly found in blood and urine of individuals who have no clinical signs or symptoms of toxicity and may be considered background or reference values [1-5]. Although urine testing for various metals in an appropriate clinical context, using proper and validated methods, is common and accepted medical practice, the use of post-challenge (a.k.a., post-provocation) urine metal testing, wherein specimens are typically collected within 48 hours of chelation agent administration, is fraught with many misunderstandings, pitfalls and risks. The American College of Medical Toxicology issues this position statement in disapproval of the use of post-challenge urinary metal testing in clinical practice and the use of such test results as an indication for further administration of chelating agents.

In current evidence-based medical practice, urinary testing is commonly used in the biomonitoring of exposure to certain metals such as arsenic and inorganic mercury and the severity of their associated toxicity. It is accepted practice to conduct such testing, e.g., in exposed individuals with clinical evidence of peripheral neuropathy, as long as validated collection and analytical methods are employed prior to, or after, a sufficiently long time interval (e.g., 3-5 days) following administration of a chelating agent, i.e., applied to non-challenge urine specimens, and the results are compared to appropriate reference values [5, 6]. In some non-evidence-based medical practices, however, assessment of metal poisoning is frequently based on non-validated post-challenge urine metal testing, which invites inappropriate comparison to normal urine reference ranges [4-7].

Chelating agents such as dimercaptosuccinic acid (DMSA), dimercaptopropanesulfonic acid (DMPS), dimercaprol (BAL), and edetate calcium disodium (CaNa2-EDTA) bind metallic and metalloid elements and have been shown to increase their elimination from the body. Chelating agents have been found to mobilize metals in healthy individuals who have a body burden considered normal for a standard reference population, as well as in those who are determined to have a high body burden of the same metallic species [4, 8-11]. More specifically, urine specimens collected in relatively close temporal proximity to administration of chelating agents, i.e., post-challenge specimens, are expected to have increased concentrations of metallic elements. This includes elements, such as zinc, that are essential to normal physiologic functions and maintenance of good health.

Normal reference values for non-challenge urine metal test results vary among and within different populations. Ranges for these values have been established in nationally certified laboratories that meet proficiency standards for urinary metal testing [5]. However, scientifically acceptable normal reference values for post-challenge urine metal testing have not been established [10]. In addition, scientific investigation to date has failed to establish a valid correlation between prior metal exposure and post-challenge test values [10]. Despite the lack of

scientific support to do so, it is also a common practice of some laboratories and care providers to provide or apply non-challenge normal reference values as a comparative means of interpreting results of post-challenge urine metal testing [5]. Currently available scientific data do not provide adequate support for the use of post-challenge urine metal testing as an accurate or reliable means of identifying individuals who would derive therapeutic benefit from chelation.

Unfortunately, the practice of post-challenge urine metal testing and its application to assessment of metal poisoning often leads to unwarranted and prolonged oral and/or intravenous administration of chelating agents, in response to the results of serial post-challenge testing that remain elevated above non-challenge reference values. Chelation therapy based on such laboratory values, in addition to being of no benefit to patient outcome, may actually prove harmful [5, 12]; catastrophic outcomes such as acute fatal hypocalcemia have been reported following the improper use of a chelating agent, edetate disodium (Na2-EDTA) [13]. In addition, the safer formulation of this agent, CaNa2-EDTA, has been demonstrated to increase urinary excretion of essential minerals such as iron, copper and zinc [8, 14]. There is published experimental evidence that deleterious effects may occur when chelation is applied in the absence of prior lead exposure. [15] Other chelating agents such as DMSA and DMPS may also increase the elimination of certain essential elements, as well as promote target organ redistribution of metallic elements of concern such as mercury [16-18].

It is, therefore, the position of the American College of Medical Toxicology that post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning.

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This statement has been developed by members of the ACMT with principal contribution in writing by Nathan Charlton, M.D. and Kevin L. Wallace, M.D., F.A.C.M.T., reviewed and approved by the ACMT Practice Committee and Board of Directors, and opened to comment by all members of the College. Disclosure statements for participating members of the ACMT Practice Committee and ACMT Board of Directors are available. (June 2009)

April 21, 2010

Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, D.C. 20510

Attn: Heather Majors Heather_Majors@epw.senate.gov

Re: Response to question submitted by Senator Klobuchar

Dear Ms. Majors:

I have received the note from Senators Boxer and Inhofe indicating the following question from Senator Klobuchar for the hearing record in reference to the February 4, 2010 hearing of the Committee on Environment and Public Works.

Senator Kobuchar asked:

"One naturally occurring toxin, Radon, can easily finds [sic] its way into people's homes and produce severe long term health problems. Aside from smoking, it's the leading cause of lung cancer in this country. From a public health perspective, are we doing enough to address the threat of radon?"

I provide the following response:

Radon is commonly present in homes, in basements or partially underground building spaces, particularly in areas of high granite content, foundation defects, or groundwater intrusion. Epidemiologic studies have suggested that the radiation released by inhaled radon and its radioactive progeny is the cause of many lung cancer cases that are not attributed to tobacco smoking. This cancer-causing effect has been shown statistically in areas of the country with significantly higher radon content (e.g. more than 50% of households having radon measurements >4 pCi/L - as opposed to the U.S. average of 1.3 pCi/L – e.g. the Iowa radon lung cancer study: Field RW, Steck DJ, Smith BJ, Brus CP, Fisher EL et al. Residential radon gas exposure and lung cancer. *Am J Epidemiol* 2000;151:1091-1102. http://radsci1.home.mchsi.com/irlcs.pdf). While nothing should distract from the primary importance of tobacco smoking as a cause of lung cancer, a precautionary approach to reduce cumulative radon exposure is not unreasonable.

Regarding the public health approach to radon, I do not have familiarity with the range of local, state, or federal statutes or regulations regarding testing for radon when purchasing or selling a home to answer that question. The EPA has recommended testing of all residential and school buildings in the lower levels to document the "level" of radon (http://www.epa.gov/radon/pubs/citguide.html) and has proposed "multimedia" steps (involving radon in drinking water and air) to reduce radon exposure (http://www.epa.gov/safewater/radon/proposal.html). The steps highlighted by the EPA are

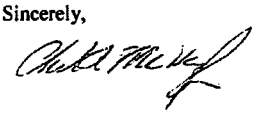
available for concerned citizens and contractors from the American Society for Testing and Materials International (ASTMI) at: http://www.epa.gov/radon/pubs/mitstds.html , with the most recent update being 2005. Concrete steps to reduce radon exposure are available at: http://www.epa.gov/radon/pubs/consguid.html .

The American Lung Society (http://www.lungusa.org/healthy-air/home/resources/radon.html) and other groups do provide public information and awareness campaigns about radon. Furthermore, radon is one of the compounds with information available from the National Library of Medicine, the Agency for Toxic Substances Disease Registry (ATSDR), and the EPA via a user-friendly web portal called "ToxTown" (http://toxtown.nlm.nih.gov/flash/town/flash.php). By moving a mouse over the graphic areas, a user can access a number of documents on a variety of potential environmental hazards.

It would seem therefore adequate information is available for the public. In order to determine the general public's awareness level and response to a potential threat posed to them by radon, I would suggest utilizing the annual telephone survey conducted by the Centers for Disease Control and Prevention (CDC). I do not think radon awareness or mitigation has been a component of the Behavioral Risk Factor Surveillance System (BRFSS: http://www.cdc.gov/brfss/), but that may be a possibility, at least in terms of an optional module or state-based query.

I would be happy to attempt to answer any other questions that the committee may have and can be reached at cmckay@harthosp.org

Sincerely,



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Senator LAUTENBERG. Thank you.

And now, let us hear from Dr. Woodruff. You come from San Francisco, and you are—what is your responsibility?

Ms. WOODRUFF. Should I just start then?

Senator LAUTENBERG. OK. We will not charge you time.

STATEMENT OF TRACEY J. WOODRUFF, PH.D., MPH, ASSOCIATE PROFESSOR AND DIRECTOR, PROGRAM ON REPRODUCTIVE HEALTH AND THE ENVIRONMENT, DEPARTMENT OF OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE SCIENCES, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Ms. WOODRUFF. Good morning, Chairman Lautenberg and members of the committee.

My name is Dr. Tracey Woodruff. I am an Associate Professor and the Director of the Program on Reproductive Health and the Environment in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco.

I would like to thank you for the opportunity to testify at this hearing. I am going to focus on three different things. One is concerning trends in reproductive and developmental health, current chemical exposures, and our policy needs.

As Chairman Lautenberg noted, there are a number of numerous concerning trends in developmental health at the U.S. population. I am going to give a few examples of those. One is that more women in the U.S., particularly women under the age of 25, which is the peak time of fertility, are reporting difficulty in conceiving and maintaining pregnancy. The percentage has doubled from about 4.3 to 8.3 percent in the last 20 years.

There are an increasing number of babies who are born too early—that is before the 37th week of gestation—which puts them at greater risk for death, learning and behavior problems and developmental delays. One out of 8 babies in the U.S. is born premature. That is a 36 percent increase since the 1980s.

Birth weights are also declining, even among normal, healthy, full-term infants, which puts them more at risk for short- and long-term health complications and chronic disease. There is a new study that just came out showing that U.S. birth weights have declined about 1.5 percent between 1990 and 2005. But this drop is not explained by maternal and neonatal risk factors or obstetric practice.

In my own State of California, gastroschisis, which is a birth defect where the abdominal wall does not form completely and the intestines intrude outside of the body, has increased by over 300 percent between 1987 and 2003. And we are of course seeing a number of different increases in childhood morbidity, including autism, certain childhood cancers, and obesity.

I just would note that there are a number of these health trends and why there is a growing concern about toxic chemical exposures are covered in this new report titled The Health Case for Reforming the Toxic Substances Control Act.

I would also say that we have very important and growing scientific evidence that there are periods of development that are more vulnerable to disruption by environmental chemicals, particularly if the exposures occur around the time of conception, during

pregnancy, and early in childhood. In particular disruptions during the prenatal period can increase the risk of effects immediately, such as birth defects or pre-term birth; in childhood, such as childhood cancers and neurodevelopmental outcomes; or even in adulthood, as was previously mentioned, such as increases in diabetes and cardiovascular disease.

As has been noted, there are many chemicals that are now in use in our environment, in our manufacturing and daily lives, and chemical production since World War II has increased more than 20-fold.

So now, environmental contaminants are ubiquitous in our air, water, food, personal care products and everyday household items, and has been mentioned, biomonitoring demonstrates these chemicals are also in our bodies. Anywhere from 70 to 100 percent of the U.S. population have measurable levels of triclosan, PCBs, polyfluoroalkyl chemicals, parabens and bisphenol A.

Many of these exposures come from every day use of products in our lives, such as personal care products, cookware and containers. These are sources that most people have previously considered to be inert, but they apparently are not.

As a population, we vary in our biological susceptibility in terms of age, disease status and chemical exposures. And so when we consider the risk of adverse health effects from exposure to any one chemical that has been reported through biomonitoring studies, the National Academy of Sciences recommends that we consider this exposure in the context of existing chemical exposures and biological susceptibilities in the population. And they have concluded that we should not assume that there is a safe level of exposure to any individual chemical unless proven otherwise.

As was raised by Dr. Birnbaum thyroid hormones and thyroid disrupting chemicals are reasons for concern. Thyroid hormones are essential for fetal brain development, particularly during the prenatal period, and pregnant women in the U.S., some portion of them, are already at risk for perturbations of thyroid hormone levels. Sixteen percent of women in the U.S. report having a thyroid disease, and about one-third of U.S. pregnant women have insufficient iodine intake, which is critical for maintaining sufficient levels of thyroid hormones.

Some of the chemicals I have already mentioned, such as PCBs, the polyfluoroalkyl chemicals, perchlorate and triclosan, have also been shown to disrupt the thyroid system. And sometimes these chemicals can be at levels which are 300 to 1,500 times higher than the levels of thyroid hormones in our bodies. So, we can be exposed to biologically relevant levels of these chemicals, and separate studies on PCBs and perchlorate have shown that.

Our current approach of using biomonitoring data as a demonstration of a problem means that it is potentially too late for people who have already been previously exposed to environmental chemicals. There are many chemicals that we have sufficient data for the Government to take action to reduce exposures. But for many chemicals we simply do not have enough information to actually ascertain whether they are a problem for the public or not.

Biomonitoring provides an excellent and appropriate tool for monitoring whether policy or regulatory actions that we have taken

can prevent harmful exposures and whether we have been successful in those activities, such as with lead.

The scientific data clearly shows that every child in the U.S. is born with a burden of multiple chemicals in their body which can impact their future health, and by taking policy actions now we can improve, as has been noted, the health not only of ourselves, but of our future generations.

Thank you.

[The prepared statement of Ms. Woodruff follows:]

Testimony of Tracey J. Woodruff, PhD, MPH
U.S. Senate Committee on Environment and Public Works on

"Current Science on Public Exposures to Toxic Chemicals"

Thursday, February 4, 2010
Dirksen Senate Office Building, Washington DC

Senator Frank R. Lautenberg, Chairman
Senator James M. Inhofe, Ranking Member

Good morning, Chairman Lautenberg, Senator Inhofe, committee members and guests. I am Dr. Tracey Woodruff, Associate Professor and Director of the Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California, San Francisco. Thank you for the opportunity to testify at this important hearing. The Program on Reproductive Health and the Environment is dedicated to creating a healthier environment for human reproduction and development by advancing scientific inquiry, clinical care and health policies that prevent exposures to harmful chemicals in our environment. Today I shall focus on concerning trends in reproductive health and development, current chemical exposures and policy needs.

Trends. There are numerous concerning trends in the developmental health of the United States population, which have been reported in the scientific literature [1, 2]. These include:

- **More women in the U.S., particularly women under the age 25, the time of peak fertility, are reporting difficulty conceiving and maintaining their pregnancies.** Between 1982-2002, the percent of women reporting that they had difficulty in conceiving and maintaining pregnancy, doubled from 4.3% to 8.3% in a national survey conducted by the National Center for Health Statistics [3, 4].
- **Increasing numbers of babies are born too early – before the 37th week of gestation – putting them at greater risk for death, learning and behavior problems, and developmental delays** [5]. One out of every eight babies is born prematurely, a rate that has increased 36% since the early 1980s [6].
- **Birth weights are declining, even among normal, healthy, full-term infants, putting more infants at risk for short and long-term health complications and chronic disease** [7]. A new study reports that U.S. birth weights declined 1.5% between 1990 and 2005, a drop that was not explained by maternal and neonatal risk factors or obstetrics practices. During the same period, the number of infants born small for gestational age increased by nearly 1% [8].
- In my own state of California, gastroschisis, a birth defect where the abdominal wall does not form completely and the intestines protrude outside of the body, has increased by over 300% between 1987 and 2003 [9].

- Increasing rates of childhood diseases, including autism [10], certain childhood cancers [11], and obesity [12].

These are among a number of adverse trends in health outcomes that have been summarized in "The Health Case for Reforming the Toxic Substances Control Act," a new report highlighting the growing concern about chemicals and increases in adverse health effects in the population [13].

We also have growing scientific evidence that environmental contaminants can impact early development, particularly if exposures occur prior to conception, during pregnancy or early in life -- periods of development that are more vulnerable to disruption by environmental chemicals [14]. In particular, disruptions during the prenatal period can increase the risk of effects during the immediate, short and long term. Some examples:

- immediate term: birth defects, pre-term birth, low birth-weight
- short term: learning disabilities and childhood cancers
- long term: diabetes, cardiovascular disease, and cancers as adults.

Chemical Exposures and policy needs: Since World War II, chemical production in the U.S. has increased more than twenty-fold [15]. As of 2006, there are over 80,000 chemical substances registered for use in U.S. commerce, and about 3,000 chemicals manufactured or imported in excess of 1 million pounds each [16]. Environmental contaminants are ubiquitous in our air, water, food and drink, personal care products, pesticides and everyday household items.

Biomonitoring – a growing area of research that measures the types and levels of chemicals in our bodies – now demonstrates irrefutably that these chemicals are contaminating our bodies in addition to our environments. For example, the National Health and Nutrition Examination Survey, an annual nationally based representative survey of the U.S. population, consistently finds measurable amounts of hundreds of environmental contaminants in people's bodies. For example, over 75% of people have triclosan in their body, up to 100% of people have some type of PCB measured in their body, over 98% of people have polyfluoroalkyl chemicals, and over 90% of people have measureable levels of bisphenol A [17]. Many of these exposures come from the everyday use of products in our lives – such as personal care products, cookware and containers – sources that most people consider to be inert.

Such high frequencies of chemical detection mean that, as a population, we are exposed to a multitude of chemicals simultaneously. As a population, we also vary in our biological susceptibility to harm by chemical exposure. This susceptibility can be due to age (prenatal, infant, child, puberty or elderly), health status (pre-existing health conditions such as immune compromise, diabetes, asthma), or socioeconomic stressors.

Therefore, when we consider the risk of adverse health effects from exposure to any ***one*** chemical reported through biomonitoring studies, the National Academy of Sciences recommends that we consider this exposure in the context of the existing chemical exposures and biological susceptibilities of the U.S. population. Given the lack of data on the impacts of

cumulative exposure to chemicals, the National Academy of Sciences also concludes that we should not assume that there is a safe level of exposure to any individual chemical unless proven otherwise [18].

Thyroid hormones and thyroid disrupting chemicals illustrate reasons to be concerned about the pattern of chemical exposure that biomonitoring studies reveal. Thyroid hormones are essential for fetal brain development during pregnancy [19]. Even small reductions in maternal thyroid hormone levels are associated with neurological deficits in the children [20, 21]. In addition, there already are conditions in the U.S. population that put pregnant women at risk for perturbations of thyroid hormone levels: 16% of U.S. women report having any thyroid disease [22] and about 1/3 of U.S. pregnant women have insufficient iodine intake [23], which is critical to maintaining sufficient levels of thyroid hormones.

Biomonitoring studies are, for the first time, demonstrating that women of childbearing age are carrying a body burden of multiple chemicals which have been shown to disrupt the thyroid system, including PCBs, perfluorinated compounds, perchlorate and triclosan. Body burdens of these chemicals can be at least 300 to 1,500 times higher than the levels of thyroid hormone circulating in our bodies, indicating that our current interactions with our environment are exposing us to biologically relevant levels of chemicals. Indeed, separate studies have found a relationship between PCBs and perchlorate and thyroid hormone levels [24, 25].

But, the value of biomonitoring is not just in the observations of exposure. Biomonitoring studies also indicate where our chemicals policies have failed to protect us from exposures that can put us at risk of reproductive and developmental effects.

What to do.
Our current approach of using biomonitoring data as a demonstration of a problem means that it is potentially too late for those people who have already been exposed.

There are many chemicals with sufficient scientific data for the government to take action to reduce exposures. And, for the many more chemicals for which we have insufficient information, we need policies that require chemical manufacturers to provide sufficient evidence that the chemicals they want to produce do not pose undue health risks to our population.

The scientific data clearly show that every child in the U.S. is born with a burden of multiple chemicals in their body that can impact their future health. By acting now, we can improve our health and the health of generations to come.

Thank you

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Response to Senators Inhofe and Vitter questions following Tracey J. Woodruff's Testimony on February 4, 2010

Tracey J. Woodruff
Associate Professor and Director
Program on Reproductive Health and the Environment
Department of Obstetrics, Gynecology, and Reproductive Sciences
University of California San Francisco

1. In your testimony you state that woman are experiencing difficulties in conception and maintaining pregnancy, which you seem to infer is at least partially attributable to the presence of chemicals detected in the body. Was this conclusion based on information you received from physicians or another objective source?

Difficulty in conceiving and maintaining pregnancy can be influenced by either difficulty in achieving conception or difficulty in maintaining a pregnancy. Difficulty in achieving conception includes inability to get pregnant, increased time to pregnancy; difficulty in maintaining pregnancy includes pregnancy loss, such as through spontaneous abortion. Both difficulty in achieving conception and difficulty in maintaining pregnancy have been described in the peer reviewed literature (Mendola et al. 2008; Crain et al. 2008). Difficulty in conceiving can be attributable to overt abnormalities in the reproductive tract, including misshaped or other anatomy abnormalities of the uterus, the oviductal anatomy or cervical anatomy, and endometriosis, which comes from the clinical literature (Crain et al. 2008). For example, prenatal exposure to diethylstilbestrol (DES), an estrogenic compound, is known to increase the risk of abnormalities of the female reproductive tract, including T-shaped uterus, abnormal oviductal anatomy and function, and abnormal cervical anatomy as reported in scientific reviews published in the peer review literature (Diamanti-Kandarakis et al. 2009). Pesticides and persistent pollutants, such as PCBs, DDT, and dioxins, can alter hormone function in women which can increase the risk of adverse reproductive effects in women, which has been identified from scientific reviews published in the peer reviewed scientific literature (Mendola et al. 2008; Diamanti-Kandarakis et al. 2009).

Reported difficulty in conceiving can also be due to male reproductive problems, in particular poor quality or inadequate semen (Hauser and Sokol 2008). Peer reviewed scientific studies in humans have evaluated the relationship between semen quality and several different types of environmental chemicals including certain phthalates, PCBs, dioxins, and nonpersistent pesticides. Recent reviews published in the peer reviewed literature report that all these chemicals have been shown to be associated with poor semen quality or low semen quality in one or more studies. In particular, epidemiological evidence supports the finding that increasing levels of PCBs are associated with a decrease in semen quality, specifically reduced sperm motility (Diamanti-Kandarakis et al. 2009; Hauser and Sokol 2008). PCBs are measured ubiquitously in the US population (Centers for Disease Control and Prevention 2008). The Endocrine Society, the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology with 14,000 members from over 100 countries representing clinicians,

scientists, industry and allied health fields, published a peer reviewed scientific statement in 2009 that stated "The evidence for adverse reproductive outcomes (infertility, cancers, malformations) from exposure to endocrine disrupting chemicals is strong, and there is mounting evidence for effects on other endocrine systems, including thyroid, neuroendocrine, obesity and metabolism, and insulin and glucose homeostasis" (Diamanti-Kandarakis et al. 2009).

There is a certain percentage of the occurrence for difficulty in conception and maintaining pregnancy for which there is no known cause. A review of the science and the scientific statement published by The Endocrine Society, stated that for female reproductive disorders that "whereas few are polygenic inherited traits and some are due to infections, the pathogenesis of the vast majority of female reproductive disorders is not well understood" (Diamanti-Kandarakis et al. 2009). We do not know the extent to which environmental chemicals are contributing to the portion of disease of unknown etiology, largely because most chemicals in commerce have not been adequately tested for reproductive and developmental health impacts. The evidence that links difficulty in fertility and fecundity to environmental contaminants comes from studies on human and non-human systems. We know three critical pieces of information, namely: (1) studies such as those cited above are part of a growing body of peer-reviewed studies that document an association between exposure to environmental contaminants and adverse reproductive health outcomes, with the strong evidence currently for those chemicals that interrupt the endocrine system; (2) disrupting the endocrine system can adversely impact reproductive health which is dependent on proper hormone function; and (3) the U.S. population incurs multiple ubiquitous exposure to endocrine disrupting and other toxic chemicals (Diamanti-Kandarakis et al. 2009). These three pieces of evidence do not prove that environmental contaminants cause these adverse impacts, but they do provide a reasonable set of evidence, and in some cases strong evidence, that environmental chemicals are likely to play some role in these conditions (Diamanti-Kandarakis et al. 2009). We are unable to calculate the exact contribution of chemicals for many of the cases of unknown etiology because most chemicals in commerce have not been tested sufficiently for reproductive and developmental health impacts tested and little information is available about where most chemicals are used and how the public may be exposed. (US Government Accountability Office 2005).

2) How does this trend correlate with the increased use of birth control pills and other menstrual modulators? Did you also account for the increase in obesity and other factors that affect human hormonal function?

The data that was discussed in my testimony on difficulty in conceiving and maintaining pregnancy comes from the National Survey of Family Growth, which is administered by the National Center for Health Statistics, Centers for Disease Control and Prevention (National Center for Health Statistics 2010). Periodically, NCHS surveys the population on certain reproductive health issues. For this particular question, they ask the individual woman if she has had difficulty in conceiving or maintaining pregnancy over the last 12 months.

A comprehensive review published in the peer reviewed literature concluded that while cessation of oral contraceptive use may delay time to conception, this delay appears to be temporary and only occurs in the early months (Barnhart and Schreiber 2009). The authors conclude that return of fertility is similar to other forms of contraception including condoms and natural family planning (Barnhart and Schreiber 2009).

Obesity has been identified as a risk factor for infertility and obesity has increased in the population, though it has appeared to level off in recent years (Ogden et al. 2007). As obesity has increased so has the production of certain environmental chemicals linked to infertility (Federal Reserve Board 2008). These (and other) risk factors for infertility can act independently or interact together, and more research is needed to understand their exact roles. A growing body of evidence is beginning to shed light on some of these potential inter-relationships. For example, there may be a relationship between exposure to certain environmental chemicals and obesity (Diamanti-Kandarakis et al. 2009; Grun and Blumberg 2007; Newbold et al. 2007). Specifically, obesity has been proposed to be another adverse consequence of developmental exposure to endocrine disrupting compounds, and experimental research by the National Institute of Environmental Health Sciences supports the idea that brief exposure early in life to environmental endocrine disrupting chemicals, especially those with estrogenic activity like diethylstilbestrol (DES), increases body weight as mice age.(Newbold et al. 2007). More research is needed to understand the applicability of these animal data to human health.

3. You say in your testimony that infants are at risk. Has infant mortality actually increased or decreased over time? Please cite your references.

Infant are at increased risk because there has been an increase in the percent of infants born premature (prior to 37 weeks of gestation) and born low birthweight over the past 10 to 20 years (Donahue et al. 2010; Davidoff et al. 2006; Martin et al. 2009; Institute of Medicine 2007). One out of every eight babies is born prematurely, a rate that has increased 36% since the early 1980s (Martin et al. 2009). Recent studies find that changing demographics and medical practice cannot explain the increases in preterm birth and low birthweight (Donahue et al. 2010; Davidoff et al. 2006). Premature birth and low birthweight can increase the risk of a number of infant mortality and morbidity conditions, including acute respiratory, gastrointestinal, immunological, central nervous system, hearing and vision problems, and childhood diseases, including learning and behavioral problems and developmental delays (Institute of Medicine 2007; Bhutta et al. 2002).

In addition, infants can be at increased risk because of their exposures to environmental chemicals that can occur prenatally and after birth. As noted by the President's Cancer Panel 2008-2009 report, authored by appointees of President George W. Bush, "numerous environmental contaminants can cross the placental barrier; to a disturbing extent, babies are born "pre-polluted" (President's Cancer Panel 2010). Both the panel and reviews of the scientific literature indicate that exposure during these important developmental windows can increase the risk of subsequent disease (Crain et al. 2008; Diamanti-Kandarakis et al. 2009; President's Cancer Panel 2010), thus putting infants at higher risk of adverse health outcomes from exposure to environmental chemicals.

Infant mortality declined between 1983 to 2000 from 10.9 per 1,000 live births to 6.9 per 1,000 live births (Federal Interagency Forum on Child and Family Statistics 2009). However, the US infant mortality rate did not decline significantly between 2000 and 2005, as discussed in a report from the National Center for Health Statistics (MacDorman and Mathews 2008). NCHS notes that the 2000–2005 plateau in the U.S. infant mortality rate is the first period of a sustained lack of decline in the U.S. infant mortality rate since the 1950s (MacDorman and Mathews 2008). The rate in 2006 is 6.71 per 1,000 live births (MacDorman and Mathews 2008). In addition, the US Government Health People 2010

target for goal for US infant mortality is 4.5 infant deaths per 1,000 live births, and the current US rate is about 50% higher than that goal (U.S. Department of Health and Human Services 2000). In 2004 (the latest year that data are available for all countries), the United States ranked 29th in the world in infant mortality, tied with Poland and Slovakia (National Center for Health Statistics 2007).

4. You say in your testimony that infants are at risk. Has infant mortality increased or decreased over time? According to the National Center for Health Statistics, National Vital Statistics System, the rate dropped from 10.9 per 1,000 births in 1983, to 6.7 per thousand births in 2006. Are they inaccurate?

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4. In your testimony you state that the incidence of gastroschisis has increased by over 300%. In the study you cite, the overall prevalence was reported to be 2.6 cases per 10,000

births, which is 0.026% of births. Does that mean that cases increased from 0.008% of births to 0.026%? Being that the most significant increase was among very young women, how do you attribute the cause of gastroschisis to chemical exposures?

The study about the increase in gastroschisis in California was published by Vu et al. and reports an overall prevalence of gastroschisis of 2.6 cases per 10,000 births (Vu et al. 2008). This is the overall prevalence of gastroschisis in their study population, which covered the years 1987 to 2003. In other words, this prevalence represents all the births and birth defects over the time period, not the prevalence in 2003. The authors performed a statistical analysis to assess the trend in gastroschisis over the time period, while accounting for other factors that may influence the trend, such as age of the mother and race. This means the authors can account for, for example, the changes in maternal age at birth, over the time period. After they take into account these demographic changes over time, they find that "the birth prevalence increased 3.2-fold (95% CI, 2.3-4.3) during the 17-year study period." This means that the birth prevalence increased 3.2 fold – or about 300% - between 1987 to 2003.

The authors note that other studies have found increases in gastroschesis in Utah, New York and North Carolina (Salihu et al. 2003; Laughon et al. 2003; Hougland et al. 2005). I discussed gastroschisis in my testimony as one of several reproductive health conditions that have been observed to be increasing over the past 1 to 2 decades either in the US or as reported for certain states. This illustrates an overall pattern of changing trends in disease and the papers cited indicate a need for further assessment of factors that can contribute to these increases. The influence on these diseases is multi-factoral, meaning that there can be a number of different risk factors that can contribute to disease, either independently or in concert. Environmental chemicals is one of the risk factors that can contribute to adverse reproductive health outcomes, and has been suggested in several of the articles as an important etiologic factor that requires further evaluation (for example, Vu et all notes "future studies are indicated to better examine the potential role of environmental factors in the risk for gastroschisis and gene-environment interactions.").

That gastroschisis is increasing among younger mothers is of concern, as we expect these mothers to have more healthy pregnancies. Data from the Federal Reserve Board show increase in chemical production in the US (Federal Reserve Board 2008). What is of concern is that younger women, more likely born during the time of higher chemical production, than in the past, could be at higher risk than their same age predecessors. Further study and data on environmental chemicals are needed to identify their potential role. Requiring comprehensive testing of chemicals on the marketplace as well as information about where people may come into contact with them is imperative to answer these questions and has been identified as a high priority for the federal government (US Government Accountability Office 2005, 2009).

5. You cite a lot of studies in your testimony. Are any of the studies you cite designed to determine the cause of a disease, or are they mainly associative studies?

To evaluate whether a chemical, or any other intrinsic or extrinsic factor, can increase the risk of disease requires evaluating available scientific information. Typically the type of information that informs whether there is a plausible link between an environmental chemical and increased risk of disease includes data from animal studies and human epidemiologic studies. Information from each of these data sources is used to identify

whether chemicals have the ability to increase risk of adverse health effects. Animal studies are particularly useful in an environmental health context, as they do not require direct human experimentation for information about the potential toxicity of chemicals.

Animals have long been used to understand the effects of chemical exposure on human reproduction and development (Holson et al. 2000). One of the first studies to use animals for reproductive and developmental assessments dates to a 1919 a study of the effects of alcohol on rats (Arlitt 1919). The reliability of experimental animal data for reproductive and developmental health has been well established and presently, there is no example of a chemical agent that has adversely affected human reproduction or development but has not caused the same or similar adverse effects in animal models (Nemec et al. 2006). Multiple studies on concordance have been performed of reproductive and developmental effects between animals and humans after exposure to a variety of chemical agents (Nemec et al. 2006; Hemminki and Vineis 1985; Kimmel et al. 1984; Newman et al. 1993; Nisbet and Karch 1983). One of earliest and most thorough is a technical report from 1984 for the National Center for Toxicological Research. This study, along with others, concluded there is concordance of developmental and reproductive effects and that humans are as sensitive or more sensitive than the most sensitive animal species (Kimmel et al. 1984). The National Academy of Sciences noted the importance of this report as it was the "first to utilize criteria of acceptance for both human and experimental animal reports that included study design and statistical power considerations." (National Research Council 2000).

Human epidemiologic studies of environmental chemicals provide the most direct evidence of the relationship between exposure and increase risk of adverse health outcomes, and are often the basis of regulatory and policy decision-making. Studies are typically designed to evaluate whether the change in the risk factor of interest, or the chemical exposure, is related to the change in the incidence or prevalence of the disease of study, while at the same time accounting for factors that may influence that relationship. For example, the studies that were used to determine that cigarette smoking was a risk factor for lung cancer evaluated whether men who smoked more had a higher risk of lung cancer. The conclusion that cigarette smoking caused lung cancer was based on this type of human epidemiologic studies, and as such, considering the studies can provide evidence that a chemical can contribute to the risk of disease. However, human epidemiologic studies require that we wait for people to develop clearly identified diseases from exposure, and thus are not an optimal public health approach.

There is uncertainty in the science, as science is always incomplete. As noted by Sir Bradford Hill, the epidemiologist who determined that cigarette smoking was a risk factor for lung cancer *"All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time. (Hill 1965) Sir Bradford Hill 1965 address to the Royal Society of Medicine.*

Authoritative bodies that review evidence to evaluate whether certain chemical exposures can increase the risk of adverse health outcomes often rely on a graded scale of evaluation to acknowledge the uncertainty in the science while still allowing sufficient evidence for decision making. Such is the case for evaluating chemicals that can contribute to cancer, and authoritative bodies such as the International Agency for Research on Cancer and USEPA have approaches that integrate findings in animals and humans to arrive at an

assessment of the potential of a chemical to increase the risk of cancer (such as known, likely, possible, suggestive, etc.).

Finally, it is important to understand the potential risks of exposures to environmental chemicals are largely unintentional and as such, intentionally exposing individuals, particularly pregnant women and children, to chemicals to identify whether there are adverse health effects would be considered unethical.

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Senator LAUTENBERG. Thank you very much.
And now, Mr. Cook, we welcome your testimony.

STATEMENT OF KENNETH A. COOK, PRESIDENT, ENVIRONMENTAL WORKING GROUP

Mr. COOK. Mr. Chairman, thank you for convening this hearing. It is timely; it is vitally important. I very much welcome the opportunity to testify.

Human exposure to toxic chemicals is exploding. You write your new legislation to fix the many problems with the Toxic Substances Control Act at a watershed moment in the science of understanding what we are exposed to and what it might mean.

We got to know 10 Americans in a very unusual study a few years back. We tested them, one collection sample, 10 of them, 1 day, we tested for 413 different toxic chemicals. No group of people has ever been tested for more. And we found in just those 10 people one sample, 1 day, 287 different toxic chemicals, chemicals of the sort that are used in consumer products in this room, chemicals that had been banned 30 years before we took the blood samples.

Now, Mr. Chairman, they were not exposed by virtue of the food they ate, by virtue of the water that they drank, or by virtue of the air that they breathed. We do not know very much about these people personally. About the only thing we know for sure is that when the exposures took place, all of them looked something like this.

This was the first time anyone had ever studied the wide range of chemical exposures in umbilical cord blood. Decades into the Chemical Revolution, no one had bothered to look. And this was the first broad look at the full range that we were able to afford spending $10,000 per sample.

Now, we learned from this study that babies come into the world polluted. Toxic, industrial pollution begins in the womb. Now, no one that I know would claim that just because a chemical shows up in people, even in a baby in the womb, that there is a health risk we can definitely point to. But what we should be able to do, and tell every parent in America, is that if a chemical is found in your child, if the exposures are taking place in the womb, we ought to be able to be very certain those exposures are safe.

This baby was receiving the equivalent of 300 quarts of blood a day circulating to him that kept him alive, nourished him, gave him the oxygen he needed, and carried these pollutants with the blood. This baby did not have a fully formed blood-brain barrier to protect him from toxic chemicals. And the other thing we know about this baby, who was not in the sample, I can tell you that, this baby is my baby. He was born in June 2008. He would be here today except for other pressing business that involved a red sled.

[Laughter.]

Mr. COOK. But I can tell you, Mr. Chairman, just by your action in 2005 and again in 2008, just by calling your bill the Kid-Safe Chemicals Act, you have invited tens of millions of people to understand in a way that they never would have before that this debate is not abstract, it does not involve smokestacks in the distance or in another town or in another part of the world. It involves them. I know it is difficult for you to give a public speech on almost any

topic without invoking your grandchildren. Now that I have a son I understand exactly why that is.

Mr. Chairman, we subsequently studied another 10 Americans, minority Americans, babies of African-American, Hispanic and Asian-Pacific heritage. We found hundreds more chemicals in them, dozens of neurotoxins, dozens of carcinogens, the thyroid toxin that Senator Boxer spoke about, showing up in the womb, bisphenol A, the chemical we are all worried about showing up in this baby even at that time.

And low doses matter, Mr. Chairman. We know from the literature that 358 different chemicals have been found in babies already. But we also know from some popular chemicals that we are more familiar with that at very low doses you can have both profound therapeutic effects and also some fairly profound side effects. Here, for example, for a little over 60 parts per billion you can inspire human reproduction, prevent it, and relax either way using Paxil. Low doses matter a great deal.

It is true with children and industrial chemicals, too. Part per billion exposures has been associated of PFOS, an industrial chemical in PFOA, with reduced birth weight and head circumference, which Dr. Woodruff just mentioned. They have been associated in adults with difficultly in conceiving, different chemicals, PBDEs, thyroid disease, and heart disease, BPA in adults.

We cannot avoid all these exposures, Mr. Chairman. We do live in the real world, and sometimes these kinds of exposures happen no matter what we try and do. But the truth of the matter is that if these exposures are going to take place we had better be careful not just because of the human toll but the economic toll.

One study looking at just a small collection of childhood diseases estimated $55 billion per year in medical costs, parental leave costs, and school educational costs associated with that. And there are at least 182 other diseases associated with chemical exposure. We cannot say because the chemicals had caused it, but we can say it is an issue.

And Mr. Chairman, unfortunately we are coming to this conclusion rather late. Why? We have not looked. We spend about $300 million a year testing dirt and water in this country through the Superfund program. Until very recently how much did we spend testing children under the age of 6? Almost nothing. Almost nothing.

And so, Mr. Chairman, I would say, from our own studies, we have tested 200 people, we have found 482 chemicals. And there are 15,000 chemicals out there in heavy use. How many are showing up in our blood? How many of them might pose a risk alone or in combination? We do not know. One reason we do not is because the identity of these chemicals and their health effects are kept secret under current law through confidential business information claims.

My little guy is doing great. I did not spend a minute during the pregnancy worrying that he was not going to turn out OK. But I spent a lot of time on Web sites, including my own at the Environmental Working Group, trying to figure out how to reduce exposures.

And that is what parents want to know. When they come into a doctor's office, and they know they have a chemical in themselves or in their child, naturally they are concerned. But they are asking, is it a dangerous chemical? What can you tell me about it? Am I exposed? What levels? And if there is some way to avoid the exposure I will take that step, but why isn't the Government protecting me? Those are the questions we hear.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Cook follows:]

Testimony of Kenneth A. Cook

President
Environmental Working Group

Before the

SUBCOMMITTEE ON
SUPERFUND, TOXICS AND ENVIRONMENTAL HEALTH
U.S. SENATE COMMITTEEE ON ENVIRONMENT & PUBLIC WORKS

On

"Current Science on Public Exposures to Toxic Chemicals"

Thursday, February 4, 2010

Mr. Chairman and distinguished Members of the Subcommittee: My name is Kenneth A. Cook, and I am the President and Co-Founder of Environmental Working Group (EWG), a nonprofit research and advocacy organization based here in Washington, DC, with offices in Ames, Iowa, and Oakland, California. I thank the members of the subcommittee for holding this important hearing and for the opportunity to testify.

Emerging science on human exposure has transformed the debate over toxic chemicals policy. This morning, I would like to talk to you about 10 Americans whose exposure to toxic chemicals has had an important impact on that policy debate. EWG tested these 10 Americans in 2004 and found more than 200 synthetic industrial chemicals in their blood, including dioxins and furans, flame retardants, and active ingredients in stain removers and carpet protectors. We also found lead, polychlorinated biphenyls (PCBs), and pesticides that the federal government banned more than 30 years ago.

We do not know much about these 10 Americans, but we do know a little about how they were exposed. Their chemical exposures did not come from the air they breathed, the water they drank, or the food they ate. They were not exposed at work or at school. They did not encounter these chemicals in personal care products or cleaning agents they used.

How do we know? These 10 Americans were newborns. The more than 200 chemicals we found in their umbilical cord blood crossed the placenta to contaminate the babies before birth. Our research uncovered a startling truth — babies are coming into the world pre-polluted with toxic chemicals.

EWG commissioned this biomonitoring study and obtained cord blood samples from the American Red Cross. We tested ten of them at a cost of $10,000 per sample. Then last year, we examined the cord blood of another group of 10 Americans — children of African American, Asian-Pacific, and Latino heritage. We found similar unsettling results, including the first national detections in cord blood in the United States of the endocrine-disrupting chemical bisphenol A (BPA) and the thyroid toxin perchlorate.

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We found no significant differences in results between the two studies. Instead, we discovered that we are all united by the disturbing reality that toxic pollution begins in the womb.

The current science makes clear that we must reform the Toxic Substances Control Act (TSCA) to ensure that industry submits pre-market evidence that its chemicals are safe for kids, our most vulnerable population. Each day brings another jarring headline as new research documents the health dangers of these exposures.

My testimony focuses on the current science of human exposure to toxic chemicals. But I want to thank you, Mr. Chairman, for your leadership over the past five years to put children's' exposure to toxic chemicals at the forefront of a policy debate that is long overdue — the debate over how to reform the 34-year-old Toxic Substances Control Act. You may not have realized it at the time, but when you named your reform proposal the "Kid-Safe Chemicals Act", Mr. Chairman, you instantly engaged millions of people in the debate over toxic chemicals.

Conduct a Google search for the (exact) phrase "Kid-Safe Chemicals Act" today and you find an extraordinary 554,000 links on the Web, including literally tens of thousands of entries about your bill in blogs, newspaper articles, discussion groups, and other online publications, written by parents, journalists, medical professionals, educators, and scientists. State legislators from Maine to Washington and numerous other states in between subsequently followed your lead and used the phrase "child-safe" or "kid-safe" in naming their initiatives for chemical policy.

And research shows time and again something that you have known throughout your career, Mr. Chairman: focus an issue through its impacts on children, their health and well being, and the American people get it. For anyone who wants proof, I would point to the current struggle to arrive at bipartisan consensus on health care reform. And I would contrast it to the successful, bipartisan effort that ultimately resulted in a major health care reform in 2009 after years of strong bipartisan support: the major expansion of the State Children's Health Insurance Program.

BIOMONITORING REVEALS EXPOSURES TO HUNDREDS OF CHEMICALS

The Centers for Disease Control and Prevention (CDC) calls biomonitoring "the most health-relevant assessment of exposure" and warns that "[f]or 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"(CDC 2010). EWG's umbilical cord study set out to address this gap. Our researchers conducted a comprehensive survey of the published scientific literature, identifying every study in which scientists had tested umbilical cord blood for industrial chemicals. 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 were first identified in EWG-led research. Altogether, biomonitoring studies have found up to 358 chemicals in cord blood from U.S. newborns (see ATTACHMENT A).

Detection of a chemical in umbilical cord blood does not prove that it will cause harm. As researchers have mapped more and more of the "human toxome," however, scientists, public health experts, and policymakers have embraced biomonitoring as the logical foundation for changing the way government regulates industrial chemicals. There is now widespread agreement that cord blood monitoring should be the starting point. The Kid-Safe Chemicals Act, S. 3040, introduced in the 110th Congress would prioritize safety assessments by focusing first on the chemicals that show up in people. The law would require phasing out production and use of toxic chemicals found in umbilical cord blood unless rigorous, expedited testing showed them to be safe.

CHEMICALS AT PARTS-PER-BILLION LEVELS ARE LINKED TO DISEASE

CDC's biomonitoring studies have revealed the presence of scores of chemicals in the blood and urine of Americans, often at concentrations as low as a few parts-per-billion (ppb). Such low levels may sound trivial, but science shows that chemicals can be biologically active even in the ppb range. In fact, many commonly prescribed medications are biologically active at concentrations in that range and below. Two examples are Cialis, which is active in the body at levels as low as 30 ppb, and the birth control device, Nuvaring, whose estrogen component is clinically effective at 0.035 ppb. At these tiny doses, these drugs can initiate procreation or prevent it. The fact that pharmaceuticals can exert their clinical effects at very low concentrations makes clear that industrial chemicals may do the same. In addition, an increasing number of toxicity studies are done at concentrations that mimic environmental exposures. If animal studies find effects at very low exposures, we must strongly consider the possibility that there are biological effects in humans. Simply put, low doses do matter.

Epidemiological studies have long since established critical links between environmental exposures and adverse health effects, including the relationship between tobacco exposure and lung cancer (Blair et al 2009). Recent biomonitoring studies have discovered associations between exposure to various industrial and consumer chemicals and adverse health effects, including reduced birth weight and head circumference in newborns, thyroid disease, aggressive behavior in children, and difficulty conceiving (Table 1). In just the last year, researchers using data from the National Health and Nutrition Examination Surveys (NHANES) have linked thyroid and heart disease to exposures to compounds such as perfluorochemicals (PFCs) and BPA respectively (Melzer et al 2010a, Melzer et al 2010b).

Table 1: Studies show everyday chemical exposures are linked to serious adverse health effects

Chemical	Study Population	Finding	Range of concentrations in population studied (ppb)
Phthalates	Infant boys (n=85)	Boys with higher prenatal exposure to phthalates (measured in maternal urine) had decreased anogenital distance (Swan et al 2005).	Mono-isobutyl phthalate (MiBP): Not detected (ND) to >7.7 Mono-benzyl phthalate (MBzP): ND to >25.8 Mono-n-butyl phthalate (MBP): ND to >38.7 Mono-ethyl phthalate (MEP): ND to >1076
Bisphenol A (BPA)	Children (n=249)	Parents of children with higher exposure to BPA during early pregnancy (as measured in maternal urine) report higher incidence of behavioral effects in daughters, including increased aggression and hyperactivity (Braun et al 2009).	ND to >37.3
Bisphenol A (BPA)	Adults (n=2,605)	Adults with higher BPA levels in urine reported higher prevalence of cardiovascular disease (Melzer et al 2010a).	ND to 80.1
Brominated flame retardants (PBDEs)	Newborns (n=288)	Newborns with higher levels of certain PBDEs in cord blood serum had decreased levels of thyroid hormones	Bromodiphenyl ether congener 47 (BDE-47): 1.1 to 311 BDE-100: 0.5 to 77

		critical to normal brain development (Herbstman et al 2008).	
Perfluorochemicals (PFCs)	Newborns (n=293)	Newborns with higher levels of two PFCs in cord blood serum, PFOA and PFOS, were found to have lower birth weight and head circumference (Apelberg et al 2007).	Perfluorooctane sulfonate (PFOS): ND to 34.8 Perfluorooctanoic acid (PFOA): 0.3 to 7.1
Perfluorochemicals (PFCs)	Adults (n=3,974)	Adults with higher levels of two PFCs in their blood serum, PFOA and PFOS, reported higher prevalence of thyroid disease (Melzer et al 2010b).	PFOA: 0.1 to 123 PFOS: 0.1 to 435
Brominated flame retardants (PBDEs)	Adult women (n=223)	Women with higher levels of certain PBDEs in their blood serum were found to have significant decreases in their ability to conceive (Harley et al 2010).	BDE-47: ND to >25.2 BDE-100: ND to >4

THE TOLL OF CHEMICAL POLLUTION ON HEALTH AND HEALTH COSTS

The last ten years have produced an avalanche of credible studies documenting the costs of diseases associated with toxic pollution. Our failure to protect the American people, and especially America's kids, from contamination by toxic chemicals has taken a tremendous toll on Americans' health and resulted in significant health care costs.

As of 2009, 182 human diseases in all had been linked to chemical exposures, according to researchers at the University of California-San Francisco and Boston Medical Center (Janssen 2008). These range from autism to birth defects to asthma to childhood cancer. Take, for example, neuro-developmental disease, which includes autism and autism spectrum disorders, speech and language disorders, learning disorders, and neurological and psychiatric disease. A Canadian study in 2001 estimated that as much as half of these afflictions may be the result of chemical exposures. The cost of treating and caring for the affected children was estimated at up to $83.5 billion a year (Muir 2001).

Toxic pollution has been linked to a variety of other childhood diseases. In 2002, researchers at the Mount Sinai School of Medicine calculated that all lead poisoning cases, 30 percent of all asthma cases, 10 percent of neurobehavioral disorders, and five percent of pediatric cancers were traceable to chemical exposures. The financial cost topped $55 billion annually as of 2002, which was nearly three percent of U.S. health care costs at the time (Landrigan 2002).

We also know that low dose chemical exposures can affect brain development in utero, in infants, and in children even when these exposures do not cause diagnosable disease. One result is lower IQ, which has huge implications for the future productivity and earning potential of affected children (Mendola 2002). Researchers at the National Institutes of Environmental Health Sciences and Mt. Sinai estimated that the figure for mercury poisoning alone is nearly $9 billion a year (Trasande 2005).

Other data suggests that toxic pollution may contribute to 80 percent of chronic childhood diseases. Mount Sinai's Philip Landrigan estimates that genetics account for only 10 to 20 percent of cases of chronic disease in childhood in the U.S. and other industrialized nations (Landrigan 2001). These include birth defects, the leading cause of infant death; developmental disorders such as attention deficit hyperactivity disorder and autism; asthma, which more than doubled in incidence from 1980

to 1996, according to the CDC (Moorman 2007); and childhood leukemia and brain cancer, on the rise since the 1970s (Gurney 1996; Linabery 2008). Dr. Landrigan's team and other specialists have determined that many diseases, from respiratory illness to immune, thyroid and neuropsychological deficits, are likely linked to environmental toxins (Etzel 2004; Sly 2008; Wigle 2008).

THE U.S. SPENDS MORE TO TEST FOR TOXIC CHEMICALS IN SOIL AND FISH THAN IN INFANTS

The federal government budgets far more to monitor soil, water, and air for chemical contamination than it spends to test for chemicals in people. The disparity is great. In 2008, for example, the government funded the CDC's human biomonitoring program, part of the National Health and Nutrition Examination Survey, at $13.6 million. Compare this to the $12 million spent on testing wildlife, including peregrine falcons in Alaska and the Arctic, for toxic chemicals (McClure 2009 and US Fish & Wildlife Service 2009). In 2008, the government paid $22.5 million to test large mouth bass, Charr, herring, eels, lamprey, minnows, and shad for persistent organic contaminants (USGS 2009). In 2008, EPA spent an estimated $300 million for soil and water testing under Superfund (EPA 2009a). Even the expansive National Children's Study, which EWG strongly supports, only includes a small fraction of its $179 million budget for the biomonitoring of 525 pregnant women. And until very recently, the federal budget for biomonitoring of cord blood was zero. We should allocate more resources to biomonitor the pollution in people.

EXTENT OF EXPOSURE IS LIKELY FAR GREATER THAN STUDIES HAVE SHOWN

Current biomonitoring studies cover just a small percentage of the chemicals that could be in our bodies. More than 80,000 chemicals have been registered for use in the U.S. since 1976, and more than 15,000 have been manufactured or imported in medium-to-high amounts in the past 25 years. Biomonitoring tests to date have involved less than one percent of those compounds. In its own work, EWG has tested more than 200 people over the past 15 years. We tested for 540 chemicals and detected up to 482 of them. The more chemicals we test for, the more we find. Meanwhile the research on biologically active low doses of toxic chemicals has exploded.

Some chemicals EWG found were banned 30 years ago. Scientists tend to rigorously investigate chemicals only after they are banned. The unfortunate reality is that we often know little about more recently introduced chemicals that are in our bodies now.

In addition to the need for more research, a recent EWG investigation showed that the identities of many new chemicals are kept hidden from the public (EWG 2010). EWG found that industry has placed "confidential business information" (CBI) claims on the identity of 13,596 new chemicals produced since 1976—nearly two-thirds of the 20,403 chemicals added to commerce in the past 34 years. A significant number of these secret chemicals are used everyday in consumer products, including artists' supplies, plastic products, fabrics and apparel, furniture, and items intended for use by children. EPA data shows that at least 10 of the 151 high volume confidential chemicals produced or imported in amounts greater than 300,000 pounds a year are used in products specifically intended for use by children.

TSCA's overbroad secrecy provisions threaten public health. Under section 8(e) of TSCA, companies must turn over all data showing that a chemical may present "a substantial risk of injury to health or the environment." By definition, compounds with 8(e) filings are the chemicals of the greatest health concern. In the first eight months of 2009, industry concealed the identity of the chemicals

in more than half the studies submitted under 8(e). Non-industry scientists and the public simply do not know how many of the chemicals that have been flagged as "posing a significant risk of injury to health or the environment" by industry, but are not identified by name because of CBI protections, could also be present in our bodies and in newborns.

RECOMMENDATIONS

In conclusion, we commend Administrator Jackson's call for TSCA reform and the steps that Assistant Administrator Owens has taken to address abuses of confidential business information claims. To protect our children's health, however, EPA needs strong authority from Congress to put the burden on industry to show a chemical is safe before it goes on the market. EPA must have express authority to require more transparency of chemical health and safety data. The federal government should use biomonitoring of cord blood to prioritize which of the 80,000 chemicals registered for use we should tackle first. Therefore, EWG looks forward to the re-introduction of the Kid-Safe Chemicals Act and urges Congress to take quick action to pass this necessary TSCA reform legislation.

We strongly support the CDC's existing biomonitoring programs and urge full funding of the national children's study. We urge CDC to consider umbilical cord monitoring as part of an expanded biomonitoring program. More funding for large, population-scale biomonitoring studies could fill this critical gap in 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 babies.

Thank you for your time. I welcome the opportunity to answer any questions you may have.

Attachments

ATTACHMENT A: Results of Select Cord Blood Biomonitoring Studies of American Infants

ATTACHMENT B: Government Spending on Testing Soil, Water & Air vs. Human Biomonitoring

ATTACHMENT C: Chart of Public Health Costs of Toxic Chemical Exposures

References

ATTACHMENT A

RESULTS OF SELECT CORD BLOOD BIOMONITORING STUDIES OF AMERICAN INFANTS
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 from 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
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 from Harvard measured cord blood concentrations of cadmium in 94 healthy babies, finding concentrations ranging from 0.003 to 0.210 ug/dl, with mean of 0.045 ug/dl. (Rabinowith 1984)	94	Boston, Mass.	1
Metal	Lead	Researchers from 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),	154	N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		1.1–1.4 ?g/dL (2nd quartile; n = 39), 1.5–1.9 ?g/dL (3rd quartile; n = 36), and 2.0–6.3 ?g/dL (4th quartile; n = 42). (Gump 2008)			
Metal	Lead	Researchers from 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 ug/dL. (Sagiv 2008)	527	New Bedford, Mass.	1
Metal	Mercury	Researchers from 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 ug/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 from 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
PBDE	Polybrominated diphenyl ether (PBDE)	Researchers from 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 from 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	10	U.S. hospitals	27-32

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		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)			
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 from 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
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 from 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)	293	Great Lakes states	7
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	U.S. hospitals	98-147
PCB	Polychlorinated biphenyl (PCB)	EWG tested cord blood from 10 newborns of minority background for 209 polychlorinated biphenyls and found at least one in all 10 samples. Among all 10 participants who tested positive for the chemicals, 98 to 144 different congeners were found. Mean total level was 22.1 ng/g lipids in blood serum. (EWG 2009)	10	Mich. Fla. Wis. Mass. Calif.	98-144

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
PCB	Polychlorinated biphenyl (PCB)	Researchers from 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, Massachusetts	>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
Pesticide	Carbamate	Researchers from 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 from 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	Herbicide	Researchers from 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
Pesticide	Imide	Researchers from 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	211	New York City, N.Y.	1

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		fungicide. (Whyatt 2003)			
Pesticide	Mosquito Repellent	Researchers from 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 from 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 DOE 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
Pesticide	Organophosphate Pesticides and Metabolites	Researchers from 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 from 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 from 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
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	10	U.S. hospitals	9

Chemical class	Chemical subclass	Summary of representative study	No. of newborns tested	Place of birth	No. of Chemicals found
		different chemicals were found with total mean concentration of 5.86 ng/g in whole blood. (EWG 2005)			
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 from 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 from 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

ATTACHMENT B: U.S. Spending on Testing Soil, Water & Air vs. Human Biomonitoring

Agency/Program	Program Description	Annual Budget/ Applicable Year
Centers for Disease Control and Prevention (CDC) – National Health and Nutrition Examination Survey (NHANES)	The NHANES program is designed to assess the health and nutritional status of adults and children in the United States. The program includes biomonitoring participants ages 6 and above for environmental contaminants.	$13.6M/ 2009 $13.3M/ 2008 (McClure 2009)
US Fish & Wildlife Service - Environmental Contaminant Program	The Environmental Contaminant Program involves monitoring the nation's fish and wildlife for contaminants. The program's research includes, for example, monitoring Artic and American Peregrine Falcons in Alaska and organochlorine residues in Alaskan peregrines.	$13.2M/ 2009 $11.98 M/ 2008 (USFWS 2009)
U.S. Geological Survey (USGS) - Fisheries and Aquatic Resources Program	The Fisheries and Aquatic Resources Program involves testing and monitoring aquatic species for various contaminants. Research includes testing the large mouth bass for persistent organic contaminants, and assessing bioaccumulation of mercury in fish and bioaccumulation of PCBs in Atlantic Charr.	$22.5M/ 2008 (USGS 2009)
U.S. Environmental Protection Agency (EPA) - Superfund	The Superfund remediation program involves the clean up and long-term monitoring of Superfund sites, including testing of soil and water.	$591M/ 2008: Total remedial budget (U.S. EPA 2009a) ~$300M/ 2008: EPA estimated budget for soil and water testing (EPA 2009b)
U.S. Environmental Protection Agency (EPA) - Healthier Outdoor Air Program	The Healthier Outdoor Air Program is designed to provide healthier outdoor air for all Americans. The program includes EPA testing outdoor air for chemical contaminants.	$587M/ 2008: Total program budget (EPA 2009) ~$235M- $294M: EPA estimated budget for air testing and monitoring (EPA 2009c)

ATTACHMENT C: Public Health Costs of Chemical Exposures

Disease	Cost or burden associated with chemical exposures	Finding
Childhood Diseases	$55 billion	An authoritative 2002 study attributed all lead poisoning cases, 30 percent of asthma cases, 10 percent of neurobehavioral disorders and 5 percent of pediatric cancers to chemical pollution. The study, led by pediatrician Philip J. Landrigan, director of the Children's Environmental Health Center at Mount Sinai School of Medicine, estimated the annual costs of this toxic disease burden at $55 billion, nearly 3 percent of U.S. health care costs at the time (Landrigan 2002).
Neurodevelopmental Disease	Up to $83.5 billion	The annual cost of neurodevelopmental disease is estimated at $81-to-167 billion per year. As much as half may be due to exposure to toxic chemicals, according to a 2001 study led by economist Tom Muir of Environment Canada (Muir 2001).
Mercury-linked IQ Loss	$8.7 billion	Low-dose exposure to mercury and other neurotoxic chemical pollution can cause severe and sometimes lifelong neurobehavioral and cognitive problems, according to the National Institutes for Environmental Health Studies (Mendola 2002). A 2005 study by Mount Sinai researchers estimated the costs of this loss of intelligence and productivity from childhood mercury poisoning at $8.7 billion a year (Trasande 2005). Mercury is just one of 201 chemicals known to be neurotoxic in humans (Grandjean 2006).
Chronic Childhood Disease	Up to 80-90%	Mount Sinai's Landrigan estimates that genetics account for only 10-20 percent of cases of chronic disease in childhood in the U.S. and other industrialized nations (Landrigan 2001). This includes: birth defects, the leading cause of infant death; developmental disorders such as attention deficit hyperactivity disorder and autism; asthma, which more than doubled in incidence from 1980 to 1996, according to the Centers for Disease Control and Prevention (Moorman 2007); and childhood leukemia and brain cancer, on the rise since the 1970s (Gurney 1996; Linabery 2008). Landrigan's team and other specialists say that many diseases, from respiratory illness to immune, thyroid and neuropsychological deficits, are likely linked to environmental toxins (Etzel 2004; Sly 2008; Wigle 2008).
Developmental Problems	28 percent	An expert committee of the National Academy of Sciences concluded in 2000 that a combination of environmental and genetic factors cause 25 percent of American children's developmental problems, including low birth weight, neurobehavioral deficits and pre- and post-natal death. The report estimated that another 3 percent are caused by toxic environmental exposures alone (NRC 2000).
Children on Medication	26 percent of all children (irrespective of link to chemical exposures)	In 2007, 26 percent of Americans age 19 and under took prescription drugs for chronic health problems, according to a major pharmaceutical benefit provider. The most commonly dispensed medications were treatments for asthma and allergy, followed by attention deficit/hyperactivity disorder (ADHD) and depression (Medco 2008). No one knows for sure how much chemical exposures contribute to this disease burden, but a wide range of compounds have been linked to the most common children's health problems, including 82 types of chemicals or pollution linked to asthma (Janssen 2009).
Lifetime Disability		Chemical injury to developing organs in a young child or an infant can cause lifelong disability (NRC 1993, U.S. EPA 1998). Numerous studies have linked early exposure to chemical pollutants to later health problems, including: asthma and respiratory disorders; thyroid deficits; cardiovascular disease; learning disabilities, intellectual delay, loss of IQ points and corresponding loss of earning potential; and neurodegenerative conditions such as Parkinson's disease (Boyd 2008; Etzel 2004; Landrigan 2002; Muir 2001; Weiss 2000).
Indirect Costs		The U.S. EPA and the European Organization for Economic Cooperation and Development (OECD) say the true costs of chronic childhood illnesses include: parents' earnings forgone to care for child; value of missed school days; child's foregone earnings; effects of reduced educational attainment on child's future earnings; reduced labor force associated with developmental disabilities. (OECD 2006, U.S. EPA 2002).
Human Diseases Linked to Exposures	182 diseases	Based on a comprehensive review of scientific literature, researchers at the University of California, San Francisco and Boston Medical Center documented 182 human diseases and health problems, including birth defects, asthma, and childhood cancers, associated with chemical exposures (Janssen 2008).
		At the 2004 international summit on chemicals and health at the United Nations

"Serious Threat to Children"		Educational, Scientific and Cultural Organization (UNESCO) in Paris, 154 prominent scientists, physicians and other experts from the U.S. and 18 other nations signed a statement asserting that chemical exposures are a "serious threat to children" (PA 2005).

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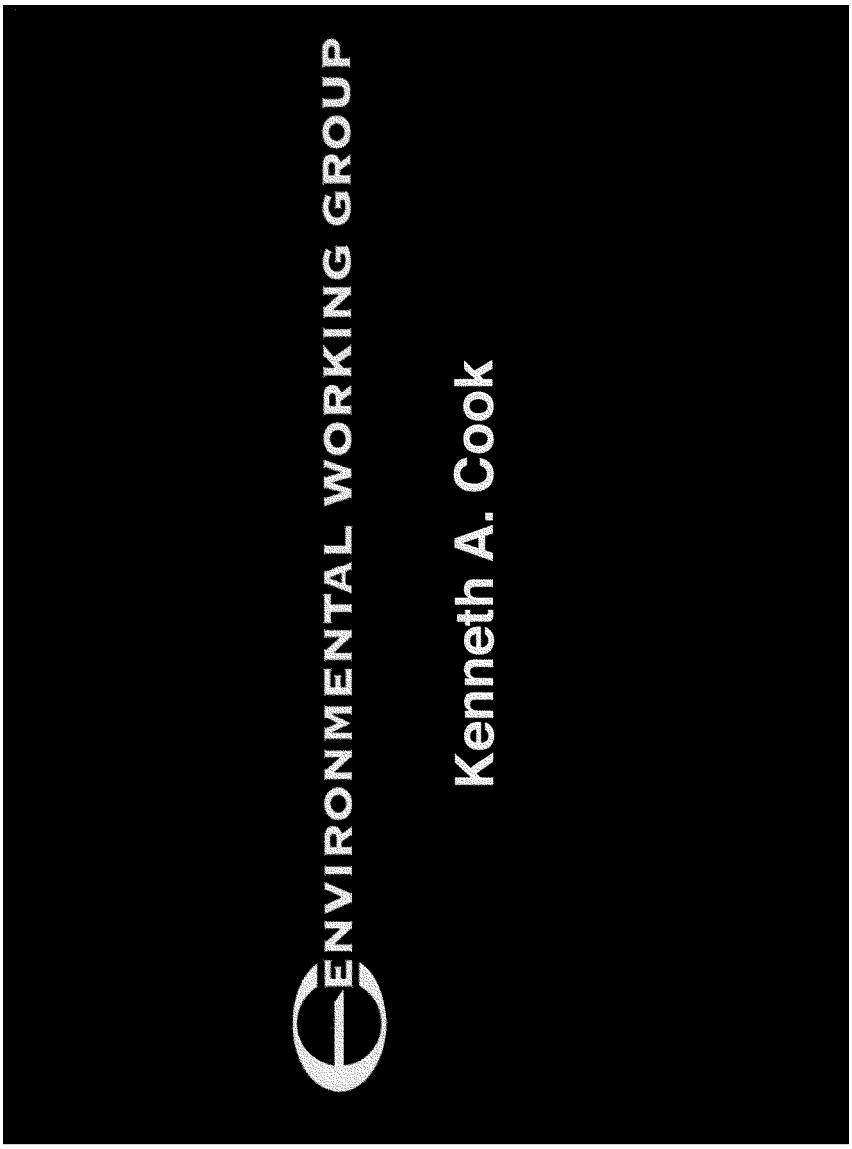
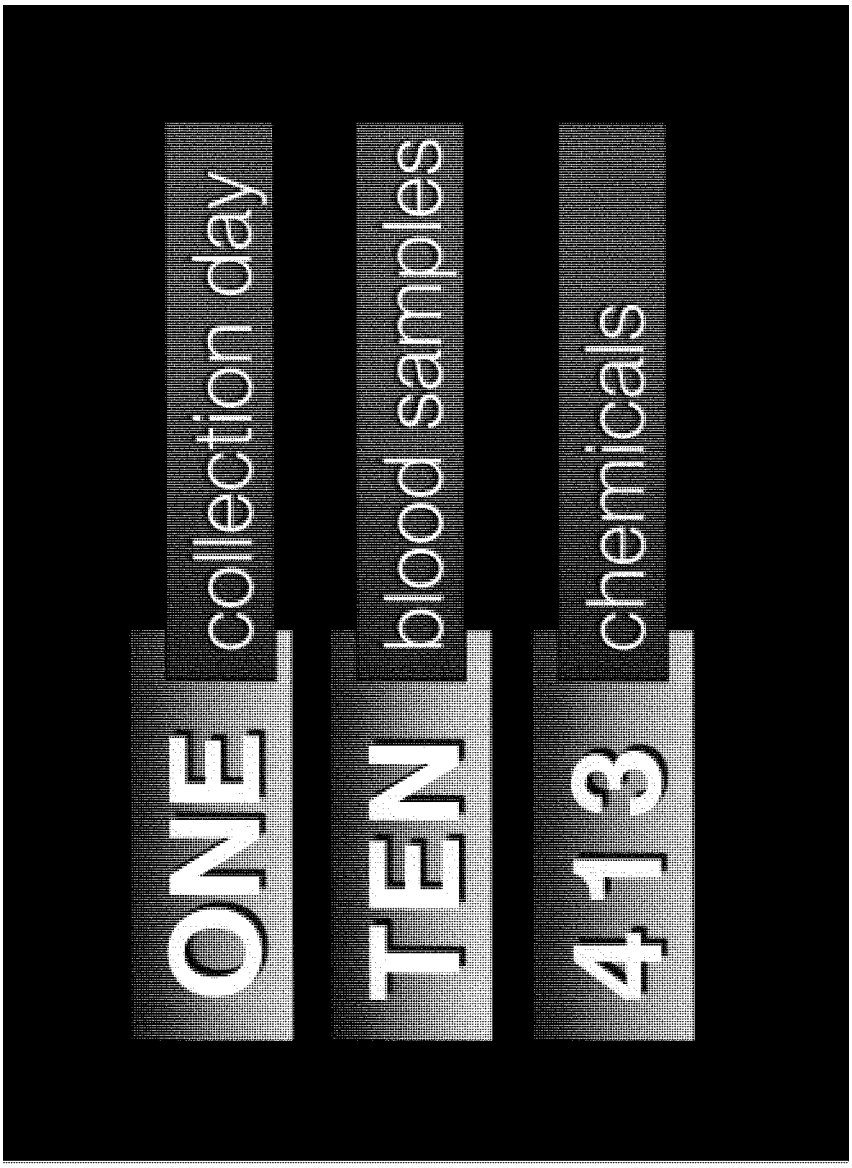

ENVIRONMENTAL WORKING GROUP
Kenneth A. Cook


ONE
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TEN
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413
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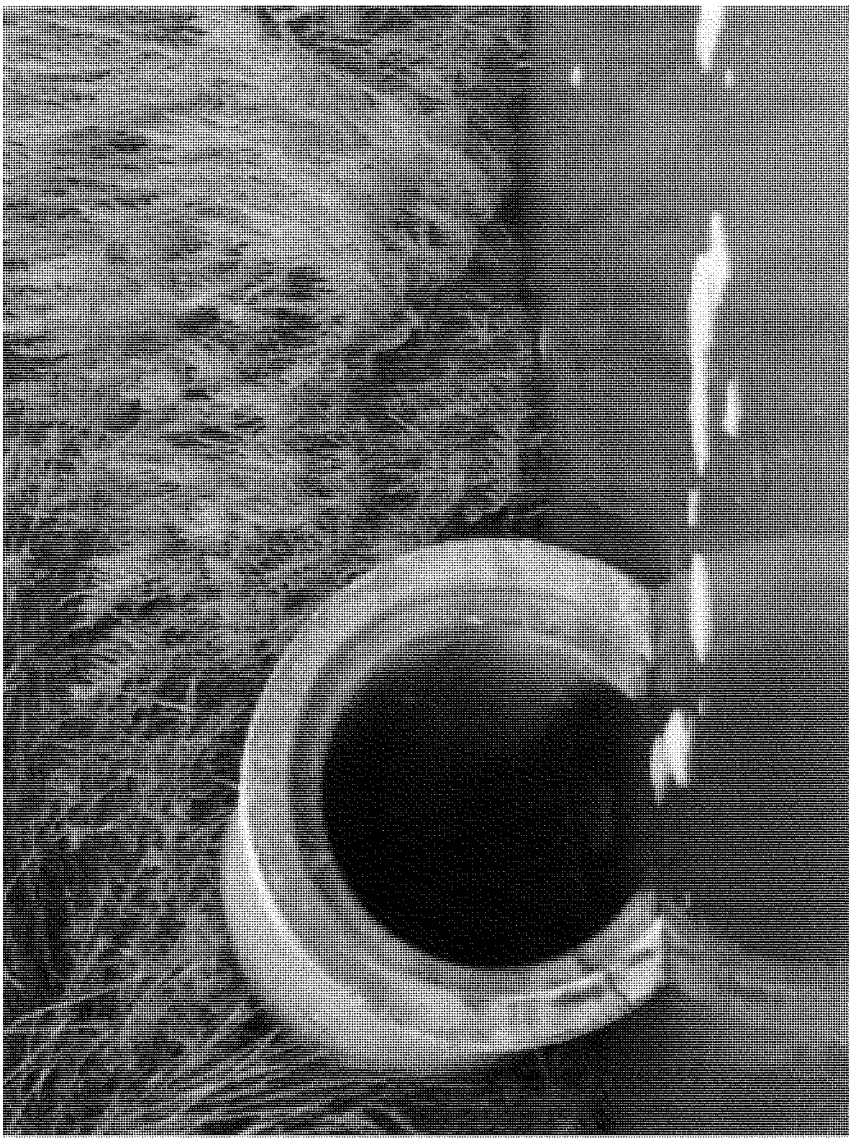
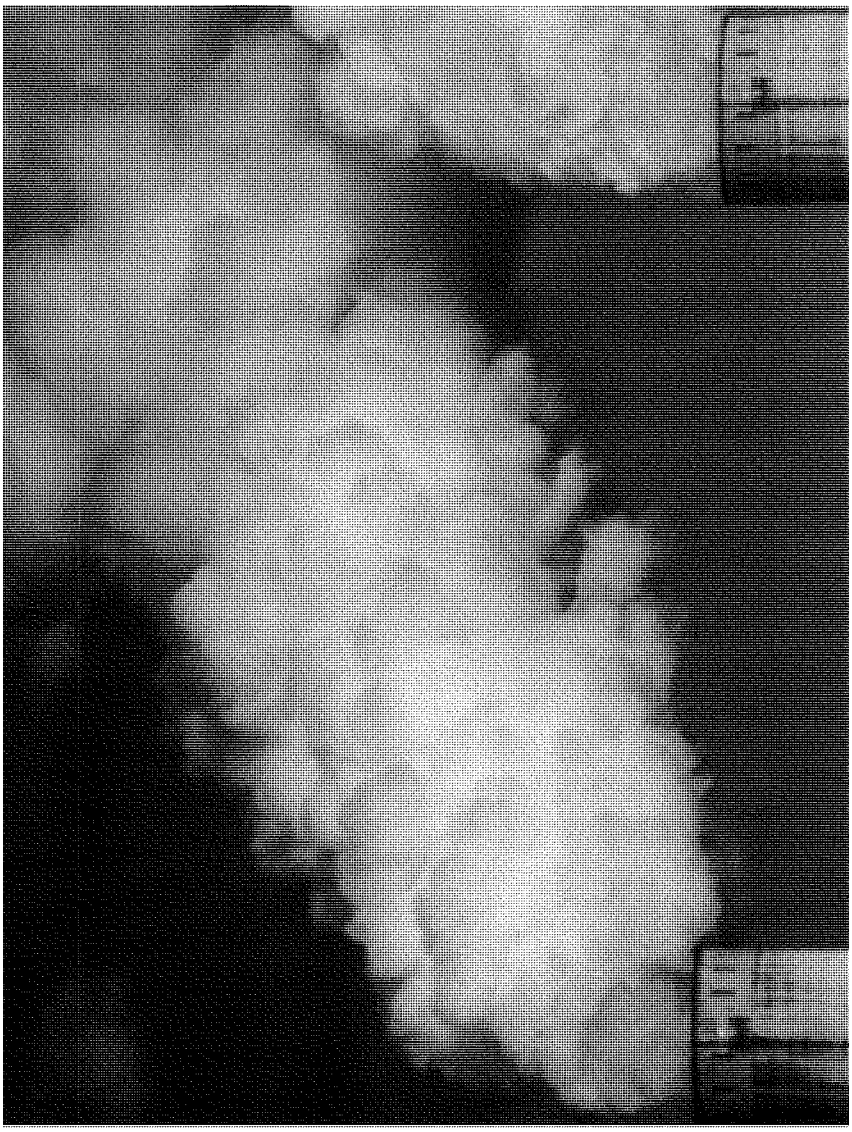
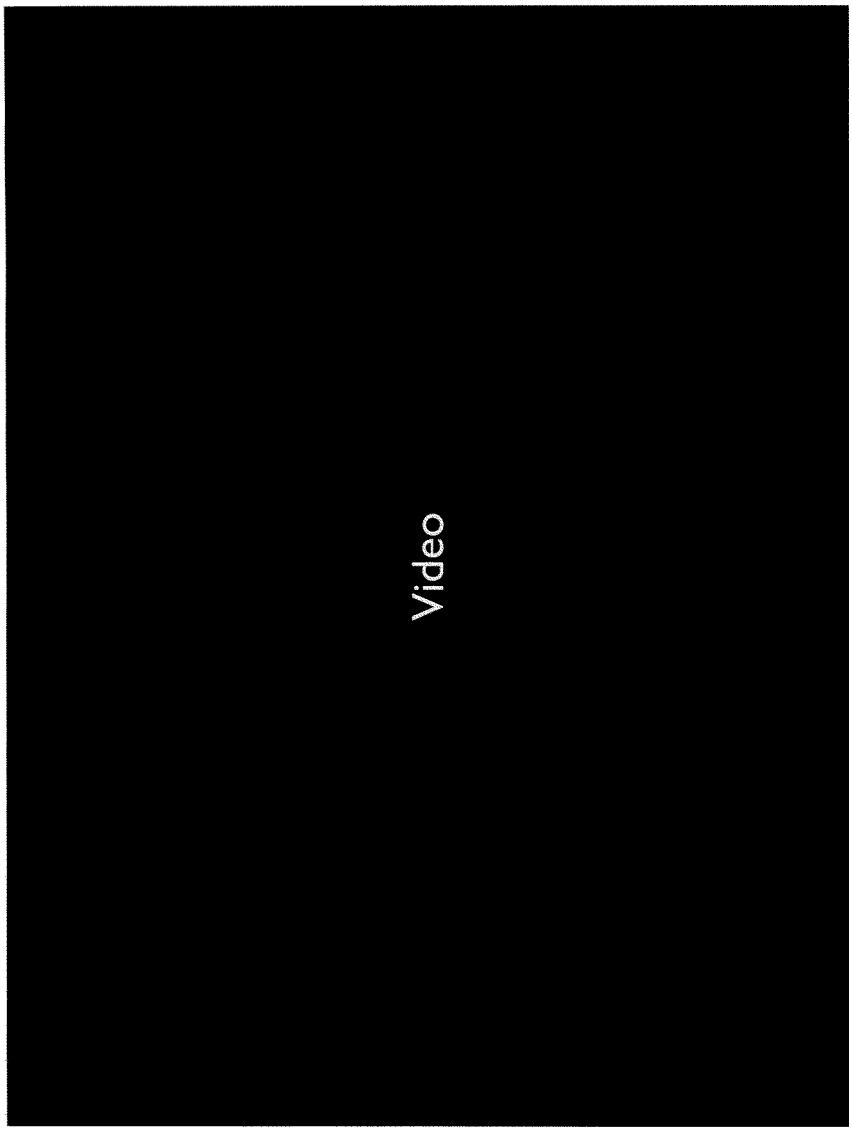
287
toxic chemicals
detected






Video

10 more
Americans

358

Selected U.S. Studies of Industrial Chemicals in Umbilical Cord Blood

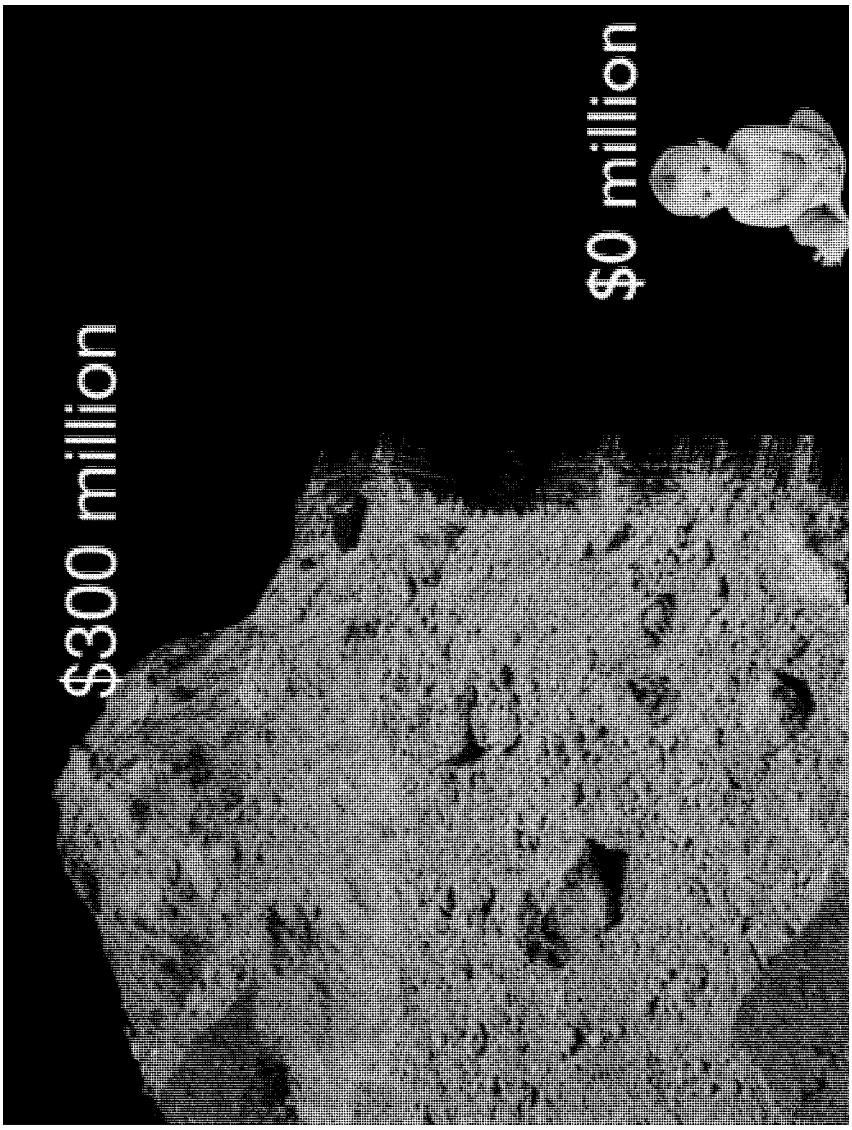
Low Doses Matter
Cialis
30 ppb
NUVARING
0.035 ppb
PAXIL
PAROXETINE HCl
30 ppb

Birth weight and head circumference
(PFOS, PFOA)

Difficulty conceiving (PBDEs),
thyroid disease (PFOS,PFOA)

Heart disease (BPA)

$55 billion per year
childhood diseases
182 diseases


$300 million
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200
people
493
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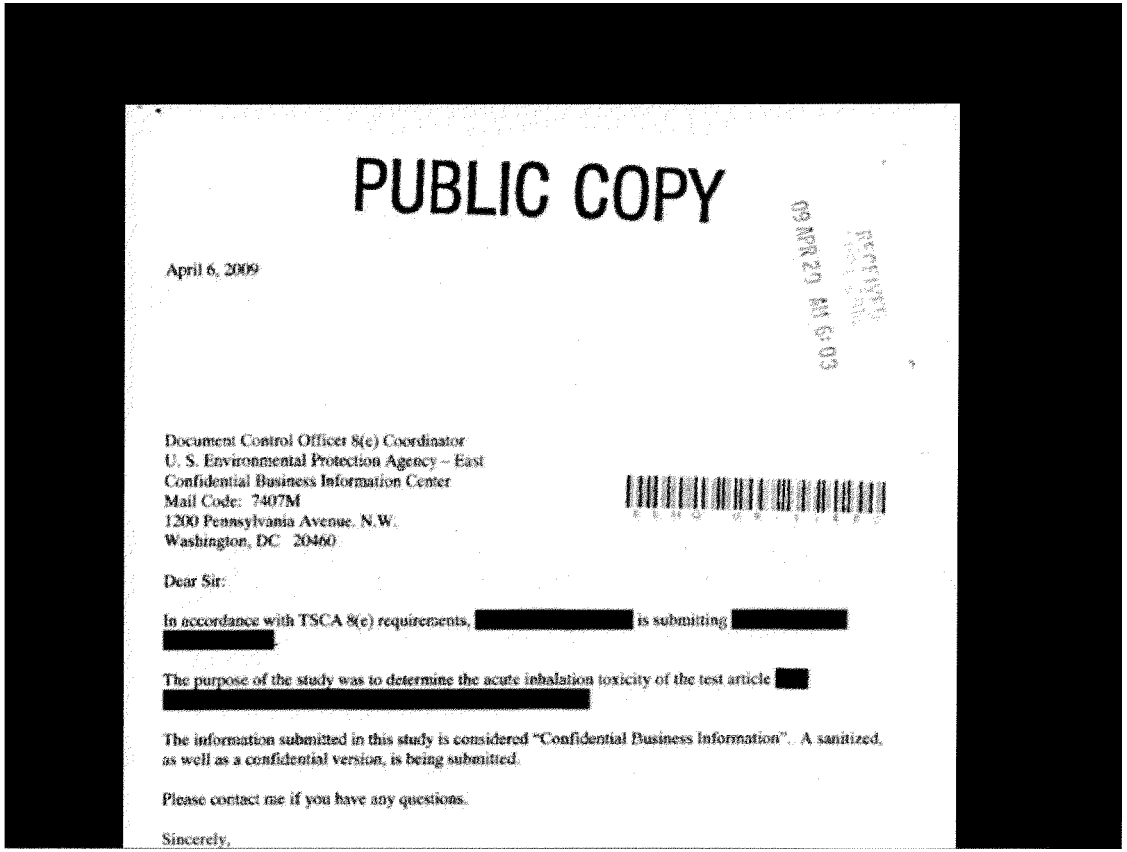
15,000
chemicals



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09 APR 20 AM 8:03

April 6, 2009

Document Control Officer 8(e) Coordinator
U. S. Environmental Protection Agency – East
Confidential Business Information Center
Mail Code: 7407M
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Sir:

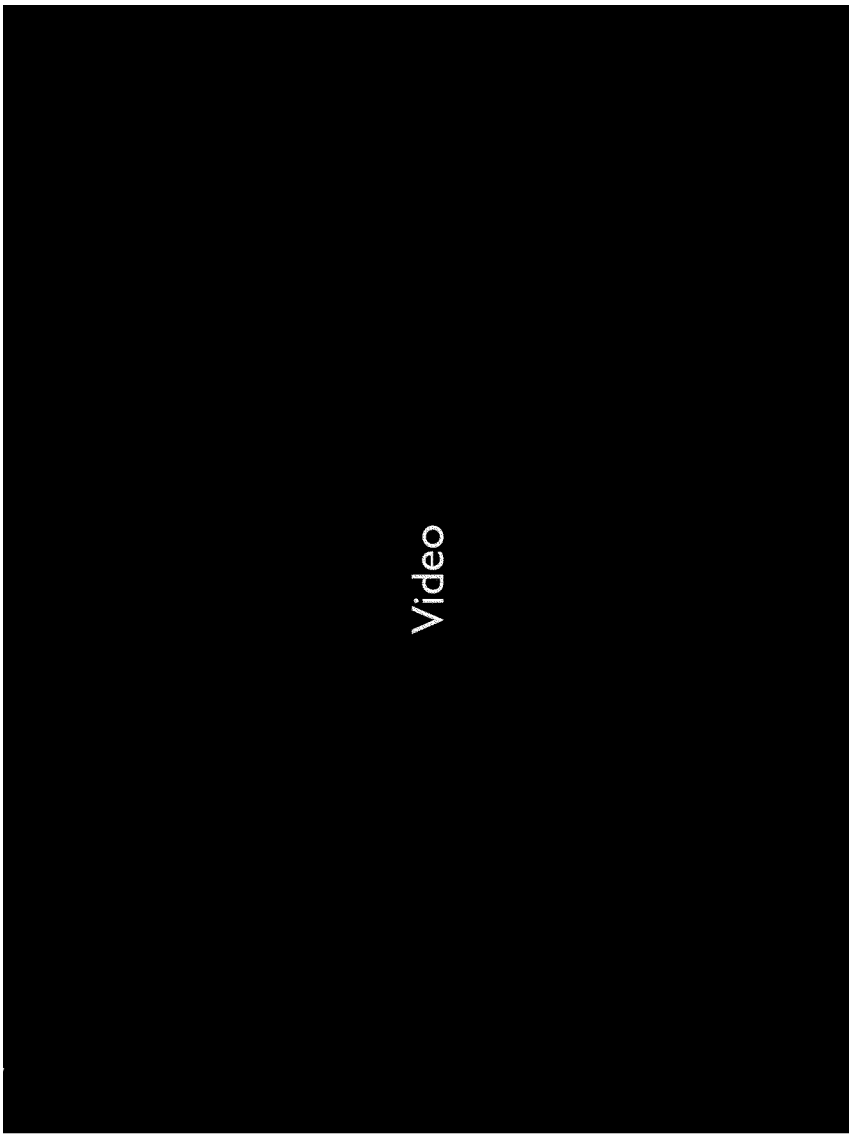
In accordance with TSCA 8(e) requirements, [redacted] is submitting [redacted].

The purpose of the study was to determine the acute inhalation toxicity of the test article [redacted]

The information submitted in this study is considered "Confidential Business Information". A sanitized, as well as a confidential version, is being submitted.

Please contact me if you have any questions.

Sincerely,


Video

1. **One naturally occurring toxin, Radon, can easily find its way into people's homes and produce severe long-term health problems. Aside from smoking, it's the leading cause of lung cancer in this country. From a public health perspective, are we doing enough to address the threat of radon?**

   In October 1988 Congress added a third title to the Toxic Substances Control Act (TSCA) regulating radon with the Radon Reduction Act (PL 100-551). This amendment was added to assist states in responding to the human health threats posed by exposure to radon. EPA was required to publish an updated citizen's guide on the health risks of radon, and to perform studies of the radon levels in government buildings and schools. According to the EPA's 2003 Assessment of Risks from Radon in Homes, exposure to radon gas is responsible for approximately 21,000 lung cancer deaths a year. The only way to detect radon is through testing. EPA provides information directing people to where they can acquire free kits to test their homes, how to purchase a test kit or hire a qualified tester as well as the steps to effectively test a home. EPA recommends testing homes and schools, as well as well water. Although EWG has not worked on radon issues in the past, we would be happy to work with the Committee to examine what more can be done to reduce this public health threat.

1. **You talk about chemicals found in the blood of 10 Americans. What you didn't say is that some of these chemicals are naturally-occurring and form as a result of natural processes in the environment – for instance, dioxin and perchlorate – or the body, or are ubiquitous in the environment at trace levels from historical uses like BPA. How can you be certain that your cord blood measurements reflect exposures from today's industrial uses and products? Where in your testimony do you account for such natural historical variables?**

   The focus of our 10 Americans study was testing for industrial chemicals that cross the placental barrier. All our biomonitoring studies have found more than 400 chemicals in Americans. These industrial chemicals can be and are passed from mother to fetus through the placenta and from mother to infant through breast milk. We found several industrial chemicals where there are no naturally-occurring sources including polychlorinated biphenyls (PCBs), musks, organochlorine pesticides, polycyclic aromatic hydrocarbons (PAHs), flame retardants such as polybrominated diphenyl ethers (PBDEs), perfluorocarbons (PFCs) and polychlorinated naphthalenes (PCNs). Although limited amounts of dioxin and perchlorate occur naturally from forest fires and southwestern soils respectively, the vast majority of human exposures come from industrial uses such as paper products and contaminated drinking water.

   People are currently exposed to BPA, for example, from various products such as the lining of cans, including canned foods or from reusable food and beverage containers. Our minority newborn study detected BPA in umbilical cord for the first time in the United States.

   Our testimony points out that historical exposures underscore the need for a strong federal chemicals policy. Industrial chemicals that have been phased out of commerce – such as PCBs and DDT – are still present in umbilical cord blood. The unfortunate reality is that these exposures of banned substances are ongoing. People living near the Fox River in Wisconsin, like those of the Oneida Nation, are still exposed to the PCBs that pollute that river despite the fact that these chemicals were banned in 1979. We must act now to prevent further exposures of other chemicals that may also be found to be persistent and bioaccumulative.

   How people are exposed to persistent, bioaccumulative chemicals matters little because they stay in the body for a long time and can pose significant risk. Even if some Americans are exposed to naturally occurring chemicals we are all also exposed to industrial chemicals through consumer products. These industrial chemical exposures are not mutually exclusive with naturally-occurring exposures. The best way to think about these exposures is to think about a risk cup. If exposure to naturally-occurring chemicals forms a layer on the bottom of the risk cup then that cup continues to fill up with other industrial chemical exposures from consumer products, food, water or elsewhere. The concern comes when those exposures add up and the risk cup overflows.

2. **Did your cord blood study use a statistically valid sample?**

   Yes. Biomonitoring studies, especially cord blood studies, usually focus on small samples. EWG commissioned tests cost approximately $10,000 per sample, which limited our sample size. EWG's findings in our human umbilical cord blood studies, however, have been confirmed by CDC's biomonitoring program, which tests blood and urine from thousands of Americans. In our most recent cord blood study "Pollution in Minority Newborns," for example, BPA and

perchlorate were found in nine out of 10 samples. CDC's biomonitoring program has found BPA is 93% of Americans 6 and older and perchlorate in 100%.

3. **Didn't the authors of the original low dose study from Tulane University, which laid the foundation for the low dose theory, have to retract that study?**

   Unfortunately, we were unable to track down this study. If you can provide us with this particular reference, we would be happy to respond to the question. However, low doses do matter, as evidenced by pharmaceuticals. Prescription drugs are effective at low doses and some have serious side effects at doses in the parts per billion range or lower. Just because a chemical is found in a person at a low dose does not mean it isn't possibly harmful. Americans are not exposed to one chemical at a time. Therefore, we must account for the effect of exposure to mixtures of chemicals no matter the dose.

Senator LAUTENBERG. Thank you very much. I thank each one of you on the panel for your illuminating, to say the least, testimony.

I want to ask Dr. McKay a question. Are you expressing a skepticism that is fairly deeply borne, if I heard directly what you are saying, that, for instance, using the lead example, taking some comfort that the presence of lead has gone down substantially? I do not know whether you are subscribing that to a natural phenomenon, but there is—lead is outlawed in many, many places. And as a consequence it looks like we have done the right thing.

So, I am not sure where you were going when you made the comparison during the greater exposure to lead in our day, and my day was way ahead of yours. What was the point of that, please?

Dr. MCKAY. Well, I think it is very complex. But the thing I would state is that when we demonstrate decreasing evidence or evidence of decreasing exposure to certain chemicals, we should not then argue that those lower levels are responsible for increasingly severe clinical effects, because that does not make sense.

It also is a difficult thing for people to interpret, and they do not pay attention then to things that maybe are more important. Senator Klobuchar's efforts with the Consumer Products Safety Initiative are, I think, one example of that. If we eliminate lead that is in 100 percent concentration, in other words, a completely 100 percent lead charm that some child swallows and dies, that is a very good thing. To try and chase after 100 parts per million of lead in any component, or 200 parts per million of lead, something that is a small fraction of a percent of lead in that product, not even being taken into the child in that amount, that is inappropriate because it takes the focus off of the——

Senator LAUTENBERG. What would you, repeat for me please, what was a good thing that you saw?

Dr. MCKAY. To take and eliminate the availability of heavily leaded products. That is a very good thing.

Senator LAUTENBERG. And you use the term heavily?

Dr. MCKAY. Yes.

Senator LAUTENBERG. Low levels do not give you concern?

Dr. MCKAY. Lower levels, as was mentioned by several of the speakers on the first panel, that is something that needs to be defined. I am saying that levels that have been put forward in legislation are so low as to not contribute to health problems. And it is difficult for people to then sort out those things they ought to be paying attention to——

Senator LAUTENBERG. I guess I am one of those. I am not a paranoiac about a lot of things, but I am about children's health. And thanks, Mr. Cook, for mentioning my 10 grandchildren.

[Laughter.]

Senator LAUTENBERG. You know, I keep a picture of them in my mind every day when I go to work because among the things that I do here is I keep the focus on children. And nothing is more painful than to see children with a disease that debilitates them and not be able to do things that healthy children should be able to do.

In my 10 grandchildren, I have one with asthma. He does pretty well. But my daughter makes sure she knows where the nearest emergency clinic is when he goes out to play one sport or another. I have another child who came up with juvenile diabetes, and I am

pleased at the progress that she is making and was pleasantly, pleasantly surprised to see her complexion and everything else at the first administration of insulin. It was just was wonderful. And among the other eight we have a very adequate distribution of allergies to all kinds of things.

And if I could, if I did nothing in this, my term in the Senate, which has been pretty long, but to say to parents, do not worry about chemicals in kids' bodies because we know that those chemicals that are present cannot bring any harm, you cannot say that. And I do not know that it will ever be able to be said. But we are going to work on that. I have a mission.

We spend billions of dollars purportedly protecting our society, protecting our people who live in America, to protect them from terrorism and violence and all that. But what kind of protection do we owe those beautiful little babies?

I now consider myself a professional grandfather, and when I see kids, if they are just cute and nice, it makes me feel good, I can tell you, even though they are not mine. I would take them all, but I do not have room.

[Laughter.]

Senator LAUTENBERG. But I do want to ask you this, Mr. Cook. Your biomonitoring studies found more than 212 chemicals that were found by CDC. Could there be even more in our bodies than biomonitoring sciences have revealed so far? You mentioned that there were over 400. Is that—do you think that you have done the full gamut of study that has to be done?

Mr. COOK. Mr. Chairman, not even close. I think because we have not been looking we have not found the chemicals that are in people. We have only just begun.

We spent $10,000 per sample to study our first set of 10 cord blood samples. We were able to study more chemicals because we were studying a smaller group. We do not purport that this is a group that is representative of the U.S. population or babies at all. It was a quick survey. But just developing the methods is important.

Chemical companies are not obligated to tell EPA, under TSCA, how to find toxic chemicals in people, babies or otherwise. So, in many cases we have had to spend money to have the laboratory techniques developed to find some of these chemicals. And now we are finding them. Every time we look for more of them we are finding them.

I would expect if you had enough money and you had enough sample, which you do not with cord blood, of course, you would probably find hundreds and hundreds if not thousands more chemicals in people in this country. And these are not people who are exposed occupationally necessarily. These are folks like all the rest of us go to work, type on a computer, talk on the phone, drive in a car, eat regular food. The chemicals are there.

Senator LAUTENBERG. Thank you.

Dr. Woodruff, EPA has overseen the regulation of pesticides for years and succeeded in taking some of the most dangerous pesticides off the market. My Safe Chemicals Bill will require testing of all chemicals under a standard similar to the one that applies

to pesticides. Has EPA's restricting the most dangerous uses of pesticides substantially damaged that industry? Do you know?

Ms. WOODRUFF. Well, I am not going to speak completely for the industrial healthiness of the agricultural industry, but suffice it to say we still have adequate food available for us in this country as well, which is one of the primary uses of pesticides in this country.

I would say that, you know, EPA has gone through a process, because of the regulatory requirements for pesticides, to require data on active ingredients in pesticides, which gives them a pretty good indication about the potential for harm for active ingredient pesticides, which then allows them to assess the risks.

And as mentioned by the previous panel some pesticides have been removed from the market, like chlorperifos, because of their identification as a potential developmental neural toxicant. And that has been very successful, also, as has been noted by some of the studies in New York City before and after the ban by EPA.

What we have as a challenge is that for many chemicals we simply just do not know because we have no information. And I would point out that the absence of information right now is being used to assume something is safe. But really all it means is that we do not know anything about a chemical.

And I think, as Mr. Cook was saying, that every time we find something new in these biomonitoring studies it appears that we have reached a threshold. But really what we have done is sort of identified the next set and that actually there are many, many more chemicals that could be out there, but we just do not know if they have been measured.

I would offer an example of xyloxene, which is a chemical that has been proposed as a substitute for perchlorethylene in dry cleaning in California. I know about this chemical because we at UCSF are participating in partnership with a State of California biomonitoring study to measure chemicals in pregnant women and their infants.

We have an interest in xyloxene because people have reported that this may be a chemical of interest and may be ubiquitous in the population. And we have been working with the State of California laboratories, as well as had some discussions with CDC, about could we measure this chemical, which we think is likely to be rather ubiquitous in the population.

It has been very challenging because xyloxene is in many consumer products. It is so ubiquitous that CDC has not yet been able to develop a method that would—a clean method room such that their samples would not be contaminated, meaning that it is ubiquitous everywhere in our environment.

We are not quite measuring it in people, and yet none of us really are talking about it because it has not emerged as something that we can measure, though there is concern about it for exposures generally in the population and as potential health effects.

Senator LAUTENBERG. Let me ask you this. So, are there new techniques for testing toxicity being developed so that scientists can move faster and with more accurate results without relying on animal testing? What might Congress do to accelerate the development and use of these newer testing techniques?

Ms. WOODRUFF. This is actually a really very exciting area of research. There has been a report by the National Academy of Sciences, Toxicity Testing in the 21st Century, which has noted that we are entering a phase where we have the ability to test chemicals in cellular assays that we previously had not had before. And I know the National Institute for Environmental Health Sciences has been actively supporting a program for rapid testing of chemicals using non-animal methods but in cellular assays.

I think there are sort of two keys pieces to this. One is further investments in the research side of this. But I think also, and I think EPA has mentioned this in their testimony earlier, is that we are going to be getting a lot of data from these things as the toxicogenome, epigenome evaluations. And how do we take that data and interpret it for the policymaking context?

We are going to see lots of different signaling pathways perturbed. And yet we need to have more resources into the side that looks at, well, now that we have all of this data, how do we interpret it in the context of when we need to make a decision? Because as people have noted you are going to see probably many different signals going off, and how do we assess that in terms of the goals of trying to evaluate health risks from environmental chemicals?

So, that would be my—I think you need to have both a research side, but you need to also focus on the research interpretation because science is very important. And as everyone has mentioned here, but it is very hard sometimes to interpret the science in the way that policymakers need, and I think we need to invest in that part as well.

Senator LAUTENBERG. Thank you.

Ms. Gray, the chemicals found in our bodies get there from many sources, air pollution, water pollution, food, and household products to name some of the biggest. Some of these sources are currently regulated by agencies other than EPA. Do you think that EPA ought to be able to review all exposure sources when deciding if a chemical is safe? I am kind of asking you an inside question here because it is—we do a lot of this review on this side of the table.

Ms. GRAY. It is an interesting question. I think for chemical reform to be meaningful, that the EPA has to take it all into account. Where are these sources? How are they ending up in our body? What are all the uses? How do they all add together?

From a consumer standpoint, before preparing for today I most certainly did not know that different agencies regulated certain chemicals and others regulated other chemicals. And so, from that standpoint as a consumer, for me that piece does not matter as much as that we are not seeing these wind up in our bodies. And so I think in order to do that, we do. We have to think in the broadest of terms and really look at the big picture to see how this is happening.

Senator LAUTENBERG. You cannot go far enough or deep enough to satisfy our obligation to make sure that things that are dangerous are discovered and at an early enough point in time so that they do not do any harm.

Ms. GRAY. Exactly.

Senator LAUTENBERG. We have noticed, for instance, a growth in the number of asthmatics in children who come up with other dis-

eases at birth and whether or not we are seeing an evolution of disease that is connected to the chemical exposures or other exposures. But we sure ought to find out because these conditions are tough. And you see the growing number of autistic children being born on a relative basis. It is a worrisome thing. And it has got to be more than a coincidence that things that they are exposed to. So, we have to do our research more thoroughly, finance wherever we can do it. And I thank you.

We are joined by Senator Whitehouse. And what I am going to do, Senator, is to promote you to be Chairman. We have an excellent panel here, and I am sure that, knowing you, you have interesting questions to put forward. I know you are concerned about children's health and the environment generally, and during our working together I believe that you have a good way of getting to the bottom of things.

Senator WHITEHOUSE. Does this give me budgetary priority so I can——

Senator LAUTENBERG. If I can give them.

[Laughter.]

Senator LAUTENBERG. And I want to say thank you to the witnesses.

Senator WHITEHOUSE [presiding]. I want to join the Chairman in thanking the witnesses but also take a moment to reflect on his own ardent leadership on these issues. It is important in the Senate for issues to have champions. When an issue has a strong champion, it is more persistently pursued, it is more vigorously pursued, it is more thoughtfully pursued, and it is ultimately more effectively pursued. And Senator Lautenberg has for a long time been a very significant champion on these health issues, particularly as it affects children's health. So, I am delighted to join him and feel, frankly, honored to share this panel with him.

Senator LAUTENBERG. If I might——

Senator WHITEHOUSE. Are you going to rebut that?

[Laughter.]

Senator LAUTENBERG. No, I am not going to take it back. I am pleased with what you said, and I could listen for a long time.

[Laughter.]

Senator LAUTENBERG. But I want to enter two things into the record, if I might. One article that appears in Environmental News Focus about whether or not there are any safe levels of lead, which we seem to have a little bit difference of view here, and also a statement by the American Chemistry Council where they say that the Association and its member welcome congressional review of the Toxic Substances Act and lending their support to it. So, with that, I reinstate your Chairmanship.

[Laughter.]

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

Senator WHITEHOUSE. Well, I would like to ask two questions, and then I will conclude the hearing because I know that everyone has been here a long time. And I appreciate your testimony.

The first has to do with the notion of asymmetry. We talk about, in the military context, asymmetrical warfare. And it strikes me that when you look at the number of chemicals that EPA actually regulates versus the explosion of chemicals that industry has pro-

duced in recent years, which we are, at this point, largely taking on faith, are not harmful, it is hard to see how under existing practices the EPA could ever catch up. They simply do not have the resources to do it.

I do not know if you had the chance to talk in this hearing about what preferred model there is for addressing that asymmetry. We obviously do not want to stop industry from producing legitimate helpful products. But we also want to make sure that harmful products are kept out of our environment and kept out of our bodies as effectively as possible.

I suspect that this situation is going to get, in terms of the asymmetry, is going to get a lot worse in the wake of the very surprising decision by the right wing activists of the U.S. Supreme Court that said that there could be no limit on what corporations could spend to influence political campaigns.

When you get to a potentially narrow issue like whether a chemical should be regulated, the corporation that produces that chemical has an enormous interest in all of that. But in the array of interests that a public is concerned with at the time of an election it is not a very big one compared to everything else that is out there. It has to compete with every other issue for attention in a different way than the manufacturer sees that particular chemical.

So, it worries me that that is going to get very asymmetrical, too, because a corporation could come into a candidate and say unless you support us on this, it is a minor matter, nobody ever needs to know about it, we are going to run a $3 million smear campaign against you the last 2 weeks of the election. We are going to do it through phony-baloney corporations that are very easy for us to set up, it is going to have a wonderful name like People for Trust, Justice, Apple Pie and the American Way, and it is going to point out everything negative that we can find out about you, and we are going to blanket the airways. Your choice. Are you with us, or are you against us? And I think that is a very dangerous proposition.

So, I think the imbalance presently between the public health effort to protect against these chemicals is about to undergo a systemic blow which makes the question of trying to fix it and resolve the asymmetry all the more important.

Let me ask Dr. McKay if he would speak first to that and then perhaps Ms. Woodruff.

Dr. MCKAY. Well, I obviously cannot speak to any of the manufacturers testing and all, but Dr. Falk and Dr. Birnbaum spoke earlier on the possibility and likelihood of being able to cluster compounds within areas of effect or likely effect. And several things have been mentioned throughout this hearing about the importance of thyroid function, particularly during neonatal development. So, that would be a way of addressing classes of compounds by likely areas of effect.

The problem with blaming a given compound for an effect that it turns out not to have, we have seen, unfortunately, very well exhibited by the discredited studies looking at thimerosal as a preservative in vaccines, multi-dose vaccines. Now that that study that started the anti-vaccine campaigns has been withdrawn, all that is left in its wake for the last 20 or so years is the number of children who have developed Hepatitis B, measles, and died be-

cause of lack of vaccination. But none of them have been prevented from harm from exposure to that ethylmercury compound.

Senator WHITEHOUSE. So, we want to get it right on both sides. You do not want false alarms.

Dr. MCKAY. Right. Exactly. So you want to be able to identify substances that truly do have a high likelihood of having an adverse effect. If they are already out in commerce those are the ones to be removed or regulated restricted.

But at the same time the benefit of whatever those products are that they are in should not be lost. And you know flame retardants are one that has been discussed, and I think that is important if we identify those as the culprit for some of the effects that are blamed on them. But I would not want to have more fires because of the lack of flame retardants.

Senator WHITEHOUSE. So, your best recommendation at this point is to expand the scope of the regulatory process so that it is by chemical category and not just by individual chemical so that more can be, the regulatory process can be used more efficiently.

Dr. MCKAY. I think that is a component of it. But then, each, you would still have to regulate each chemical within that category based on some decision process. And to determine whether something is safe or not is really a difficult question because everybody's definition of safe has to incorporate the substance that that chemical is in, what is provided by it. The people in Haiti right now are I think very happy to get the water that is being delivered to them in a plastic jug that has bisphenol A leaking out of it. That cannot be done through glass containers or other kind of distribution networks.

There is always a risk-benefit process, and if there are chemicals that are identified as high risk, and that I believe is EPA's job, it is the manufacturer's responsibility I think to do that as well. But then decision has to be made about which ones have to have the highest priority and where the line is drawn between more benefit and more risk.

Senator WHITEHOUSE. Ms. Woodruff.

Ms. WOODRUFF. Yes, I think you bring up a really excellent point because as people have mentioned there are thousands of chemicals, yet EPA has been very challenged in terms of evaluating them and often when they do do the risk assessments they can be extraordinarily slow, formaldehyde, trichlorethylene, dioxin, all chemicals which EPA is still doing a risk assessment on even though it has been 10 to 20 years.

And I think there are two parts to the answer to your question. The first is the research part, which is, as I had previously mentioned, we have a whole new arena of scientific tools in terms of toxicity testing that are before us that we should invest in.

I think also we need to move what we have called upstream to looking at more of early biological perturbations in terms of adverse health effects. Thyroid hormones is a perfect example where we should be looking to see if chemicals cause thyroid hormone disruption and not wait to see the note about metal outcome. The science is quite clear in this area, and EPA is quite legitimate in terms of moving up to more early indicators which would make the testing process more efficient.

Senator WHITEHOUSE. Unfortunately, the——

Ms. WOODRUFF. Could I just say one more thing?

Senator WHITEHOUSE. I was just elaborating on the one point you made, then please go ahead back to it. Unfortunately, industry has gotten quite good about sewing doubt about whatever scientific uncertainty there may be, even if it is only a 1 percent doubt.

Ms. WOODRUFF. I should have listened to you because you actually led me to my next point, which was that science is only one part of the decisionmaking process. Clearly part of the challenge for EPA is making their decisions in the face of uncertainty and the fact that, as you mentioned, many different people have a stake in the outcome, and some people have more resources than others to sort of engage in that activity in terms of influencing the outcome.

I think that it is challenging to try and address this through the policy process. But there are tools that have been identified, primarily through the research in the tobacco literature and the pharmaceutical industry influence on pharmaceutical drug literature, that show both how the industry can influence science but also tools that the Government can use to try and counter that type of influence. They include Sunshine Laws so that there is complete disclosure of information about who is participating in scientific research. There are also conflict of interest policies that can be put in place. The International Agency for Research on Cancer has a very nice set of conflict of interest policies that helps to minimize the influence of people who may have a vested interest in the research outcome.

And then I would also say that this is an area that is ripe for research itself, much like the tobacco industry and the pharmaceutical industry, what we know about how the industry can influence the scientific and public policy process comes from actually basic research on that actual subject matter. We have no such research on the environmental health field. But you can imagine that it would be an appropriate place to have better information so that we can learn.

I mean, it is a very difficult thing, as you mentioned, to try and counter. But currently we are not really actually applying all of the tools we could to really make a difference in terms of trying to minimize the conflict of interest and trying to balance the playing field in terms of how decisions are made.

Senator WHITEHOUSE. Well, it gets particularly difficult around here when members of the Senate reject the precautionary principle, which I think, Dr. McKay you have in your testimony.

It seems a reasonable thought. Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent degradation. It seems like a non-controversial principle. It is one that I suspect every one of us applies in our daily lives, taking reasonable precautions. If the fire alarm goes off in the night, and your children are asleep, there is of course a less than complete scientific certainty that there is a fire. It could be a spider got into the alarm system, it could be any number of things. But I think a prudent parent wakes up and goes downstairs and checks.

And our blindness to that, particularly in this body, I think is a very dangerous development, and frankly it is an irrational development. It puts articles of faith ahead of logic and takes us back to, well, we had enlightenment for a reason, we had a year of rationality for a reason.

But the time has expired. I just want to say I appreciate so much all of your testimony. I am sorry I did not have the chance to talk longer.

Anybody seeking to add anything to the record of this proceeding has, I believe, a week to do so, and then the record will close.

Again, with my gratitude to both panels of witnesses, this hearing is adjourned.

[Whereupon, at 12:07 p.m. the subcommittee was adjourned.]

[Additional statements submitted for the record follow:]

STATEMENT OF HON. BENJAMIN L. CARDIN,
U.S. SENATOR FROM THE STATE OF MARYLAND

Mr. Chairman, thank you for holding this hearing today.

Senator Lautenberg, I applaud your tireless efforts to reform toxic chemical regulation and look forward to working with you on forthcoming legislation to reform the Toxic Substances Control Act because reform of the process and methods for chemical testing and use determinations is desperately needed to protect the public health.

There is no denying that the chemical industry has done miraculous things in the development of medical science, aeronautics and vehicle safety, energy efficiency and home improvement and many other modern conveniences. However, lax regulation backed by weak public protection laws has placed the public's safety at risk.

The fact that water bottles, including baby bottles, containing bisphenol A, a known endocrine disruptor, are still being sold in this country is a perfect example of how ineffective our toxic chemical laws are at protecting the public.

Fortunately, many large chain retailers like REI and Whole Foods Markets took it upon themselves to protect their customers by removing plastic bottles containing BPA from their shelves, thus sending a strong message to industry. Companies like Nalgene, makers of popular and durable water bottles reacted responsibly and quickly to market demands and changed their products to BPA-free plastics.

While it's refreshing to know there are good actors in marketplace, we must not overlook that BPA plastic baby bottles are still manufactured and sold by retailers all across the country. By and large this is an environmental injustice that impacts the health of children because people living in underserved communities often do not have access to retailers that sell a wide variety of alternative plastic products that are known to be safe. Since chemical labeling is not required many consumers lack information about the safety of the chemical composition of the products they use every day.

I am pleased that there is an effort underway right now in Annapolis to pass legislation to protect Marylanders, particularly children, from products containing BPA. However, reforms to Federal law to protect the public from BPA and other harmful chemicals are the more prudent way of addressing this issue.

BPA, for better or worse, has become the poster child of the hundreds of potentially dangerous and loosely regulated chemicals that millions of Americans are exposed to on a daily basis. As we are sure to hear from testimony today, independent results from a variety of voluntary biomonitoring studies have found a wide range of chemicals in people from all walks of life.

One particular study revealed the environmental justice component of this problem that I alluded to earlier. Biomonitoring tests were done of five environmental justice leaders who live and work in communities like the Gulf Coasts of Texas and Louisiana and Richmond, California, where residents breathe the air, drink the water, and share the land of their community with major chemical plants and oil refineries.

The startling findings from the biomonitoring reports of leaders in communities that are subject to high chemical exposure revealed that they were in the higher percentiles of Americans with extremely elevated levels of chemicals like BPA, polycylic musks, mercury, perchlorate and lead. Beyond that these people tested positive for 37 or 45 of the 75 chemicals they were screened for.

Many of the residents of these communities livelihoods are dependent on these companies, yet the chemicals these plants expose residents to also threaten their health as well.

Children growing up in these communities and who are exposed to these chemicals during times in their lives when they are most vulnerable are the most at risk. Persistent exposure to certain chemicals affects brain and cognitive development, bone density, pulmonary and respiratory function, endocrine disruption and can cause cancer.

I want to address a wide range of issues on chemical safety and work toward enacting legislation that improves regulatory authority and increases the public's access to information on the toxicity of the chemicals that pervade our daily lives.

I thank the Chairman for holding this hearing, and I look forward to working with my colleagues on the committee to reform our national chemical control policy.

STATEMENT OF HON. KIRSTEN GILLIBRAND,
U.S. SENATOR FROM THE STATE OF NEW YORK

Thank you, Chairman Lautenberg, for holding this very important hearing.

I'd also like to thank our witnesses who are here today and look forward to their testimony on these critical issues

Mr. Chairman, the issues being explored today are central to the health and welfare of our country. As a mother of two young children, I am deeply and personally concerned about the exposure of the most vulnerable in our society to toxic substances.

Over the past 34 years Americans have been unknowingly exposed to over 80,000 industrial chemicals through our air, food and water. Of this number, a staggering 60,000 were grandfathered into current law with little or no testing to determine the safety of these chemicals.

The Toxic Substances Control Act or TSCA—signed into law in 1976—was designed to safeguard the Nation's health. This statute has failed. Today we see an increased risk of chronic diseases—some of which are attributable to environmental chemical exposure.

The Safer Chemicals, Healthy Families Campaign recently issued a report that makes the case for reforming TSCA, which in turn may lead to reduced health care costs. Their report draws from over 30 years of environmental health studies that demonstrate that chemicals are playing a role in the increase in chronic diseases and disorders our Nation is facing.

A study released in 2002 from researchers from the Mt. Sinai School of Medicine Center for Children's Health and the Environment in my home State of New York estimated that the toxic chemicals that our children are exposed to in air, food and water in the places we live, work, study and play are linked to 5 percent of childhood cancers, 10 percent of neurobehavioral disorders and 30 percent of asthma.

As the mother of a child with asthma, this is a staggering statistic.

The Mt. Sinai study further illustrates the quantitative cost of these exposures. It estimates that every year we spend more than $2.3 billion on medical costs related to childhood cancer, asthma and neurobehavioral disorders linked to exposures to toxic chemicals.

Asthma is the leading cause of school absences for children aged 5 to 17 due to a chronic illness. Direct costs for asthma related medical expenses, including hospitalizations, account for nearly $10 billion.

300,000 school-age children in New York State have asthma, with nearly 200,000 of those being elementary school age. In 2005 alone the total cost of asthma hospitalizations in New York State was approximately $502 million for an average cost of $12,700 per hospitalization.

If exposure to harmful chemicals is contributing to negative health effects in our children, it is our responsibility to act.

Mr. Chairman, one chemical that has received a lot of attention lately is bisphenol A—commonly referred to as BPA. This is a chemical that has been linked to birth defects, obesity, certain cancers, and other neurological disorders.

I am working with my colleagues, Senators Feinstein and Schumer, on two pieces of legislation concentrating on the threats of BPA. The BPA Free Kids Act and the Ban Poisonous Additives Act take significant steps to address the threats posed by BPA in food containers and products for our children.

According to the Fourth National Report on Human Exposure to Environmental Chemicals, published by the Centers for Disease Control's National Center for Environmental Health, 90 percent of Americans show traces of BPA in their urine.

The widespread exposure of BPA currently in the bodies of every day Americans is staggering.

Mr. Chairman, as I stated at the previous hearing on TSCA, when considering 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.

Mr. Chairman, thank you again for holding this important hearing, and I look forward to working with you and my fellow Senators on the committee as we look to bring the Toxic Substances Control Act into the 21st century.

[Additional material submitted for the record follows:]

Statement by

Collin P. O'Mara
Secretary of Natural Resources and Environmental Control
State of Delaware
Thursday, March 4, 2010

Submitted to
U.S. Senate Committee on Environment & Public Works
and its Subcommittee on Clean Air and Nuclear Safety

Legislative Hearing: S. 2995, The Clean Air Act Amendments of 2010

Good Morning. My name is Collin O'Mara and I serve as Secretary of the Department of Natural Resources and Environmental Control under the leadership of Governor Jack Markell in the state of Delaware. I would like to thank Chairwoman Boxer, Ranking Member Inhofe, Subcommittee Chairman Carper, Ranking Member Vitter, and all the members of the Environment and Public Works Committee and its Clean Air and Nuclear Safety subcommittee for the opportunity to share our thoughts on the proposed amendments to the Clean Air Act to establish a multi-pollutant regulatory program for the electric generating sector.
I would be remiss not to begin my comments by recognizing Senator Carper's steadfast dedication to our environment and his tireless efforts to ensure that all Americans have the right to clean, healthy air. I specifically want to recognize Senator Carper's efforts in the area of diesel emissions reduction and the introduction and funding of the Diesel Emissions Reduction Act which has enabled us to implement a number of diesel retrofit activities—activities that would not have otherwise been possible. Thank you, Senator Carper, for your leadership in Delaware and across the nation.

Every year millions of people in the U.S. are exposed to unhealthful levels of air pollution, resulting in lost work days, hospitalization, respiratory and cardiac diseases, premature mortality, and billions of dollars of adverse impacts on our economy. Delaware is not immune to these challenges correlated to air pollution and faces some of the highest rates of cancer and respiratory diseases in the nation.

In our effort to provide cleaner air to our citizens, Delaware has adopted many regulations ranging from rules for inspection and maintenance of automobiles, standards for consumer products, and requirements applicable to many industrial sources. As a result, we have seen our state's air quality improve over the years. Last year, Delaware had no exceedances of the

old 0.08 eight-hour Ozone standard and we are working hard to figure out what is needed to meet the future Ozone standard which will certainly be lower than 0.075 parts per million.

One of the greatest regulatory successes we have had is the adoption of multi-pollutant regulations for the coal and oil fired Electrical Generating Units. The outcome-driven regulation establishes performance standards for NOx, SO2 and mercury to be met by each unit. We found controls necessary to meet the regulatory limits were technically feasible and highly cost effective. The coal fired units are all meeting mercury emissions reductions in excess of 80% and are on track to meet the next phase which requires 90% control by 2013. The units remaining in operation are also meeting the first phase of the NOx and SO2 reduction and are on track for the final compliance phase which begins at the end of 2011.

For these and other efforts, Delaware is recognized as having one of the more robust air pollution control programs in the country. We have also worked with our regional partners in the Ozone Transport Commission and have adopted a number of programs to reduce emissions that are generated within the OTR. The most notable and perhaps most effective of such programs was the OTC NOx Budget Program which targeted NOx emissions from the EGU sector, and which was later mirrored and adopted by the EPA in the NOx SIP Call.

Unfortunately, despite this progress, Delaware's air quality still fails to meet attainment standards mostly because of high levels of pollution imported from other states. As Senator Carper often says, "Delaware sits at the end of America's tailpipe." We are heavily impacted by air emissions coming from the West. The most significant of these contributors are emissions and air pollution from the hundreds of uncontrolled or poorly controlled electric generating units in upwind states. In addition to air quality and associated health impacts from these sources, this inequity places consumers who depend on power from cleaner EGUs at an economic disadvantage compared to those in upwind states who have failed to implement such controls. (This argument was central to our pending Section 126 petition from 2008.)

Air pollutants do not recognize state boundaries and it is with this backdrop that we are here today to lend our support to a bill that proposes a national solution to the elusive national challenge of improving air quality by addressing the emissions of multiple air pollutants from the electric generating sector. Previous attempts to gain reductions from this sector have proved that controls are feasible and highly cost effective; unfortunately, these efforts did not go far enough. Today, 80% of the SO2 emissions nationwide come from uncontrolled coal fired EGUs and only 25% of the EGUs have installed SCR to control NOx. Significant emissions reductions are possible and achievable from this sector without a need for significant lead times. After the adoption of Maryland's Healthy Air Act, nine scrubbers and eight SCRs were installed on the affected EGUs in two years time.

The Clean Air Act Amendments of 2010 introduces a tough and meaningful national SO2 cap which we anticipate will result in installation of controls on many of the currently uncontrolled EGUs. SO2 emissions are a precursor to fine particles formation and reductions associated with this bill will have significant public health benefits. The bill also proposes an aggressive 90% reduction of mercury and builds upon the best practices of Delaware and other states.

The bill preserves State's rights under Sections 110 and 126 and it does not interfere with the New Source Review provisions of the Clean Air Act. The certainty that comes along with legislation will aid the states and industry with planning for design, permitting, fabrication and installation of controls. By focusing on outcomes, the bill is also likely to spur innovation because it will provide predictable targets for industry to meet and sufficient lead time for commercialization of many ideas.

The bill provides EPA the authority needed to implement the phase I of CAIR and we would encourage the consideration of additional EPA authorities for adjusting the annual sulfur dioxide emissions budgets and annual and/or seasonal NOx emission budgets as necessary to protect public health, meet current and new standards, and address transport emissions.

The bill also proposes a 53% nationwide reduction in NOx by 2015. On this point, please allow me to share with you briefly our experiences in Delaware. What we have learned through collaboration with the OTC is that controlling NOx emissions from EGUs may be the silver bullet for meeting the ozone standard. We have learned that significant NOx reductions are feasible, cost effective, and necessary for us to reach attainment and are readily achievable through existing, cost-effective technology. We believe that adopting a more aggressive approach and/or a more accelerated implementation timeline for NOx reductions would help states like Delaware achieve attainment of the ozone standard more rapidly than would be otherwise possible.

In conclusion, Delaware believes that the proposed legislation represents an important step forward in reducing harmful emissions from EGU's across our nation and improving public health outcomes. We look forward to working with the Committee as you continue to refine and strengthen this significant legislation. Thank you again for opportunity to speak today about this important issue and I am available to answer any questions.

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