

**TITLE I OF THE TOXIC SUBSTANCES CONTROL
ACT: UNDERSTANDING ITS HISTORY AND
REVIEWING ITS IMPACT**

HEARING
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT AND THE
ECONOMY
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED THIRTEENTH CONGRESS
FIRST SESSION

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TITLE I OF THE TOXIC SUBSTANCES CONTROL ACT: UNDERSTANDING ITS HISTORY AND REVIEWING ITS IMPACT

THURSDAY, JUNE 13, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY,
COMMITTEE ON ENERGY AND COMMERCE
Washington, DC.

The subcommittee met, pursuant to call, at 10:16 a.m., in room 2322 of the Rayburn House Office Building, Hon. John Shimkus (chairman of the subcommittee) presiding.

Members present: Representatives Shimkus, Pitts, Murphy, Harper, Cassidy, Bilirakis, Johnson, Tonko, Green, DeGette, Capps, McNerney, Barrow, and Waxman (ex officio).

Staff present: Charlotte Baker, Press Secretary; Jerry Couri, Senior Environmental Policy Advisor; Kirby Howard, Legislative Clerk; David McCarthy, Chief Counsel, Environment and the Economy; Tina Richards, Counsel, Environment; Chris Sarley, Policy Coordinator, Environment and the Economy; Jacqueline Cohen, Democratic Counsel; Greg Dotson, Democratic Staff Director, Energy and Environment; Elizabeth Letter, Democratic Assistant Press Secretary; Stephen Salsbury, Democratic Special Assistant; and Ryan Skukowski, Democratic Staff Assistant.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. This subcommittee will come to order. I will recognize myself for 5 minutes for my opening statement.

Today's hearing is on Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact. TSCA Title I addresses chemical substances and mixtures in commerce. Title I gives EPA extraordinary authority to regulate manufacturing and interstate commerce affecting chemical substances and mixtures, from their manufacture, processing and distribution in commerce, to their use and disposal.

TSCA is not your garden-variety environmental law. To help place the size and scope of it into context, the American Chemistry Council estimates based on the Numerical List of Manufactured Products prepared by the Census Bureau, more than 96 percent of all manufactured goods are touched by the business of chemistry and the activities potentially regulated by EPA under TSCA. Title I of TSCA has remained largely unchanged for 37 years. Mr. Dingell has been here longer than that, though most have not. Indeed,

many of the nuts and bolts of TSCA policy evolution have occurred outside the legislative context.

Legislation recently introduced in the other body has heightened interest in congressional action on TSCA. I, for one, think we should closely examine TSCA and be open to legislation to update and reform it. Any attempt to do so from our end should start with fundamental oversight of how TSCA is designed and operated. With many new members on this committee and subcommittee, today's hearing is the first installment towards that end.

Let us start by asking the following questions: What authorities does EPA have under TSCA? What is TSCA's practical legal reach? How many chemicals are currently in commerce? How wide is TSCA's regulatory reach concerning chemicals in the commercial universe? Which authorities is EPA using? Which authorities is EPA not using? How do TSCA authorities relate to one another and to other federal laws? What activities are currently being carried out under TSCA? What parts of TSCA do or do not work well? Are there legal gaps in TSCA? How does EPA currently set an agenda for reviewing chemicals? Does it need legal authority to do so? What is the history and extent of information protection under TSCA? What are the issues that come with it?

Thanks to our distinguished witnesses for joining us today to help us get a better handle on what the law is, how EPA has been implementing it, what it is like being regulated under it, and where witnesses think its successes and failures lie.

I urge members to make every effort at this hearing to learn the fundamentals of current law. That is the purpose of today's hearing, rather than to argue for or against any TSCA reform legislation.

I now yield 5 minutes to the ranking member of our subcommittee, Mr. Tonko from New York.

[The prepared statement of Mr. Shimkus follows:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS

Today's hearing is on Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact. TSCA Title I addresses chemical substances and mixtures in commerce.

Title I gives EPA extraordinary authority to regulate manufacturing and interstate commerce affecting chemical substances and mixtures, from their manufacture, processing, and distribution in commerce, to their use and disposal.

TSCA is not your garden variety environmental law. To help place the size and scope of it into context, the American Chemistry Council estimates based on the Numerical List of Manufactured Products prepared by the Census Bureau more than 96 percent of all manufactured goods are touched by the business of chemistry and the activities potentially regulated by EPA under TSCA.

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Legislation recently introduced in the other body has heightened interest in congressional action on TSCA. I, for one, think we should closely examine TSCA and be open to legislation to update and reform it. Any attempt to do so from our end should start with fundamental oversight of how TSCA is designed and operated. With many new members on this committee and subcommittee, today's hearing is the first installment towards that goal.

Let's start by asking the following questions:

- 1.) What authorities does EPA have under TSCA?
- 2.) What is TSCA's practical legal reach?
- 3.) How many chemicals are currently in commerce?

- 4.) How wide is TSCA's regulatory reach concerning chemicals in the commercial universe?
- 5.) Which authorities is EPA using?
- 6.) Which authorities is EPA not using?
- 7.) How do TSCA authorities relate to one another and to other federal laws?
- 8.) What activities are currently being carried out under TSCA?
- 9.) What parts of TSCA do or do not work well?
- 10.) Are there legal gaps in TSCA?
- 11.) How does EPA currently set an agenda for reviewing chemicals? Does it need legal authority to do so?
- 12.) What is the history and extent of information protection under TSCA? What are the issues that come with it?

Thanks to our distinguished witnesses for joining us today to help us get a better handle on what the law is, how EPA has been implementing it, what it's like being regulated under it, and where witnesses think its successes and failures lie.

I urge members to make every effort at this hearing to learn the fundamentals of current law. That's the purpose of today's hearing, rather than to argue for or against any TSCA reform legislation.

#

OPENING STATEMENT OF HON. PAUL TONKO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TONKO. Thank you, Chair Shimkus. Good morning, everyone, and thank you, Mr. Chair, for holding this hearing on the Toxic Substances Control Act, better known as TSCA. I understand the subcommittee will be holding additional hearings on this program. I look forward to hearing from additional witnesses on this very important topic.

We have all heard the stats related to chemical production and use. Some 80,000 chemicals are in use with hundreds of new chemicals coming into production every year. The advances in chemistry and biology and the adoption of new manufacturing processes over the past decade have shortened the time necessary for development and manufacture of new chemicals.

There are many benefits to this progress, and some challenges. The line between chemistry and biology has become much less definitive. We should give some consideration to how well current law is suited to evaluate new chemicals in light of these new developments. This law has been with us now for many years, enough years to provide us with ample experience of its application and its utility.

The law has not lived up to expectations. It has not provided a sufficient amount of information for the public about the potential hazards of chemicals that they encounter in their daily lives. There are many chemicals in commerce today that have very little information about their potential risks to human health or the environment. Some have none at all.

Successive Administrations have devised policies to reduce the backlog of chemical assessments. None of these efforts have been very successful. The law has also proven ineffective at removing harmful chemicals from the market. Congress had to take separate action to eliminate PCBs and asbestos when mounting evidence demonstrated the problems with these chemicals. It is not a good track record.

If we have safer alternatives to chemicals on the market, the Environmental Protection Agency should be able to act in a timely

fashion to remove harmful substances, making way for safer products to move into commerce. I am certain we will hear about all of these issues this morning from our expert team of witnesses.

I recognize there are several proposals introduced in the Senate to amend this law. This hearing and the additional one to come will provide us a solid base from which to evaluate these proposals against current law.

I look forward to the testimony of our witnesses again here today, and I thank you all for being here to share your views on what is a very important topic.

With that, I yield back. Thank you, Mr. Chair.

Mr. SHIMKUS. The gentleman yields back his time. Is there anyone else seeking recognition for an opening statement on the majority side? Is there anyone seeking recognition on the minority side? Seeing no one, we will then move to our panel. We would like to welcome you all here. All your statements have been submitted for the record. You will be given 5 minutes to give your oral statement. We are not going to be punitive in punishing but don't go too long because this is a large panel. Just for your information, there is another committee hearing going on on the first floor. Members will be coming up and down for that. You are competing with the Secretary of Energy. You can see where I am. Many members are down there trying to get their licks in on him. Let me start by recognizing and welcoming Kathleen Roberts, who is the Vice President of B&C Consortia Management LLC. You are recognized for 5 minutes.

STATEMENTS OF KATHLEEN ROBERTS, VICE PRESIDENT, B&C CONSORTIA MANAGEMENT, LLC; CHARLES M. AUER, PRINCIPAL, CHARLES M. AUER & ASSOCIATES, LLC; ALFREDO GOMEZ, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE; BETH BOSLEY, PRESIDENT, BORON SPECIALTIES, LLC; DANIEL ROSENBERG, SENIOR ATTORNEY, HEALTH AND ENVIRONMENT PROGRAM, NATURAL RESOURCES DEFENSE COUNCIL; AND JEANNE RIZZO, PRESIDENT AND CEO, BREAST CANCER FUND

STATEMENT OF KATHLEEN ROBERTS

Ms. ROBERTS. Thank you, Chairman Shimkus, Ranking Member Tonko, members of the subcommittee. I am here today to provide a brief overview of the regulatory program under the Toxic Substances Control Act, a TSCA 101, if you will.

I have spent more than 20 years with chemical companies to understand and comply with TSCA. I was with the American Chemistry Council for 17 years, and I have been with Bergeson and Campbell for 4 years, where I work as a non-attorney professional. As stated, I currently am Vice President of Bergeson and Campbell's affiliate B&C Consortia Management. My remarks today are on my own behalf and do not necessarily reflect the views of Bergeson and Campbell, B&C Consortia Management or any of their clients.

In my view, the regulatory process under TSCA is logical and almost element in its simplicity. New chemicals must be notified to

EPA. This is a small, very simple flow chart trying to show how they connect. New chemicals must be notified to EPA. For any chemical on the TSCA inventory, EPA can gather information through Section 8. If more information is needed, EPA can require testing under Section 4. If there are still concerns, EPA can apply necessary risk management controls through Sections 5 or 6.

When TSCA was first enacted, companies informed EPA which chemicals were produced or imported into the United States at that time. This resulted in the initial TSCA inventory and was issued in 1979. These chemicals are also often referred to as grandfathered chemicals. Any chemical that was developed and marketed after 1979 has gone through a New Chemical Assessment under Section 5. This involves the submission of a Premanufacture Notice that includes information on chemical identity, description of byproducts, anticipated production volumes, molecular formula, intended categories of use, and other available information. EPA's decision options for PMN-subject chemicals are: entry into commerce not allowed, entry into commerce allowed with no restrictions, entry into commerce allowed after submission of additional data, or entry into commerce allowed with certain regulatory or testing actions applied.

Assuming EPA has allowed the chemical to enter into commerce, the manufacturer typically submits a Notice of Commencement, and at that time the new chemical is added to the TSCA inventory and becomes an existing chemical. All existing chemicals, meaning all those listed on the TSCA inventory, are subject to regulations under 4, 5, 6 and 8. There are other sections of TSCA that also apply to existing chemicals but in the brevity of time I will not try to go through all of them.

Section 8, as I mentioned, is focused on information collection. Section 8(a) authorizes EPA to issue rules requiring companies to submit information on categories of use, quantities produced or imported, and/or health and environmental effects. As of 2006, EPA has issued 33 8(a) rules covering about 1,200 chemicals.

Also under Section 8(a) is the Chemical Data Reporting Rule. This is an existing cyclical reporting cycle under which manufacturers and importers are required to report production, process and use information for chemicals manufactured or imported over 25,000 pounds per year at a single site. The last reporting cycle was in 2012, and information on about 7,700 chemicals was submitted. Section 8(c) requires companies to record and retain allegations of significant reactions to any chemical substance. If EPA issues an 8(c) data call-in, companies are required to submit that information to EPA. Only two such data call-ins have been issued.

Section 8(d) authorizes EPA to issue rules requiring companies to submit lists or copies of ongoing and completed unpublished studies. As of 2006, EPA has issued 51 8(d) rules on about 1,200 chemicals resulting in about 50,000 studies being submitted to EPA on a broad range of end points.

Under TSCA 8(e), entities are required to immediately report information that reasonably supports the conclusion that a chemical substance presents a substantial risk. As of 2006, there were about 16,500 8(e) notices submitted. According to EPA statistics, about 200 notices are submitted per year. EPA can use the information

collected or submitted under these 8(c) provisions to identify whether a particular chemical is of concern or if more information is needed. If that is the case, EPA can use its Section 4 authority to issue test rules requiring companies to conduct tests on certain chemicals. EPA has required testing for about 200 chemicals under Section 4 or under its enforceable consent agreement options. Keep in mind, however, that as I have mentioned, EPA can require testing as part of that new chemical review, and that has occurred for about 300 chemicals.

Section 6 authorizes EPA to issue rules to manage risks for existing chemicals. Risk management options include restrictions on production levels, restrictions for certain uses, restrictions on releases to environments, warning labels and the like.

As noted earlier, under Section 5, EPA is authorized to issue restrictions on new chemicals. They also can be applied to existing chemicals pursuant to EPA's Significant New Use authority. While only six chemicals have been subjected to Section 6 requirements, EPA has applied restrictions to thousands of chemicals through Section 5.

I would like to briefly highlight three challenges or three areas that I think there may be some issues with. In my view, EPA has been particularly constrained when trying to use its TSCA authorities that require rulemakings. These challenges aren't necessarily unique to TSCA rulemakings as I think all rulemakings are fairly cumbersome and often take 3 to 5 years. Likewise, while I see great output from EPA's New Chemical Review process, there is less so in the existing chemical arena. In my view, that may be because the new chemical notification has a statutory review period of 90 days. There is nothing similar in the existing chemicals program.

And finally, I would like to touch on the issue of confidential business information as that is often raised as a red flag for TSCA. Keep in mind that TSCA compels chemical companies to provide a wealth of sensitive data. For example, companies have to provide detailed information on how chemicals are processed and manufactured. And while there are clearly legitimate needs for EPA to have this type of information to achieve its statutory goals, I believe there are also very legitimate needs for companies to have that information protected as confidential.

Thank you so much for this esteemed opportunity. I would be pleased to answer any questions.

[The prepared statement of Ms. Roberts follows:]

**Summary of Testimony of
Kathleen M. Roberts
Bergeson & Campbell, P.C./B&C® Consortia Management, L.L.C.**

Submitted on June 11, 2013
to
Subcommittee on Environment and the Economy
U.S. House of Representatives
Committee on Energy and Commerce

Regarding a June 13, 2013, Hearing on
“Title I of the Toxic Substances Control Act:
Understanding Its History and Reviewing Its Impact”

The TSCA regulatory process is logical and simple. New chemicals must be notified to EPA and can be allowed into commerce for commercial purposes following the end of a 90-day review period. For any chemical listed on the Inventory, EPA has the authority to gather existing, updated information through various provisions under TSCA Section 8. If that information is believed by EPA to be insufficient to make a risk assessment, EPA is authorized to require manufacturers and/or processors of chemicals to generate additional data under TSCA Section 4. After assessing the information gathered under Section 8 and/or Section 4, if EPA decides regulatory restrictions are needed to abate risks, EPA is authorized under Sections 5 and/or 6 to apply additional risk management controls.

The TSCA Inventory should not be viewed as a list of all chemicals in commerce. Once a chemical is listed, it remains on the list regardless of whether it falls into disuse. A more reasonable measure of TSCA-regulated chemicals in commerce might be the listing of chemicals reported under the Chemical Data Reporting rule under TSCA Section 8.

In the areas under TSCA where regulated entities are required to submit certain notifications or reports, EPA appears to be successful in compiling information needed to conduct risk assessments. EPA has been constrained when trying to use other TSCA authorities, particularly those that require rulemakings, because the current rulemaking process is long and complicated.

Likewise, the existing chemical reviews have not been as successful as the new chemical reviews. EPA could implement a prioritization process for existing chemical review. There is nothing in the legislative language prohibiting that action.

Confidential Business Information is incredibly important. TSCA compels industry to provide a wealth of sensitive data and while there are very legitimate needs for EPA to have this type of information to achieve its statutory goals, there are also very legitimate needs for business to have that information remain confidential.

**Testimony of
Kathleen M. Roberts
Bergeson & Campbell, P.C./B&C[®] Consortia Management, L.L.C.**

Submitted on June 11, 2013

To

Subcommittee on Environment and the Economy
U.S. House of Representatives
Committee on Energy and Commerce

Regarding a June 13, 2013, Hearing On
"Title I of the Toxic Substances Control Act:
Understanding Its History and Reviewing Its Impact"

Good morning. My name is Kathleen Roberts. I am here today to provide an overview of the regulatory program under the current Toxic Substances Control Act -- a TSCA 101, if you will. Rest assured, my remarks today will not be a comprehensive, in-depth analysis of TSCA, but instead will be a briefing that is intended to assist Committee members to recognize how the various sections of TSCA fit together to provide a comprehensive program for the management of risks from chemicals.

I have spent more than 20 years working with chemical companies to understand and comply with TSCA implementing regulations enforced by the U.S. Environmental Protection Agency (EPA). I was with the American Chemistry Council for 17 years and have been with Bergeson & Campbell, P.C., a Washington, D.C. law firm, for four years where I work as a non-attorney professional. I currently am Vice-President of Bergeson & Campbell, P.C.'s affiliate, B&C Consortia Management, L.L.C., an organization that provides management services to chemical consortia involved in advocacy, research, testing, and communications.

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My remarks today are on my own behalf, and do not necessarily reflect the views of my employer or any client of either organization.

General TSCA Overview

TSCA was enacted in 1976. TSCA provides EPA with broad authority to review new chemicals before they are manufactured, gather information on existing chemicals, and regulate chemicals as necessary. TSCA is not the only statute that regulates chemicals. TSCA's scope does not include chemicals used in pesticide active ingredients and products containing pesticides, tobacco, nuclear materials, and food, drugs, and cosmetics because those substances are regulated under other laws.

TSCA Framework

In my view, the TSCA regulatory process is logical and almost elegant in its simplicity. New chemicals must be notified to EPA and can be added to the TSCA Inventory and allowed into commerce for commercial purposes following the end of a 90-day review period. For any chemical listed on the Inventory, EPA has the authority to gather existing, updated information through various provisions under TSCA Section 8. If that information is believed by EPA to be insufficient to make a risk assessment, EPA is authorized to require manufacturers and/or processors of chemicals to generate additional data under TSCA Section 4. After assessing the information gathered under Section 8 and/or Section 4, if EPA decides regulatory restrictions are

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needed to abate risks, EPA is authorized under Sections 5 and/or 6 to apply additional risk management controls. I will briefly review these various sections in more detail.

TSCA Inventory

I would like to start with the TSCA Inventory. When TSCA was first enacted, companies informed EPA which chemicals were produced or imported into the United States at that time. The goal was to get an accurate baseline of chemicals in commerce. That list of chemicals resulted in the initial TSCA Inventory, which was issued around 1979. This initial list of chemicals is also sometimes referred to as “grandfathered” chemicals because EPA conducted no assessment of any chemical listed on the initial Inventory. Any chemical subject to TSCA that was developed and marketed AFTER 1979 has gone through a new chemical assessment under TSCA Section 5, which I will briefly cover in a moment.

A common misperception is that the TSCA Inventory is a list of all chemicals in commerce, but that is not accurate. The TSCA Inventory has been added to since 1979, and now contains approximately 83,000 chemicals. Once a chemical is listed, it remains on the list regardless of whether a chemical falls into disuse. Hotel California comes to mind -- you can check out, but you can never leave. It is my belief that a large number of listed chemicals are no longer in production, but they nonetheless remain listed on the Inventory.

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A more reasonable measure of TSCA-regulated chemicals in commerce might be the listing of chemicals reported under the Chemical Data Reporting (CDR) rule under TSCA Section 8. That listing includes all chemicals manufactured in the United States in quantities over 25,000 pounds at a site per year. Admittedly, that does not include chemicals manufactured at lower levels or chemicals that might be exempt from CDR reporting -- such as polymers -- but in my view, this listing is a more realistic number of chemicals currently being manufactured and distributed in commerce today. During the last CDR reporting cycle in 2012, there were about 7,700 chemicals reported.

New Chemical Review

Chemicals not already listed on the TSCA Inventory are subject to premanufacture review by EPA and must undergo a new chemical notification under TSCA Section 5 before they can be manufactured and used in commerce for commercial purposes. Under Section 5, an entity wishing to commercialize a chemical substance considered "new" must submit a premanufacture notice (PMN) to EPA. Information included on a PMN includes chemical identity, description of byproducts, anticipated production volumes, molecular formula, intended categories of use, and other available information. There is no requirement to test a new chemical prior to submitting a PMN, but if the submitter has any test data, it must submit those data to EPA along with the PMN.

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When EPA reviews a PMN, it conducts an initial review and develops a hazard profile. A question that is often raised is how does EPA develop a hazard profile if no hazard data were submitted with the PMN? Over the years, EPA has developed numerous approaches and methods for hazard review. It often relies on the fact that chemicals of similar molecular structures often have similar hazard profiles. This is known as structure activity relationship (SAR). So, while EPA may not have data on the chemical that is the subject of the PMN, it may have data on an analog chemical -- one that has structural similarities -- and EPA can and does rely on those data in its initial evaluation. I should note EPA does such modeling with some fairly conservative assumptions. So a lack of data on a specific chemical does not mean that the EPA review is more lenient than if data were available. In fact, it is more likely the opposite. The hazard profile includes not only health effects, but also environmental effects and environmental fate.

EPA then develops profiles looking at anticipated releases into the environment; and occupational, consumer, and general population exposures. In addition to the information provided in the PMN, EPA uses the outputs from numerous computer modeling programs to assist in the development of these exposure and release profiles.

EPA's decision options for entry into commerce by the subject chemical are (1) entry into commerce not allowed, (2) entry into commerce with no restrictions, (3) entry into commerce allowed after submission of additional data by the submitter, or (4) entry into commerce allowed with certain regulatory and/or testing actions applied. These regulatory actions involve either (1)

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a consent order under Section 5(e) that imposes certain restrictions on the manufacturer of the subject chemical or (2) a significant new use rule (SNUR) under Section 5(a)(2) that imposes certain restrictions on the manufacturer of the subject chemical and all future manufacturers. Many consent orders under Section 5(e) eventually become regulations under Section 5(a)(2).

Assuming EPA has allowed the chemical to enter into commerce, the manufacturer typically submits a notice of commencement (NOC) of manufacture to EPA, and at that time, the “new” chemical is added to the TSCA Inventory and becomes an existing chemical. In some cases, even though entry into commerce can occur, the manufacturer never submits the NOC. In that case, the chemical is not added to the Inventory and thus is not considered an existing chemical despite the fact EPA has reviewed the chemical.

The new chemical notification program under TSCA Section 5 is generally viewed as science-based and reasonable. EPA can and does use its authorities as part of the new chemical notification program to compel additional data and implement certain restrictions. The computer modeling developed by EPA for the new chemical review process is, in my opinion, top-notch. EPA has made that software publicly available, as well as issued guidance on chemical categories of concern. Industry’s awareness and understanding of what chemicals are of concern to EPA and why enables entities to focus their research and development work accordingly, and to avoid chemicals that are perceived to cause problems and to develop chemicals that will pass EPA’s review process.

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Existing Chemicals

All existing chemicals -- those listed on the TSCA Inventory -- are subject to regulations under Sections 4, 5, 6, and 8. There are other sections of TSCA that also apply to existing chemicals, but I do not plan to cover those in my remarks today.

Section 8 -- as I already mentioned -- is focused on information collection.

Section 8(a) authorizes EPA to issue rules requiring companies to submit information on categories of use, quantities, byproducts, and/or health and environmental effects. This information collection occurs only when EPA promulgates a rulemaking. As of 2006, EPA issued 33 8(a) rules covering about 1,200 chemicals.¹

There is also another information gathering exercise under TSCA Section 8(a) -- the Chemical Data Reporting rule. The CDR is an existing, cyclical reporting requirement under which manufacturers are required to report production, process, and use information for chemicals manufactured or imported over 25,000 pounds per year at a site. The last reporting cycle was in 2012, and information on about 7,700 chemicals was submitted. The cyclical reporting occurs every four years, so the next reporting cycle is in 2016.

¹ EPA, Office of Pollution Prevention and Toxics, "Overview: OPPT Laws and Programs" (Mar. 2008) at 16, available at <http://epa.gov/oppt/pubs/oppt101-032008.pdf>.

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Under TSCA Section 8(c), EPA is authorized to require companies to record and retain allegations of significant adverse reactions to any chemical substance. If EPA issues a TSCA Section 8(c) data call-in, companies must submit this information to EPA. EPA has only issued two such call-ins under Section 8(c).²

Under TSCA Section 8(d), EPA is authorized to issue rules requiring companies to submit lists/copies of ongoing and completed unpublished health and safety studies. As of 2006, EPA has issued 51 8(d) rules on about 1,200 chemicals. In response, EPA received 50,000 studies covering a broad range of health and ecological endpoints, as well as information on chemical/physical properties, environmental fate, and exposure.³

Under TSCA Section 8(e), entities are required immediately to report information that reasonably supports the conclusion that a chemical substance or mixture presents a “substantial risk.” As of 2006, there were about 16,500 Section 8(e) notices submitted and about 7,500 follow-up submissions. According to EPA statistics, around 200 8(e) notices are submitted per year.⁴

² *Id.*

³ *Id.*

⁴ *Id.* at 17

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EPA can use the information collected or submitted under these Section 8 provisions, particularly 8(e) submissions, to identify whether a particular chemical is of concern, or if more information is needed. If that is the case, EPA can require testing under Section 4.

TSCA **Section 4** authorizes EPA to issue test rules requiring companies to conduct certain tests on specified chemical substances. To issue a TSCA Section 4 test rule, EPA must make one of two findings:

- EPA must determine that existing data show that the subject chemical “may present an unreasonable risk of injury to health or the environment” and that the probability of exposure to the subject chemical substance is more than just theoretical; and/or

- EPA must show that the chemical is produced or imported in substantial quantities, and either enters the environment in substantial quantities or there is substantial or significant human exposure.

Information to support either of these findings should be available through the Section 8 reporting requirements.

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In addition to these findings, EPA must also find that existing data are inadequate for risk assessment, and that testing is needed to develop the data necessary to conduct the needed risk assessment. In other words, EPA cannot require testing simply for testing's sake.

Since EPA began reviewing chemicals in 1979, EPA has required testing for about 200 existing chemicals under Section 4 test rules or under enforceable consent agreements. Keep in mind, however, that EPA can require testing under Section 5 during its new chemical notification review. More than 300 chemicals have been tested as part of that process. The type and amount of testing required by EPA varies, depending on what EPA needs to evaluate the chemical.

Sections 5 and 6

Should EPA determine that a subject chemical presents an unreasonable risk, TSCA Section 6 authorizes EPA to issue rules to manage those risks for existing chemicals. The risk management options include production level restrictions, warning labels, and restrictions for certain uses and/or releases into the environment. As noted earlier, under TSCA Section 5, EPA is authorized to issue restrictions on new chemicals before they are introduced into commerce. Section 5 restrictions can also apply to existing chemicals pursuant to EPA's Significant New Use Rule authority. Under this authority, EPA is authorized to require advance notification on uses deemed "significant and new" for existing chemicals. While only six chemicals have been subject to Section 6 restrictions, EPA has applied restrictions to thousands of chemicals through the Section 5 new chemical notification rule. Those restrictions remain in place after the

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chemical is added to the Inventory. In addition, EPA can also use its authorities under Section 5 to apply new use restrictions for existing chemicals.

That only six chemicals have been subject to regulation under Section 6 seems odd. And in referring to Section 6, I am not referring to TSCA Section 6(e), which addresses PCBs. EPA has developed a mature and very successful program under TSCA Section 6(e), which really stands alone as it addresses a very specific problem.

For EPA to be authorized under TSCA Section 6, EPA must find that there is a reasonable basis to conclude that a chemical substance “presents or will present an unreasonable risk of injury to health or the environment,” where “unreasonable risk” is a risk-benefit standard. EPA must consider risks, costs, and benefits of a substance to be regulated, including the availability of substitutes. TSCA requires that EPA select the “least burdensome” regulatory measure that provides adequate protections. Therefore, in promulgating regulations under TSCA Section 6, EPA must consider:

- The effects of the chemical substance on health and the magnitude of human exposure;

- The effects of the chemical substance on the environment and the magnitude of environmental exposure;

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- The benefits of the chemical substance and the availability of substitutes;
and

- The economic consequences of the rule.

Attachment 1 is a depiction of the framework that I just reviewed. I want to clarify that the framework does not necessarily require an action under Section 8 before EPA can use its authorities under Section 4, Section 5, or Section 6, shown on the flowchart with the dotted lines. Nonetheless, I think the drafters of the original TSCA legislation were brilliant in the logical flow provided in the legislation to ensure EPA can access information needed for risk review.

Attachment 2 -- perhaps no longer simple or elegant -- is much more detailed of the specifics that I just reviewed. I hope the attachments may be helpful as a reference in the future.

Challenges

In the areas under TSCA where regulated entities are required to submit certain notifications or reports -- including Section 5 new chemical notification, Section 8 Chemical Data Reporting, and Section 8(e) significant risk notification -- EPA appears to be successful in compiling information needed to conduct risk assessments. In my view, EPA has been particularly constrained when trying to use other TSCA authorities, particularly those that require rulemakings, because the current rulemaking process is long and complicated. These challenges

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are not unique to TSCA rulemakings as all rulemakings are cumbersome, and often take three to five years to complete. This is not a deficiency in TSCA, *per se*.

Likewise, while I see great output from EPA in its new chemical review process, there is less so in the existing chemical arena. In my view, that is because the new chemical review includes a statutory deadline -- a 90-day review period for a new chemical notification -- so there is a well understood EPA process and prioritization of work to be conducted. EPA could implement a prioritization process with specified timelines for existing chemical review. There is nothing in the legislative language prohibiting that action. In fact, EPA has begun a small prioritization process -- involving 83 chemicals -- where EPA is conducting focused risk assessments for these 83 chemicals under its TSCA Work Plan Chemicals program.

Finally, the issue of Confidential Business Information (CBI) is often raised as a red flag for TSCA. In my view, CBI is incredibly important. I believe that the members of Congress that drafted the original TSCA language were very cognizant of what type of information would be required under this law, and that is why they built in the strong protections for CBI under Section 14. Keep in mind that TSCA compels industry to provide a wealth of sensitive data, such as:

- Chemical identity for a new substance that may not yet have received patent protection;

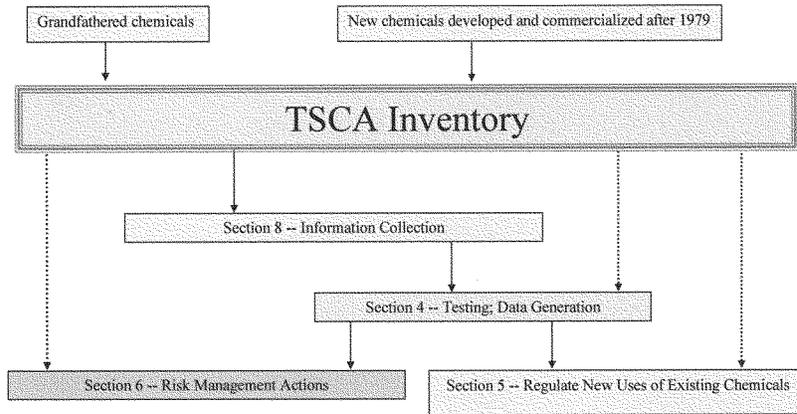
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- Detailed information on how new chemicals will be manufactured and processed;
- Volume produced, which would signal to competitors the potential market size for the chemical;
- Molecular weight range for a new commercially valuable polymer; and
- Impurities, which can signal key information on process or precursor substances.

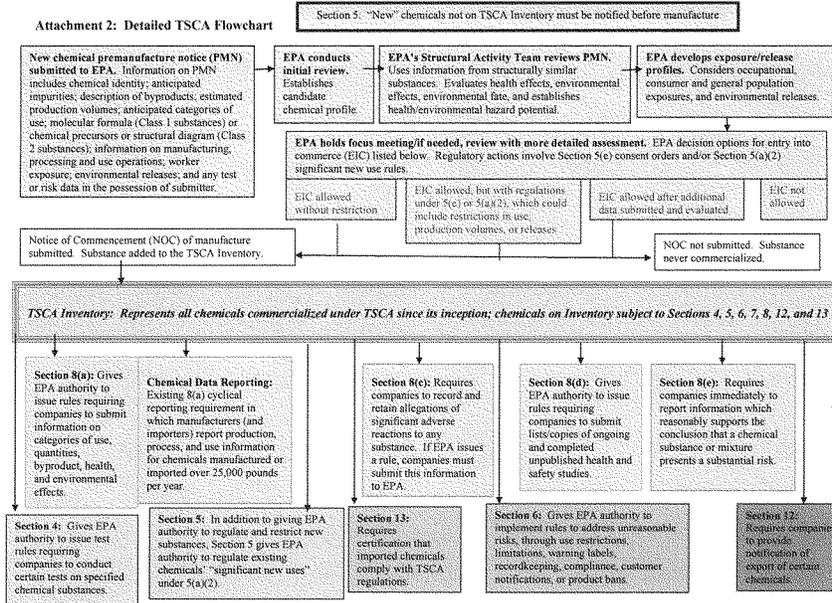
And while there are very legitimate needs for EPA to have this type of information to achieve its statutory goals, there are also very legitimate needs for business to have that information remain confidential.

Thank you very much for this esteemed opportunity. I would be pleased to answer any questions at this time.

Attachment 1: Simple TSCA Flowchart



Attachment 2: Detailed TSCA Flowchart



Mr. SHIMKUS. Thank you very much.

If the panel will hold for a minute, we welcome the ranking member of the full committee, Mr. Waxman. Without objection, I would like to allow him to give his opening statement. Then we will return to the panel. It is always good to take care of the ranking member of the full committee. So with that, I recognize Mr. Waxman for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I thank the panel for allowing me to give my opening statement, even though you have already started your presentations to us.

I want to commend the chairman for holding this hearing, which begins our committee's work on the Toxic Substances Control Act. TSCA is an important law because of its role in protecting the American public from dangerous chemicals, and it is long overdue for strengthening.

In recent years, EPA has undertaken a serious effort to reform TSCA through the exercise of its regulatory authorities. The Agency has formulated action plans for ten chemicals and classes of chemicals, which are some of the most dangerous chemicals on the market, and Agency deserves credit for those efforts.

But EPA's authority is limited and progress has been slow, even for the chemicals that are the worst of the worst. Four years ago, there was widespread agreement among industry, labor and non-governmental organizations that TSCA needs to be reformed. The EPA Administrator said that TSCA had proven to be "an inadequate tool for providing the protection against chemical risks that the public rightfully expects."

The American Chemistry Council said it wanted to work with "stakeholders, Congress, and the Administration to make reform a reality." And a coalition of public interest groups said that "By updating TSCA, Congress can create the foundation for a sound and comprehensive chemicals policy that protects public health and the environment, while restoring the luster of safety to U.S. goods in the world market."

The Committee put considerable effort into building on this consensus and modernizing TSCA. In 2009 and 2010, we held numerous hearings and convened a robust stakeholder process. We examined what testing should be required for all chemicals, how information should be protected, and what safety standard chemicals should be required to meet. While we made considerable progress, we did not complete the job. And that is why this hearing and the future ones to come are so important.

We need to hear from all stakeholders and work together, if we can, to modernize this important environmental law. Even with recent progress towards bipartisan cooperation, we have significant work ahead of us to achieve that goal, but it is certainly a worthy goal for this Congress.

I thank all of the witnesses for being here today. I look forward to hearing your testimony. I want to apologize that I am not going to be here the whole time because I have no control over the sched-

ule, and we have another subcommittee meeting at the same time with the Secretary of Energy and I am trying to be back and forth. If I am not here to hear your testimony, I will probably be here to ask you questions about your testimony because our staff has had a chance to review it in advance.

Thank you, Mr. Chairman, for allowing me to make this statement, and I yield back.

Mr. SHIMKUS. The gentleman yields back his time.

The chair now recognizes Mr. Charles Auer, Principal, Charles Auer & Associates LLC, so you are recognized for 5 minutes.

STATEMENT OF CHARLES M. AUER

Mr. AUER. Thank you, Mr. Chairman. I thank you for this opportunity to provide an oral summation of my written testimony to this TSCA hearing—I do have a copy of the law. It is very old, an original copy—before the Subcommittee on the Environment and the Economy. I am pleased to be part of this esteemed panel. I also appreciate and note the chairman’s statement of openness to reform. Thank you for that. Very important.

As outlined in my testimony, I was a long-time EPA employee who worked on TSCA issues for over 30 years. I am a chemist by training, and at my retirement held the position of director of the EPA office responsible for TSCA implementation. I left EPA in early 2009 and now work as a consultant for a variety of clients including companies, trade associations and others. I note that my testimony is mine alone and that I am not speaking for or on behalf of anyone else.

The first section of my testimony provides an overview of TSCA’s authorities, which Kathleen has nicely covered. The second section reviews available statistics relating to various TSCA provisions and attempts to describe the footprint of regulatory and voluntary actions taken by EPA. The section explores several sections including how many new chemicals have been submitted to and been regulated by EPA. Available statistics indicate that about 48,000 new chemicals have been notified to EPA including as Premanufacture Notifications and as regulatory exemptions under Section (5)(h)(4).

As I thought about my testimony, I came to several realizations, and one of these is that over 15,000 new chemicals have received some kind of regulatory action under TSCA. I am sure this is news to most people in the room. This includes action under Section 5(e) as a consent order, a Significant New Use Rule, a section 5(h)(4) regulatory exemption or a voluntary withdrawal action. I have included the Section 5(h)(4) exemption chemicals in this list because the exemptions process requires a grant or deny determination by EPA and the chemicals are legally subject to the terms of the exemption. One aspect that can be confusing is that the use of the term “exemption” refers to a chemical being exempted from the normal new chemicals process and instead such new chemicals are subject to the exemption process. Note also that companies choose to go the exemption route because it combines timeliness and certainty. EPA will decide within 30 days, for example. And EPA likes them because it produces an acceptable outcome without a protracted negotiation. Voluntary withdrawals by the company are in-

cluded because this is often done in the face of possible EPA regulation.

This set of 15,000 new chemicals regulated represents over 30 percent of all new chemicals submitted to EPA under TSCA, and as I noted, this is an interesting statistic that I even though I had been in the program for lo these many years had not previously appreciated.

How many existing chemicals have been tested or were the focus of risk management efforts? The story is not so good here. About 200 chemicals were tested under Section 4, and a small number, a very small number of chemicals were regulated under TSCA in section 6 including PCBs. However, it is useful to note, EPA has also used Section 5(a)(2), Significant New Use Rule authority, in regulating over 300 existing chemicals including PBTs, carcinogens and other toxic or risky chemicals, and among those are some very well known bad actors. See my testimony for details.

The third section discusses relevant TSCA sections with an eye to exploring which aspects have worked or not worked. Areas that I suggest have worked include the initial creation and maintenance of the inventory, the new chemicals program and the citizens petition process. The existing chemical programs on testing and management are identified and discussed as areas that did not work very well, although as alluded to in my testimony, some very good outcomes have been obtained under both Democratic and Republican Administrations. With that, let me step back for a moment.

This is not a partisan issue although important principles are at play. The issue is, however, complex, and that complexity needs to be both recognized and be respected. Getting it right is critical and essential to protecting health and the environment while assuring the future competitiveness of the United States. To achieve these goals, the final product of any TSCA reform effort, in my view, must be workable and effective for both EPA and the regulated industry. Back on testimony.

With regard to legal gaps, I note that while Sections 4 and 6 may not rise to legal gaps in authority, although I suspect others might differ, there is a need to strengthen and improve these authorities. Concerning actual legal gaps, I point to the need for implementing legislation if the United States is to join treaties such as Rotterdam and Stockholm. I also suggest TSCA revision to allow appropriate sharing with and receiving of confidential business information from State and possibly foreign governments that satisfy legal requirements. I note that both Canadian and EU law allow for such sharing with other national governments.

The fourth and last section reviews the history of EPA's effort to set an agenda for reviewing existing chemicals, and I attempt to answer the question: why haven't these earlier attempts worked? I observed that a key issue is the way that TSCA provides broad authority but vague priority to guide EPA's work.

Mr. SHIMKUS. Sir, we need you to move a little bit quicker.

Mr. AUER. Further, I opine that EPA could do a better, more effective job if it had appropriate policy guidance outlining what among the various possibilities EPA should be doing. I briefly elaborate on a series of underlying points. I also recount that despite several attempts by EPA to create an agenda over the dec-

ades, it has proven difficult for EPA to figure the issue out on its own. In fact, it sometimes appears that EPA is always initiating a new approach. See GAO's testimony. And I take note of Mr. Tonko's useful comment in this regard, which helps to make the case for one of the central arguments in my testimony.

I respectfully note that Congress has not shown much interest in TSCA over the statute's history. This is part of the problem.

Mr. SHIMKUS. You are going to have to sum up.

Mr. AUER. All right. I will do my best. I mean, I think this is important.

Mr. SHIMKUS. Well, why don't we just—we will go to questions, and once you get asked questions.

Mr. AUER. Let me—

Mr. SHIMKUS. You are 3 minutes, almost 4 minutes over time.

Mr. AUER. I thought that was how much time I had left.

Mr. SHIMKUS. No. We have been overly compassionate here.

[The prepared statement of Mr. Auer follows:]

Testimony of
Charles M. Auer
President, Charles Auer & Associates, LLC
17116 Campbell Farm Road
Poolesville, MD 20837

Submitted on June 11, 2013
To
Subcommittee on Environment and the Economy
U.S. House of Representatives
Committee on Energy and Commerce

Regarding a Hearing On

“Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact”

Introduction

My name is Charles M. Auer. I was formerly an employee of the U.S. Environmental Protection Agency (EPA) until my retirement in January 2009. While at EPA I gained experience in hazard and risk assessment, policy development and implementation, rule-writing, and related aspects of the Administrative Procedure Act, and also participated as a U.S. negotiator in the development of and final agreements on the Stockholm and Rotterdam Conventions. I started at EPA as a staff chemist and spent my entire EPA career in the Office of Pollution Prevention and Toxics (OPPT) and its predecessors where, starting as a GS-5, I rose through the ranks in a variety of technical, policy, management, and executive positions. In 2002, I was selected as the Director of OPPT and held that position until my retirement. Over my career, I developed an in-depth knowledge and an integrated understanding of scientific, technical, policy, and legal issues encountered in implementation of the Toxic Substances Control Act (TSCA). Following my retirement, I formed a small consulting company to provide advice and analysis on, among other matters, chemical assessment and management. I also affiliated with Bergeson & Campbell, P.C., a Washington, DC, law firm specializing in TSCA and related areas. Since forming the consulting company, I have worked with a variety of clients, including chemical companies,

trade associations, law firms, and international intergovernmental organizations. While I have had industry clients, I have not done any representational work before EPA or other agencies.

I am pleased to have the opportunity to provide testimony at this hearing. *The testimony I am offering is mine and I am not speaking for or on behalf of anyone else in offering it.* Finally, my testimony includes several points that (and which I try to acknowledge) represent “my views;” I have no doubt that others will disagree to a smaller or larger extent with those views and I welcome that, in the hopes that such debate can lead to both understanding and improvements.

I. Overview of TSCA Authorities and EPA Rulemakings

After working with and trying to apply TSCA for over 30 years, I believe the law to be well and clearly drafted. It is a compact and almost elegant statute. TSCA Title I has never been revised, although additional Titles were added, since it was enacted in 1976 and, as discussed in this part of my testimony and beyond, there are issues that have arisen over the decades regarding certain of the provisions.

TSCA gave EPA authority in TSCA §8(b) to create an **Inventory** of existing chemicals in commerce (TSCA’s definition of “chemical substance” does not include chemicals used as pesticides, drugs, etc. as such chemicals/uses are subject to other laws) and EPA completed this task by rule in the late 1970s (all Section (“§”) references in this testimony go to Sections of TSCA unless otherwise noted and are intended to also reference the associated implementing regulations, where such exist). The so-called initial Inventory contained approximately 62,000 chemical substances, including “Class 1” and “Class 2” substances, and polymers. Class 1 substances have a discrete structure while Class 2 substances are complex mixtures of various types. The nonpolymer chemicals can be further subdivided into organic chemicals and inorganic chemicals, some of which are Class 2 “UVCBs” (chemicals of “unknown or variable composition, complex reaction products and biological” materials) or “statutory mixtures.”

The Inventory having been created served to distinguish “existing chemicals” in commerce from “**new chemicals**” not on the Inventory that require advance notification under §5(a)(1) to EPA prior to their manufacture for commercial purposes (“manufacture” as defined under TSCA includes “import”). The so-called Premanufacture Notification (PMN) must also meet the reporting requirements under §5(d)(1). EPA reviews the PMN and evaluates the new chemical as a “gatekeeper” to assess potential risk or production/exposure concerns and based on this review can impose conditions to restrict or ban manufacture, uses, releases, etc., and/or to require testing. Formal regulatory action is generally implemented via a Consent Order under §5(e) and requires certain determinations by EPA that available information is insufficient to permit a reasoned evaluation of the chemical and that it “may present an unreasonable risk” or that it has substantial production and substantial/significant exposure/release. EPA has also relied on “voluntary” testing, including an informal “ban pending testing” arrangement to obtain testing that is relatively inexpensive to conduct (e.g., acute aquatic toxicity testing).

EPA can also impose Significant New Use Rule (SNUR) requirements (§5(a)(2)) on new chemicals that require advance notification to EPA prior to initiating the “significant new use.” SNURs require consideration by EPA of a series of “factors” in taking the rulemaking and can be used to, in effect, extend the §5(e) consent order requirements to other companies beyond the notifier and/or more generally to require Significant New Use Notification (SNUN) for uses beyond those identified in the PMN.

Following the end of the 90-day review period (and which can be extended per §5(c)), PMN chemicals can be manufactured (subject to any conditions imposed by EPA); if manufacture occurs the PMN notifier is required to submit a Notice of Commencement (NOC) of manufacture to EPA after which the former new chemical is added to the Inventory. It is interesting to note that, historically, only ~50% of PMN chemicals actually commenced manufacture.

Finally, TSCA §5(h) includes several statutory exemptions (e.g., §5(h)(1) concerning “test marketing”) and rulemaking authority for regulatory exemptions under §5(h)(4). Currently available

regulatory exemptions include ones for chemicals that meet “low volume” or “low release/low exposure” requirements, and for certain polymers. Under this section, EPA can “regulatorily exempt” companies from some or all of the PMN requirements upon an EPA determination that the manufacture, processing, etc. of the subject chemical “will not present an unreasonable risk.” EPA has established eligibility criteria for the regulatory exemptions and, if granted by EPA, manufacture and use of the chemical is subject to the terms of the exemption and the chemical is not added to the TSCA Inventory.

Additional, more detailed discussion of the new chemicals program can be found below and in the Annex; also, several of the “Additional References” cited below discuss aspects of or the TSCA new chemicals program, in general.

Certain §5 authorities have not been used to any significant extent in my view by EPA or others (as appropriate), including: §5(b) Submission of Test Data; §5(f) Protection Against Unreasonable Risks; and §5(g) Statement of Reasons for Not Taking Actions. I do note that EPA has a pending matter before the Office of Management and Budget concerning a §5(b)(4) rulemaking and that there were a handful of actions that used §5(f) in the 1980s. I do not recall specific cases but §5(g) statements may have been published by EPA relating to SNUNs submitted under §5(a)(1) but for which no regulatory actions were taken, although in general few SNUNs were received during my time at EPA.

Existing chemicals on the other hand were essentially grandfathered under TSCA without any requirement for EPA review. TSCA §8(e) did mandate immediate reporting of “substantial risk” information to EPA by manufacturers, processors, and distributors and EPA in addition received broad TSCA authority to require by rule, inter alia, reporting of existing exposure and hazard information (§8(a) and §8(d)), to require testing (§4), and to regulate unreasonable risks (§6).

EPA has promulgated several types of §8 reporting rules, including:

- §8(a) rules, including the Preliminary Assessment Information Reporting (PAIR) rule, and §8(d) rules have been used to meet information needs identified by the Interagency Testing Committee (ITC) per §4(e) and by EPA more generally
- The Inventory Update Reporting (IUR)/Chemical Data Reporting (CDR) rules (§8(a)) have been in place since 1986 and have required regular periodic reporting (at intervals of four to five years) on production volume and, more recently, processing and use information. IUR reporting occurred in 1986, 1990, 1994, 1998, 2002, and 2006, and CDR reporting occurred in 2012, with the next report due in 2016. Basic production volume information has been required on chemicals meeting a production trigger (e.g., 10,000 or 25,000 pounds/year at a site) and the scope of subject chemicals included organic chemicals and, more recently, inorganic chemicals, but not polymers. Estimates of the numbers of workers reasonably likely to be exposed to such chemicals and maximum concentration information are also reported. Reporting of processing and use information is generally required only on higher volume chemicals meeting a trigger (e.g., production of > 300,000 lbs/yr at a site, and more recently >100,000 lbs/yr at a site, and dropping to 25,000 lbs/yr at a site in the 2016 reporting cycle). The 2016 cycle will also include reporting of the production volumes during the intervening years and other changes.

§8(a) includes a reporting exemption for small businesses which generally limits EPA's ability to require reporting from such entities. Notably the exemption did not apply in the development of the initial Inventory under §8(b), thus ensuring that reporting by small businesses contributed to that compilation.

Testing can be required by rulemaking (§4(a) if certain findings are made by EPA including:

- The chemical "may present an unreasonable risk" or is produced in substantial quantities and has substantial or significant exposure/release. Concerning the latter finding, EPA developed an

“exposure-based policy” via notice and comment, which in 1993 defined substantial production (as ≥ 1 million pounds/year) and several exposure and release terms (58 Fed. Reg. 28736);

- Insufficient data are available to determine the effects on health and the environment; **and**
- Testing is necessary.

EPA also developed an “enforceable consent agreement” (ECA) process for obtaining testing via a public negotiation process as an alternative to rulemaking.

TSCA §6(a) gives EPA authority to regulate existing chemicals if EPA finds that the manufacture, processing use, etc. of a chemical “presents or will present an unreasonable risk of injury to health or the environment.” EPA in regulating such a chemical “shall by rule apply” any “one or more” of a number of regulatory measures at Subsections 6(a)(1) – 6(a)(7) “to the extent necessary to protect adequately against such risk using the least burdensome requirements.” In taking the action, EPA is required by §6(c) to consider and publish a statement concerning a number of factors relating to “unreasonable risk,” including the effects of the chemical and magnitude of exposure, the benefits and the availability of substitutes, and the reasonably ascertainable economic consequences of the rule. This section also imposes a number of specific procedural requirements on the rulemaking, including the possibility of an “informal hearing.”

EPA can also use §5(a)(2) SNUR authority to require (by rule and considering a series of “factors”) advance notification (i.e., a SNUN) concerning significant new uses of existing chemicals. Following review of a SNUN on an existing chemical, EPA can regulate the significant new use and/or require testing using authority under §5(e).

Authorities under §§4, 6, and 8 that have not, in my view, been used to any significant extent by EPA or others (as appropriate) include: §4(f) Required Actions (while there were several “4fs” in TSCA’s early decades, the provision has not been used in some years); §4(g) Petitions for Standards for the Development of Test Data; of the TSCA §6 provisions only §6(e) on regulation of PCBs (polychlorinated biphenyls) has seen any significant use; EPA promulgated an §8(c) rule concerning records of “significant

adverse reactions” but last did a data call-in many years ago (although EPA more recently has expressed interest in using this section).

TSCA also includes **other provisions** relating to “imminent hazards” (§7), TSCA’s relationship to other Federal laws (§9), exports (§12), imports (§13), confidential business information (§14), preemption (§18), citizens petitions (§21), etc. Concerning these sections, the following in my view have not been used to any significant extent by EPA or others (as appropriate): §7 Imminent Hazards; §9 Relationship to Other Federal Laws (other than “informal §9 referrals” and efforts to coordinate with other Agencies (§9(d)); and §18 Preemption (the limited number of TSCA §6 actions is likely a factor in few, if any, §18(b) exemption requests being received by EPA).

II. A Sampling of TSCA Statistics and My Impressions of TSCA’s Footprint of Regulatory and Voluntary Actions

TSCA was enacted in 1976 and came into force in 1977. Since that time, EPA has taken a number of regulatory and voluntary actions to test, assess, and manage the risks presented by commercial chemicals. While it is clear to me that much more needs to be done to safeguard health and the environment than has been possible under TSCA, based on a fuller accounting of the actions taken and as discussed briefly below, I believe the chemical regulatory, management, and oversight actions taken by EPA have been more extensive and significant than has been generally recognized. **Note:** unless otherwise noted the statistics that follow were taken from a 2008 report by EPA’s Office of Pollution Prevention and Toxics entitled “Overview: OPPT Laws and Programs” (<http://epa.gov/oppt/pubs/oppt101-032008.pdf>). The information and tables in the report range from approximately 2003 through 2006, and as such, may be considerably out of date.

How many TSCA chemicals are likely currently in production?

A straightforward answer to this question is not readily available; however, it may be possible to piece together an estimate, as follows. The initial TSCA Inventory contained about 62,000 chemicals and

through 2006, approximately 21,000 new chemicals were added by EPA following receipt of an NOC, yielding over 83,000 chemicals listed on the Inventory. In addition, as of 2006, EPA had received requests for TSCA §5(h)(4) regulatory exemption requests for over 11,000 new chemicals and polymers (recall that these are not listed on the Inventory) which, when combined with the Inventory count, totals over 94,000 chemicals. Based on the most recent (2012) CDR reporting, there were almost 7,800 nonpolymeric Inventory chemicals produced at or above 25,000 lbs/yr at a site; such information is not available on lower volume chemicals or on polymers. Nonpolymeric chemicals accounted for about 65% (53,400) of the 83,000 Inventory chemicals, while polymers represented about 35% (29,500); thus based on the 2012 CDR reporting about 15% of the nonpolymeric chemicals are in production at or above 25,000 lbs/yr at a site while 85% (or 45,390) are either produced below this level or are out of commerce entirely. It is not known how many of the ~30,000 Inventory polymers or the over 11,000 §5(h)(4) regulatory exemption substances are currently in production. If, however, one assumes that 50% of the non-CDR reported chemicals are *actually* in commerce at some level, this would yield, with the addition of the 2012 CDR chemical count (~7,800), approximately 51,000 chemicals in commerce. My suspicion is that this is an overestimate and that the actual number in commerce is lower, but as noted, there is no way of checking its accuracy at present.

How many new chemicals have been submitted to EPA and how many have been regulated by EPA? How much voluntary testing (e.g., "ban pending testing") has occurred?

The 2008 EPA report indicated that 36,600 PMNs were submitted to EPA as of 2003, and as of 2006 over 2,600 new chemicals were regulated using §5(e) consent orders and/or §5(a)(2) SNURs. An additional 1,700 new chemicals were withdrawn voluntarily by the submitter (this often occurs in the face of EPA regulation) and EPA obtained voluntary testing on over 300 new chemicals. In addition, all of the over 11,000 §5(h)(4) exemption chemicals are regulated and subject to the terms of the exemption (most such exemptions are granted, often with EPA conditions added; I do not have statistics on the ratio of

“grants” to “denials”). Thus, EPA has taken action (including withdrawals) on over 15,000 (or over 30% of) new chemicals based on these relatively dated statistics.

How many chemicals have been subjected to testing using §4 authority? How much voluntary testing of existing chemicals has occurred? Is it true that to require testing, EPA already has to have information showing the chemical is toxic or risky?

EPA reports (2008) that §4 testing has been required on 200 chemicals (note that this figure does not include testing required on new chemicals via §5(e) regulatory authority).

Starting in the late 1990s, EPA implemented the voluntary High Production Volume (HPV) Challenge Program to obtain screening level data on the approximately 3,000 nonpolymeric organic chemicals produced at or above 1 million lbs/yr. Commitments were received on 2,200 HPV chemicals under the Challenge Program or a related effort by the Organization for Economic Cooperation and Development (OECD); EPA’s report on the “Status and Future Directions of the HPV Challenge Program” (seemingly issued around 2004) presents interim information on progress made but does not provide final counts of the number of chemicals for which the HPV Challenge commitment was met. EPA has also used §4 test rules to obtain information on “orphan” or unsponsored HPV chemicals and this work continues.

Concerning TSCA’s testing authority, as noted above, §4(a) allows EPA to require testing based on potential risk and/or exposure-based findings. Neither risk nor toxicity factor into the latter finding.

How many existing chemicals have been regulated? Were any voluntary risk management actions taken?

TSCA §6 rules have been issued and remain in effect for a number of chemicals, including PCBs (which is the subject of the bulk of the §6 regulations). The actual number of chemicals regulated depends on how one counts them and the 2008 EPA report cited earlier included a table which listed nine (9) proposed or final actions under §6 and, of these, four (4) rules which remained in effect. One of these

nine actions is a TSCA §6 rule to regulate asbestos, which was largely overturned in 1991 and today only a few asbestos items remain as banned products.

EPA has also used TSCA §5(a)(2) SNUR authority to regulate over 300 existing chemicals, including a number of “PBTs” (e.g., 6 PBBs (polybrominated biphenyls, the brominated analogue of PCBs), 2 PBDEs (polybrominated diphenyl ethers), and over 270 PFAS (perfluoroalkyl sulfonate derivatives), known or suspected carcinogens (including 24 benzidine dyes, the flame retardant “tris” (tris(2,3-dibromopropyl)phosphate), and erionite (an asbestos-like fiber)), and other toxic and risky chemicals. The SNUR “triggers” for EPA notification range from “any use” for the PBBs to, in the case of the PFAS derivatives, uses other than specific ongoing low volume/low release uses for which alternatives are not available. EPA should be able to provide a comprehensive listing of such existing chemical SNURs and the concerns that resulted in the regulation, including the details of the SNUR triggers applied, if of interest.

In 2006, EPA and the eight major companies in the industry launched the “2010/2015 PFOA Stewardship Program,” in which the companies committed to voluntarily reduce their global facility emissions and product content of PFOA and related long-chain perfluorinated chemicals (PFCs) by 95 percent by 2010, and to work toward eliminating such emissions and product content by 2015. According to EPA’s Action Plan on Long-Chain PFCs, “most companies have reported significant progress in meeting” the goals of the Stewardship Program. Voluntary actions have been taken on other existing chemicals over the years (a prominent example was the chemical acrylamide when used in sewer grout), but I cannot do the subject justice with the information available to me.

III. What does or does not work well under TSCA? What legal gaps exist?

A number of TSCA issues and concerns as well as aspects that work well, are discussed in several papers cited as Additional References at the end of this testimony. I summarize my thoughts here.

What has worked well in TSCA? Creation of the TSCA Inventory under §8(b), the new chemicals program under TSCA §5 and the citizens petition process under §21.

Creation of the TSCA Inventory in the late 1970s was an unprecedented activity. No government had ever before attempted to compile an authoritative list of the chemicals in commerce and EPA's completion of this effort within 3 years of TSCA's entry into force was a prodigious accomplishment. The TSCA Inventory served as the standard and the model for other national inventories developed since then; many of the policies, approaches, and even terminology (e.g., UVCB) developed in the initial TSCA Inventory have been applied by other countries. Since that time EPA has done a good job of keeping the guidance and the listings current which is key given the way the Inventory serves as TSCA's "bedrock."

In my view, experience over the past 30+ years has shown that TSCA struck a good balance in its approach to new chemicals under §5 and that the program has been effective and efficient in its oversight of new chemicals. It has encouraged the introduction of safer and greener new chemicals while also working to move industry away from potentially problematic chemicals through both regulatory and voluntary efforts. The new chemicals program has been a driver for innovation in the U.S. More discussion on this important program and its successes can be found in the Annex.

The §21 petition process has proven useful as a means of bringing issues and concerns to EPA's attention. Under this section, citizens can petition EPA to take certain actions under TSCA §§ 4, 5, 6, or 8, and EPA is required to respond to the petition within 90 days. If EPA grants the petition, it is required to promptly commence an appropriate proceeding; if EPA denies the petition, the reasons for denial must appear in the *Federal Register*. EPA has received numerous petitions over the years (OPPT's web site provides a listing of 12 petitions received since 2007). In my view, these petitions have been effective in causing EPA to take a close look at the petitioned issue and to promptly consider whether the requested activity should be undertaken based on the information available to EPA as well as the requirements under §21. This type of petitioning opportunity, at its essence, is both useful and helpful in a participatory democracy. In addition, a number of activities which I consider to be useful have resulted --

directly or indirectly -- from such petitions, including, e.g., a recently proposed EPA regulation on formaldehyde emissions from composite wood products. More detail should be available from EPA on §21 petitions and their outcomes, if of interest.

One other effort that might appear on a future list of “successes” is the §8(a) IUR/CDR effort to collect volume, processing, and use information on existing chemicals. This effort has become more useful as it was expanded over time to include inorganic chemicals in addition to organic chemicals, added requirements for basic reporting on the number of workers “reasonably likely to be exposed to a chemical,” maximum concentration, etc., and added reporting of processing and use information and then lowered the volume triggers for such reporting. It also made better efforts to distinguish commercial from consumer uses of chemicals and expanded requirements for substantiation of CBI claims. The 2016 CDR cycle promises to be even better with reporting on subject chemicals including production volumes for each of the intervening years and with the trigger volume for reporting of processing and use information being further reduced to 25,000 lbs/yr at a site.

What hasn't worked well in TSCA? The testing program under §4 and risk management under §6.

The statistic that §4 has been required testing on about 200 chemicals says a lot about why this program is being discussed in this context. While TSCA §4 seemed like a reasonable approach to obtaining testing, in practice the §4 rulemaking requirements have proven cumbersome to implement and as structured did not allow EPA to obtain testing to the level and extent needed to inform assessment and regulatory decisions under TSCA. EPA found, for example, that satisfying the findings, particularly the “data insufficiency” finding, could be time-consuming. Other problems were associated with the generally slow and complicated nature of rulemaking, an issue which is not unique to §4 rules. However, part of the problem with the long duration of the rulemaking process was that it could (and did) force reconsideration of the findings and redrafting of the rule text and rulemaking support documents (findings document (especially the exposure assessment portions), economics report, etc.) to reflect new information which EPA received; an example is the ripple that would result from a new IUR/CDR report

which changed the information available to EPA concerning production volumes, number of manufacturers of record, number of workers, uses, etc. EPA also attempted to use multi-chemical rulemakings to obtain testing in the hopes that such “combined efforts” would be more efficient; unfortunately in many cases, EPA found that the test rule process could only go as fast as the most problematic of the chemicals and that dropping chemicals or breaking up the rulemaking was needed in many cases.

Because of the difficulties encountered in developing test rules, EPA developed an enforceable consent agreement process to obtain negotiated testing. While this proved helpful in some cases, in other instances, the negotiations were never able to result in an agreement.

As noted earlier, in the late 1990s EPA identified an interest in obtaining screening level testing on High Production Volume (HPV) chemicals and, recognizing the number of chemicals at play (~3,000) and the difficulties in using §4 rules generally and specifically for such a large number of chemicals, decided to attempt to meet the need through a voluntary testing program. While the HPV Challenge Program was successful in increasing both access to and the availability of test data on many but by no means “all” of the HPV chemicals, EPA ultimately had to shift gears and use §4 test rules to deal with unsponsored “orphan chemicals,” a process that has been under way for over a decade and is yet to be finished.

TSCA §6 had surprising early success in efforts between 1978 and 1980 to regulate fully halogenated chlorofluorocarbons used as aerosol propellants, PCBs, and a site-specific rule regulating a storage facility in Arkansas handling dioxin-contaminated waste (the first and third of these rules were later superseded by actions taken under other statutes). Then in 1984, §6 was used to regulate three new chemicals used in metal working fluids. In 1989 EPA promulgated a ban and phase-out regulation under §6 on asbestos products. This rule regulated most of the use of asbestos but, following a legal challenge, was largely overturned, a decision which was not appealed. While much has been discussed and written about this rulemaking and the court decision, in my view, the requirements in TSCA §6(a) for a finding of

“will present an unreasonable risk” and the need to apply “the least burdensome” measures, combine to represent a largely unworkable legal standard for regulation.

Note that some number of my estimated “51,000 existing chemicals actually in commerce,” are *actually* former new chemicals which were regulated when they came through the §5 program and, having been the subject of an NOC, were added to the Inventory. It is not possible to estimate this number for the reasons given earlier; it would nonetheless be interesting to understand how many former new chemicals have been the subject of reports under the CDR. EPA should be able to provide this information, if of interest.

Having acknowledged the success of the new chemicals effort and the lack of success of the existing chemicals program, it is nonetheless useful to take a step back and place that latter effort into a context *vis-a-vis* new chemicals. Certain aspects of new chemicals were in my view a factor in the success seen. These include the fact that EPA was typically dealing with only one company concerning a chemical with a generally limited spectrum of uses that were described in the PMN (along with exposure and release information, manufacturing process descriptions, etc.), and the production and uses of which represented future market potential. Existing chemicals, on the other hand, typically involved: several to many companies; uses that could be multiple and varied with possibly different exposures and releases associated with each; substantial gaps in the available understanding (IUR/CDR reports while helpful lack the detail found in a PMN); and the fact of an established market with in-place infrastructure involving production, processing, use, employment, etc. Without a doubt, for these reasons as well as other reasons discussed in this section, dealing with existing chemicals presents the greater challenge under TSCA.

What legal gaps exist in TSCA? While current TSCA §§4 and 6 may not rise to “legal gaps” in authority (although some might argue this point), there is need to strengthen and improve these authorities.

Concerning legal gaps, in no particular order, I offer the following:

- EPA needs domestic authority to implement Convention obligations under Stockholm, Rotterdam, and LRTAP (Long-Range Transboundary Air Pollution) and open the door to

consider ratification of these treaties by the Senate; achieving these steps (among others) would enable the U.S. to join these Conventions as a Party;

- EPA should be allowed to share CBI with, and receive CBI from, States and possibly foreign governments that satisfy legal requirements and provide assurances of their ability to prevent disclosure of CBI. Note that both Canada (under the Canadian Environmental Protection Act of 1999) and the EU (under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation) allow for sharing/receiving of CBI with other governments that can adequately protect the CBI.

The 2009 and 2010 papers cited in the Additional References discuss a number of other areas where I believe TSCA could be improved.

IV. How does EPA currently set an agenda for reviewing chemicals? Does it need legal authority to do so?

EPA has developed and is currently using an Existing Chemicals Program Strategy to set an agenda for reviewing chemicals. A description of the approach can be found at http://www.epa.gov/oppt/existingchemicals/pubs/Existing_Chemicals_Strategy_Web.2-23-12.pdf. This is the most recent of numerous attempts by EPA over the decades to develop and implement an agenda to guide its work on testing and assessment of existing chemicals under TSCA. From my time at EPA, I can recall the so-called “15 Chemicals” strategy from the early years of TSCA (which was focused on risk assessment and risk management), the Master Testing List from the early 1990s (which was an attempt to create and publicize an “agenda” for §4 testing), an approach using preparation of “Risk Management 1” and “Risk Management 2” assessments (so-called RM1 and RM2 documents as part of an effort to focus risk assessment and risk management efforts) which, as I recall, dates from the 1990s, and the Chemical Assessment and Management Program (ChAMP) from 2007-2008. I am most familiar with ChAMP, an approach which involved, among other more traditional elements, efforts to

- apply the newly-received IUR reporting of processing and use information to assess exposures and
- use tools more generally associated with the new chemicals program (such as Structure Activity Relationships (SAR) analysis) to assess potential hazards

as part of an effort to screen and prioritize large numbers of existing chemicals for more detailed assessment and possible risk management, and thereby create an agenda for EPA. While TSCA is very broad in its authority, it is vague as to the important areas that EPA should focus on in dealing with the tens of thousands of existing chemicals and this “gap” has presented a long term and so far insolvable problem for EPA (the jury is still out on the latest effort; although, as EPA learns to use the CDR data and particularly the increased scope of reporting in the 2016 cycle, if the Agency, in setting its priorities, appropriately relies on the factual exposure information represented by the CDR data, that could make an important difference).

A great question is “why haven’t these earlier attempts worked?” It is my view that this combination of “broad authority and vague priorities” never came together in a way that could yield an agreed set of program goals that would then be pursued in a disciplined manner over the longer term to sort, test, assess, and act, as appropriate, in managing the risks of the thousands of chemicals in commerce. Further, given this “gap,” if you will, it is my view that EPA could do a better job and would be more effective in its work if it had some policy guidance that it could rely on as to what, among the many possibilities, the Agency should be doing, including ideally short and longer term goals. To elaborate on these critical points:

- In the case of new chemicals under TSCA, while there was not a statutory requirement for EPA to review the new chemical and take a decision, the fact of the PMN notices coming in to EPA on an almost daily basis, plus the discipline provided by the 90-day clock, served to create an agenda which EPA responded to very effectively. This kind of driver for shaping an agenda for existing chemicals does not exist in TSCA.

- As shown by the demise of ChAMP and all the other earlier EPA attempts to get its work organized, it has proven difficult for EPA to do this on its own. A TSCA advisory committee set up several years back under the Federal Advisory Committee Act (FACA) offered early promise in this regard, but that committee has ceased to exist.
- There is also the practical issue that in a bureaucracy with many claimants on resources, those programs that can point to strong drivers are the ones that get the resources. While the TSCA program has received more resources of late, this was not true for most of its existence, and especially for several decades after it was no longer a “new” statute.
- Another problem contributing to TSCA’s difficulties in developing and implementing an agenda for existing chemicals, to be frank, has been the lack of Congressional interest and oversight for most of TSCA’s history; hopefully this hearing is the start of ongoing and sustained interest by this Subcommittee.
- And, if I may continue to be direct, and with due respect, I believe, given the history I have reviewed in my testimony, that this situation is not likely to change appreciably until and unless the Congress debates and provides policy guidance if not requirements (along with any legal authority needed to implement the guidance or requirements) to enable EPA to focus on developing and then working to implement an agreed approach to dealing with existing chemicals over time.

The experience in Canada under the Canadian Environmental Protection Act and its 1999 revision (CEPA-1999) is, I believe, instructive as an example regarding the general question of the need for and value in an agenda and why such Congressional input is essential. This revision to Canada’s “TSCA equivalent” law occurred after a period where the Canadian regulatory authorities also struggled to get their arms around the “problem of existing chemicals.” Recognizing the issues, challenges, and needs, the Parliament debated and agreed to a legislative revision to their law which set in motion a process requiring that the government:

- screen and “categorize” the chemicals on the Canadian inventory to identify those presenting certain concerns, and then
- conduct screening-level risk assessments on all “categorized” chemicals to determine if they warrant consideration for further action, including controls.

By dint of hard work and resourcefulness, Environment Canada and Health Canada working together were able to complete the categorization process in 2006 and identified 4,300 chemicals (among the 23,000 on their inventory) needing further attention. This was by all accounts a remarkable achievement, especially considering the prior struggles. The Government of Canada in 2006 then swept up this accomplishment and announced a “Chemical Management Plan,” which included several key “next step” actions and established a deadline of 2020 for addressing all of the priority chemicals. Progress has continued apace.

The clear goals and purposes of the Canadian “agenda” were, in my view, central to their success, as was the careful design of the other relevant parts of their CEPA-1999 authority. Note also that the approach in CEPA-1999 was broadly supported by Canadian stakeholders, and, as I understand it, that support continues to this day. Finally, please recognize that while I like elements of the Canadian approach, in citing this example, I am not necessarily suggesting anything specific regarding how the U.S. might approach the question of developing an agenda under TSCA.

I thank you for the opportunity to have provided this testimony.

Additional References

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Annex

Additional discussion concerning “What works well in TSCA?” as it relates to the new chemicals program under TSCA §5.

Experience has shown that TSCA struck a good balance in its approach to new chemicals and that the program has been effective and efficient in its oversight of new chemicals:

(1) One of the major issues when TSCA was being debated in the 1970s concerned whether to require an upfront “base set of testing” on new chemicals. In the end, this testing was not required as part of the PMN notice, although EPA was given a flexible “may present an unreasonable risk” regulatory standard which essentially recognized the scientific uncertainties that a lack of test data would present to EPA in reviewing new chemicals. This standard encouraged EPA to regulate new chemicals that were a “potential problem” and led EPA to develop and rely on Structure Activity Relationships (SAR) analysis as a tool to assess and identify potentially hazardous new chemicals. I believe that these predictive assessment tools have worked reasonably well to identify potential problem chemicals, as shown in several EPA efforts to “check its work,” including:

- a 1993 study conducted jointly by EPA and authorities in the European Union that compared the results of EPA’s SAR predictions with the results of base set testing done on a set of new chemicals in the EU, and
- regular checks by EPA of §8(e) “substantial risk” submissions and §5(e) (and voluntary) testing done on new chemicals to compare the results of the testing with EPA’s predictions.

While these EPA efforts are not dispositive of the question, the use of SAR approaches is now generally recognized by the OECD, Canada, and the EU (under the REACH program) as a valuable component in an initial assessment of chemicals.

(2) Augmenting the “may present” standard and EPA’s use of SAR, TSCA also provided “exposure-based” and SNUR regulatory authority. The former can be thought of as an encouragement for EPA to obtain greater scientific certainty on higher volume/higher exposure new chemicals. It can also help improve EPA’s approach as a check on “false negative” new chemicals (chemicals which EPA does not identify as a potential problem in initial review, but which are subsequently found to be toxic based on testing; §8(e) reports, unless they consist of §5(e) testing, can also be thought of as a check on false negatives). SNURs, on the other hand, provided a flexible regulatory authority that allowed EPA where indicated to get “another bite at the apple” for new chemicals that exceeded their SNUR triggers.

(3) EPA has used its TSCA regulatory tools to control new chemicals presenting risks or uncertainties and this can be seen in the regulatory action counts discussed earlier. EPA has also used its assessments and regulatory outcomes over time to communicate understandings to industry about potential problem chemicals and to encourage them to shift away from some chemistries, while at the same time encouraging industry to consider safer new chemicals. Specifically, EPA has:

- released a “PMN categories” document that discusses groups of new chemicals that EPA has typically identified as presenting possible concerns,
- made its SAR and exposure estimation tools available on-line,

- encouraged industry to discuss, as part of the PMN, the pollution prevention (or “P2”) benefits that may be associated with a new chemical,
- has implemented an informal “P2 recognition” program that highlights noteworthy new chemicals, and
- has also used the “Sustainable Futures” program to encourage industry to use EPA’s assessment tools to identify potentially risky new chemicals early in the development process and use that understanding to develop safer alternatives that also meet performance requirements.

(4) I believe, based on my experience as a former EPA staff scientist and official who participated directly in the review of thousands of new chemicals, that new chemicals are generally “safer and greener” than their existing chemical competitors and, over time, than their new chemical predecessors. New chemicals also often provide greater energy efficiency or product efficiency, or provide approaches that can help deal with known problem chemicals by offering alternatives that reduce risks while meeting performance requirements. Most of the time the improvements seen with an individual new chemical are incremental (however, there are exceptions to this rule of thumb), but over time a strong continuous improvement effect is not infrequently realized. Thus, I believe that the TSCA new chemicals program has been an important contributor to innovation in the chemical industry.

(5) The decision not to require upfront testing in TSCA also had the effect of reducing the economic impacts and time delays (due to the time required for testing) in introducing new chemicals, recognizing that regardless, such chemicals had to compete with existing chemicals and demonstrate their commercial value in the marketplace (recall that only ~50% of new chemicals actually commence manufacture and it is not known how many or how long commenced new chemicals remain in the market, although some of this turnover is likely “creative destruction” along the lines of the “continuous improvement” discussion, above).

(6) A review of available information indicates that the EU has seen dramatically fewer numbers of new chemicals introduced into commerce in comparison to the U.S. experience:

over a 20-plus year period (from the early 1980s until the entry into force of REACH in 2007), the EU with its requirement for base set testing saw the introduction of “about 3,000” new chemicals,¹ while the U.S. over approximately the same period saw the introduction into commerce of a corresponding ~17,000 new chemicals (see further explanation of this number below). These figures thus indicate that *relative to the EU’s experience, there were approximately six (6) times as many new chemicals introduced in the U.S. over this period*, put another way, the EU’s total number of new chemicals notified represents about 18% of the U.S.’s corresponding total.

The U.S. figure, taken from the 2008 EPA report cited earlier, includes commenced PMNs and §5(h)(4) regulatory exemption requests submitted during this period and have been adjusted to reflect the regulatory scope applied to new chemicals in the EU; for example, the U.S., unlike the EU, required notification on all new chemical polymers. The U.S. figure thus includes both commenced nonpolymeric

¹ Van Leeuwen, C.J., B.G. Hansen and J.H.M. de Bruijn, “The Management of Industrial Chemicals in the EU,” in *Risk Assessment of Chemicals: An Introduction*, 2nd ed., Springer, The Netherlands, 2007 (pp. 511-551; see p. 512 for the information cited).

PMNs (8,200 “as of 2006”) and §5(h)(4) regulatory exemption chemicals (8,826 Low Volume and 33 Low Release/Low Exposure regulatory exemptions through September 2006; most of these are nonpolymeric substances (given the separate regulatory exemption that is available for certain polymers) but there could be some polymers included as well; a more careful analysis would need to be done by EPA to determine the actual number of nonpolymeric regulatory exemption chemicals if this question is of interest).

Conclusions. I believe that the U.S. over time has greatly benefited, both competitively and environmentally, from the increased number of new chemicals introduced into commerce because of the flexible and less burdensome approach under TSCA, and the appropriately measured response by EPA in its regulatory efforts and in working as an advocate for environmental stewardship in the development of new chemicals. As discussed above, I believe that new chemicals notified to EPA are in general safer and greener than the chemicals they have substituted for, while also, particularly over time, being more energy efficient and delivering higher technical and commercial performance. For reasons such as these, it is my belief that the new chemicals program has been one of TSCA’s great successes.

Mr. SHIMKUS. We will pause here. We will move to our next panelist and hopefully through the questions and answers we can ferret out some of your other fine points that you want to make.

So the chair now recognizes Alfredo Gomez, Director, Natural Resources and Environment for the Government Accountability Office. Sir, you are recognized for 5 minutes, and maybe a minute or two over.

STATEMENT OF ALFREDO GOMEZ

Mr. GOMEZ. Mr. Chairman, Ranking Member Tonko, members of the subcommittee. I am pleased to be here today to discuss EPA's implementation of TSCA.

Tens of thousands of chemicals are listed with the EPA for commercial use in the United States with an average of 600 new ones added each year. Although chemicals are important in producing goods and services, some may adversely affect human health and the environment. Congress passed TSCA to give EPA the authority to obtain more health and safety information on chemicals and to regulate chemicals it determines pose unreasonable risks of injury, to human health or the environment. EPA's authority is established in five major sections of TSCA, some of which have already been discussed.

My statement today summarizes GAO's past work, describing challenges EPA has historically faced in regulating chemicals, and the extent to which EPA has made progress in implementing its new approach.

I would like to begin by focusing on three of the biggest challenges EPA has faced in implementing TSCA. First, under Section 4 of TSCA, EPA has found it difficult to obtain adequate information on chemical toxicity and exposure because TSCA does not require companies to provide this information. Instead, the law requires EPA to demonstrate the chemicals pose certain risks before it can ask for such information. In June 2005, we reported that while TSCA authorizes EPA to review existing chemicals, the statute generally provides no specific requirement, time frame or methodology for doing so. We suggested that Congress consider amending TSCA to provide EPA explicit authority to enter into enforceable agreements requiring chemical companies to conduct testimony and to require chemical manufacturers and processors with substantial production value to develop test data.

Second, under Section 6, EPA has also had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use. We reported that since Congress enacted TSCA in 1976, EPA has issued regulations to ban or limit the production or restrict the use of only five existing chemicals or chemical classes out of tens of thousands of chemicals listed for commercial use. EPA told us that even if EPA had substantial toxicity and exposure data and wants to protect the public against known risks, the Agency's challenge is meeting this statutory requirement under TSCA to limit or ban chemicals.

Third, under Section 14, EPA has limited ability to publicly share the information it receives from chemical companies. While companies assert that their information is confidential business information, EPA is limited from sharing it with States and foreign

governments. This potentially limits the effectiveness of these organizations' environmental risk programs. We reported that EPA had not routinely challenged companies' confidentiality claims.

EPA has made some progress in implementing its new approach to managing chemicals while results in other areas have yet to be realized. For example, EPA has increased its efforts to obtain chemical toxicity and exposure data and initiating chemical risk assessments. However, it may take several years before EPA obtains much of the data it is seeking. Moreover, given the difficulty that EPA has faced in the past using Section 6 of TSCA, since 2009 EPA has taken other actions that may discourage the use of certain chemicals, some of which have already been mentioned. However, it is too early to tell whether some of these actions will reduce chemical risks.

Thus, it is unclear whether EPA's new approach will position the agency to achieve its goal of ensuring the safety of chemicals. EPA officials have said that the Agency's new approach is summarized in its 2012 Existing Chemicals Program Strategy. However, this strategy does not discuss how EPA will address challenges associated with obtaining toxicity and exposure data, banning or limiting the use of chemicals, or identifying the resources needed. We recommended that EPA develop strategies for addressing these challenges. In response, EPA said that while strategic planning is a useful exercise, absent statutory changes to TSCA, the Agency will not be able to successfully meet the goal of ensuring chemical safety now and into the future.

This completes my statement. I would be pleased to respond to any questions.

[The prepared statement of Mr. Gomez follows:]

United States Government Accountability Office



Testimony
Before the Subcommittee on
Environment and the Economy,
Committee on Energy and Commerce,
House of Representatives

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CHEMICAL REGULATION

Observations on the Toxic Substances Control Act and EPA Implementation

Statement of Alfredo Gomez, Director
Natural Resources and Environment

GAO Highlights

Highlights of GAO-13-696T, a testimony before the Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

In 1976, Congress passed TSCA to give EPA the authority to obtain more health and safety information on chemicals and to regulate chemicals it determines pose unreasonable risks of injury to human health or the environment. GAO has reported that EPA has found many of TSCA's provisions difficult to implement. In 2009, EPA announced TSCA reform principles to inform ongoing efforts in Congress to strengthen the act. At that time, EPA also initiated a new approach for managing toxic chemicals using its existing TSCA authorities.

This testimony summarizes GAO's past work describing: (1) challenges EPA has faced historically in regulating chemicals and (2) the extent to which EPA has made progress implementing its new approach, and challenges, if any, which persist. This statement is based on GAO reports issued between 1994 and 2013.

GAO is not making new recommendations in this testimony. In prior reports, GAO suggested that Congress consider statutory changes to TSCA to give EPA additional authorities to obtain information from the chemical industry and shift more of the burden to chemical companies for demonstrating the safety of their chemicals. In these reports, among other things, GAO recommended that EPA require companies to provide chemical data they submitted to foreign governments, require companies to reassert confidentiality claims, and develop strategies for addressing challenges that impeded EPA's ability to ensure chemical safety. EPA's responses to these recommendations have varied.

View GAO-13-696T. For more information, contact Alfredo Gomez at (202) 512-3841 or gomezj@gao.gov.

June 13, 2013

CHEMICAL REGULATION

Observations on the Toxic Substances Control Act and EPA Implementation

What GAO Found

GAO reported in June 2005 that EPA has historically faced the following challenges in implementing the provisions of the Toxic Substances Control Act (TSCA):

- *Obtaining adequate information on chemical toxicity and exposure.* EPA has found it difficult to obtain such information because TSCA does not require companies to provide it; instead, TSCA requires EPA to demonstrate that chemicals pose certain risks before it can ask for such information.
- *Banning or limiting chemicals.* EPA has had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use under section 6—provisions for controlling chemicals. The agency issued regulations to ban or limit production or use of five existing chemicals, or chemical classes, out of tens of thousands of chemicals listed for commercial use. A court reversal of EPA's 1989 asbestos rule illustrates the difficulties EPA has had in issuing regulations to control existing chemicals.
- *Disclosing data and managing assertions of confidentiality.* EPA has not routinely challenged companies' assertions that data they provide are confidential business information and cannot be disclosed. As a result, the extent to which companies' confidentiality claims are warranted is unknown.

GAO reported in March 2013 that EPA has made progress implementing its new approach to managing toxic chemicals under its existing TSCA authority but, in most cases, results have yet to be realized. Examples are as follows:

- EPA has increased efforts to collect toxicity and exposure data through the rulemaking process, but because rules can take 3 to 5 years to finalize and 2 to 2½ years for companies to execute, these efforts may take several years to produce results. Specifically, since 2009, EPA has (1) required companies to test 34 chemicals and provide EPA with the resulting toxicity and other data, and (2) announced, but has not yet finalized, plans to require testing for 23 additional chemicals.
- EPA has increased efforts to assess chemical risks, but because EPA does not have the data necessary to conduct all risk assessments, it is too early to tell what, if any, risk management actions will be taken. In February 2012, EPA announced a plan that identified and prioritized 83 existing chemicals for risk assessment; the agency initiated assessments for 7 chemicals in 2012 and announced plans to start 18 additional assessments during 2013 and 2014. At its current pace, it would take EPA at least 10 years to complete risk assessments for the 83 chemicals.

In addition, it is unclear whether EPA's new approach to managing chemicals will position the agency to achieve its goal of ensuring the safety of chemicals. EPA's *Existing Chemicals Program Strategy*, which is intended to guide EPA's efforts to assess and control chemicals in the coming years, does not discuss how EPA will address identified challenges. Consequently, EPA could be investing valuable resources, time, and effort without being certain that its efforts will bring the agency closer to achieving its goal of ensuring the safety of chemicals.

Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee:

I am pleased to be here today to discuss the Environmental Protection Agency's (EPA) efforts to assess and control toxic chemicals. Tens of thousands of chemicals are listed with EPA for commercial use in the United States, with an average of 600 new chemicals listed each year. EPA's ability to effectively implement its mission of protecting public health and the environment depends on credible and timely assessments of the risks posed by toxic chemicals. In 1976, Congress passed the Toxic Substances Control Act (TSCA) to provide EPA with the authority to obtain more information on chemicals and to regulate those chemicals that EPA determines pose unreasonable risks to human health or the environment. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals).¹

We have reported in the past that EPA has found many of the provisions of TSCA difficult to implement. In our past reports, we have suggested that Congress consider making statutory changes to strengthen EPA's authority to obtain toxicity information from the chemical industry and establish a framework for taking action that is less burdensome for EPA. We have also made several recommendations to better position EPA to collect chemical toxicity and exposure-related data and ensure chemical safety under existing TSCA authority. Among other recommendations, in June 2005,² we recommended that EPA strengthen its ability to regulate harmful chemicals under TSCA by, for example, promulgating a rule requiring that companies submit copies to EPA of any health and safety studies, as well as other information concerning the environmental and health effects of chemicals that they submit to foreign governments.³ In

¹Existing chemicals are composed of those that were in commerce in 1979 when EPA began reviewing chemicals, as well as those listed for commercial use after that time.

²GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

³Throughout this testimony, the phrase "chemical companies" refers generally to companies that manufacture, import, process, distribute in commerce, use, or dispose of chemicals regulated under TSCA. When it is important to differentiate between, for example, manufacturers and processors, the type of company to which I am referring is specified.

that report, we also recommended that EPA improve and validate its models for assessing and predicting the risks of chemicals and revise its regulations to require chemical companies to reassert confidentiality claims within a certain period.⁴ EPA implemented our 2005 recommendation to improve its models. EPA did not disagree with our 2005 recommendations regarding obtaining health and safety studies and other information that companies submit to foreign governments and requiring companies to reassert confidentiality claims, but it provided substantive comments and has not fully implemented these recommendations.

In 2009, EPA announced principles for reforming TSCA to help inform efforts under way in Congress. These principles include goals for reforming TSCA so that: (1) EPA would have clear authority to establish safety standards that are based on scientific risk assessments; (2) manufacturers' data on toxicity, exposure,⁵ and use for chemicals would be required at sufficient levels so that EPA could support a determination that a chemical meets the safety standard; (3) EPA would have clear authority to take regulatory or other actions when chemicals do not meet the safety standard, with the flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns; (4) EPA would have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations; and (5) EPA would receive a sustained source of funding from manufacturers of chemicals to support the costs of agency implementation, including the review of information provided by manufacturers.

Along with the announcement of these principles in 2009, EPA initiated a new approach to managing chemicals within the limits of existing authorities that focuses largely on existing chemicals. According to agency documents, EPA will transition from an approach dominated by voluntary data submissions by industry to a more proactive approach in which the agency will use its data collection and other rulemaking

⁴As described later in this testimony, TSCA contains provisions for governing the disclosure of chemical data. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information.

⁵In this testimony, exposure represents the magnitude, frequency, and duration of contact with a chemical. Toxicity represents the degree to which a chemical is harmful. In this testimony, the terms toxicity and hazard are used synonymously.

authorities under TSCA to ensure chemical safety. In February 2012, EPA summarized many of the activities it had initiated under its new approach in the agency's *Existing Chemicals Program Strategy*. Collectively, these activities address the following four areas: (1) collecting toxicity and exposure data, (2) conducting risk assessments, (3) discouraging the use of some chemicals, and (4) expanding public access to some chemical data.

In our most recent report in March 2013, we reported on the extent to which EPA had made progress implementing its new approach.⁶ We recommended, among other things, that EPA consider promulgating a rule requiring chemical companies to report exposure-related data from processors to EPA. EPA stated in its comments that downstream chemical processors have little exposure-relevant data—which suggests that it does not intend to implement that recommendation.⁷ Because EPA has not developed sufficient chemical assessment information to limit exposure to many chemicals that may pose substantial health risks, among other reasons, in 2009, we added EPA's processes for assessing and controlling toxic chemicals to our list of programs at high risk of waste, fraud, abuse, and mismanagement.⁸

My testimony today is based on our prior work on EPA's processes for assessing and controlling toxic chemicals. Specifically, my statement today discusses: (1) challenges EPA has faced historically in regulating chemicals and (2) the extent to which EPA has made progress implementing its new approach, and challenges, if any, which persist. This statement is based on our extensive body of work on TSCA and EPA's programs to assess and control chemicals, including reports issued from September 1994 to March 2013. Detailed information on our scope and methodology is available in each issued product. We

⁶GAO, *Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach*, GAO-13-249 (Washington, D.C.: Mar. 22, 2013).

⁷This position, however, conflicts with EPA's principles for TSCA reform, which state that, "EPA's authority to require submission of use and exposure information should extend to downstream processors..." In addition, EPA officials have said that data from downstream processors would provide the agency with a better understanding of potential exposure to chemicals, for example, chemical exposure from consumer products such as those designed for children.

⁸GAO, *High-Risk Series: An Update*. GAO-09-271 (Washington, D.C.: Jan. 22, 2009).

conducted this work in accordance with generally accepted government auditing standards.

Background

Federal laws have been enacted over the years to determine the health and environmental hazards associated with toxic chemicals and to address these problems. Even with the existence of media-specific environmental laws enacted in the early 1970s, such as the Clean Air Act and the Clean Water Act, problems with toxic chemicals continued to occur. In addition, Congress became increasingly concerned about the long-term effects of substantial amounts of chemicals entering the environment.

TSCA was enacted to authorize EPA to collect information about the hazards posed by chemical substances and to take action to control unreasonable risks by either preventing dangerous chemicals from making their way into use or placing restrictions on those already in commerce. Under the act, EPA can control the entire life cycle of chemicals from their production, distribution in commerce, and use to their disposal. Other environmental and occupational health laws generally control only disposal or release to the environment, or exposures in the workplace. The scope of TSCA includes those chemicals manufactured, imported, processed,⁹ distributed in commerce, used, or disposed of in the United States but excludes certain substances regulated under other laws.¹⁰ TSCA also specifies when EPA may publicly disclose chemical information it obtains from chemical companies and provides that chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information.

EPA's authority to ensure that chemicals in commerce do not present an unreasonable risk of injury to health or the environment is established in five major sections of TSCA. The purpose and application of these sections are shown in table 1 and described in further detail below.

⁹Processing refers to the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.

¹⁰Excluded substances include certain nuclear materials, pesticides, food, food additives, tobacco, drugs, and cosmetics.

Table 1: Purpose and Application of TSCA's Major Sections

Section	Purpose	Provides EPA with a mechanism to:
4	Chemical testing	Require companies to develop toxicity data under certain circumstances
5	New chemical review and significant new use rules	Review existing information, including exposure and toxicity data for new chemicals and certain new uses of existing chemicals
6	Control of chemicals	Limit or ban a chemical, among other controls
8	Industry reporting of chemical data	Obtain existing data, including exposure and toxicity data
14	Disclosure of chemical data	Disclose certain data provided to or obtained by EPA while also protecting confidential business information

Source: GAO analysis of TSCA.

Under the provisions for chemical testing in section 4 of TSCA, EPA can promulgate rules to require chemical companies to test potentially harmful chemicals for their health and environmental effects. However, EPA must first determine that testing is warranted based on some toxicity or exposure information. Specifically, to require such testing, EPA must find that a chemical (1) may present an unreasonable risk of injury to human health or the environment or (2) is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities. EPA must also 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.

Under the provisions for new chemical review and significant new use rules in section 5 of TSCA, chemical companies are to notify EPA at least 90 days before beginning to manufacture a new chemical (premanufacture notice review). Section 5 also allows EPA to promulgate significant new use rules, which require companies to notify EPA at least 90 days before beginning to manufacture a chemical for certain new uses or in certain new ways (significant new use notice review). Such rules require existing chemicals to undergo the same type of review that new chemicals undergo. For example, EPA may issue a significant new use rule if it learns that a chemical that has previously been processed as a liquid is now being processed as a powder, which may change how workers are exposed to the chemical. Section 5 of the act also authorizes EPA to maintain a list of chemicals—called the chemicals of concern

list—that present or may present an unreasonable risk of injury to health or the environment.

Under the provisions for chemical regulation in section 6 of TSCA, EPA is to apply regulatory requirements to chemicals for which EPA finds a reasonable basis exists to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. To adequately protect against a chemical's risk, EPA can promulgate a rule that bans or restricts the chemical's production, processing, distribution in commerce, disposal, or use or requires warning labels be placed on the chemical. Under TSCA, EPA must choose the least burdensome requirement that will adequately protect against the risk.

Under the provisions for industry reporting of chemical data in section 8(a), EPA is to promulgate rules under which chemical companies must maintain records and submit such information as the EPA Administrator reasonably requires. This information can include, among other things, chemical identity, categories of use, production levels, by-products, existing data on adverse human health and environmental effects, and the number of workers exposed to the chemical, to the extent such information is known or reasonably ascertainable. Under section 8(a), EPA issues rules to update the TSCA inventory. For example, in August 2011, EPA finalized its TSCA Chemical Data Reporting rule (previously referred to as the Inventory Update Reporting Modifications Rule); the rule requires companies to report, among other things, exposure-related information, such as production volume and use data, on chemicals manufactured or imported over a certain volume per year. In addition, section 8(d) provides EPA with the authority to promulgate rules under which chemical companies are required to submit lists or copies of existing health and safety studies to EPA. Section 8(e) generally requires chemical companies to report any information to EPA that reasonably supports a conclusion that a chemical presents a substantial risk of injury to health or the environment.

Under the provisions for disclosure of chemical data in section 14, EPA may disclose chemical information it obtains under TSCA under certain conditions. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must protect confidential business information against public disclosure unless necessary to protect against an unreasonable risk of injury to health or the environment. Other federal agencies and federal contractors can obtain access to this confidential business

information to carry out their responsibilities. EPA may also disclose certain data from health and safety studies.

Historical Challenges EPA Has Faced Regulating Chemicals under TSCA

We have previously reported that EPA has historically faced challenges implementing many of the provisions of TSCA, in particular (1) obtaining adequate information on chemical toxicity and exposure through testing provisions; (2) banning or limiting chemicals; and (3) disclosing chemical data and managing company assertions of confidentiality.

Obtaining Adequate Information on Chemical Toxicity and Exposure

EPA has found it difficult to obtain adequate information on chemical toxicity and exposure because TSCA does not require companies to provide this information and, instead, requires EPA to demonstrate that chemicals pose certain risks before it can ask for such information.

Specifically, we reported in 2005 that under section 4—provisions for chemical testing—EPA has found its authority to be difficult, time-consuming, and costly to use.¹¹ The structure of this section places the burden on EPA to demonstrate certain health or environmental risks before it can require companies to further test their chemicals. While TSCA authorizes EPA to review existing chemicals, it generally provides no specific requirement, time frame, or methodology for doing so. Instead, EPA conducts initial reviews after it receives information from the public or chemical companies that a chemical may pose a risk. As a result, EPA has only limited information on the health and environmental risks posed by these chemicals. In our June 2005 report, we suggested that Congress consider amending TSCA to provide explicit authority for EPA to enter into enforceable consent agreements under which chemical companies are required to conduct testing, and give EPA, in addition to its current authorities under section 4 of TSCA, the authority to require chemical substance manufacturers and processors to develop test data based on substantial production volume and the necessity for testing.

In addition, we reported in June 2005 that under section 5—provisions for new chemical review—TSCA generally requires chemical companies to submit a notice to EPA (known as a "premanufacture notice") before they manufacture or import new chemicals and to provide any available test

¹¹GAO-05-458.

data. EPA estimated that most notices do not include any test data and that about 15 percent of them included health or safety test data. These tests may take over a year to complete and cost hundreds of thousands of dollars, and chemical companies usually do not perform them voluntarily. However, chemical companies are not generally required under TSCA to limit the production of a chemical or its uses to those specified in the premanufacture notice or to submit another premanufacture notice if changes occur. For example, companies may increase production levels or expand the uses of a chemical, potentially increasing the risk of injury to human health or the environment.

Banning or Limiting Chemicals

EPA has had difficulty demonstrating that chemicals should be banned or have limits placed on their production or use under section 6—provisions for controlling chemicals. Specifically, we reported, in June 2005, that since Congress enacted TSCA in 1976,¹² EPA has issued regulations under section 6 to ban or limit the production or restrict the use of five existing chemicals or chemical classes out of tens of thousands of chemicals listed for commercial use on the agency's TSCA inventory.¹³

EPA's 1989 asbestos rule illustrates the difficulties EPA has had in issuing regulations to control existing chemicals. In 1979, EPA started considering rulemaking on asbestos. After concluding that asbestos was a potential carcinogen at all levels of exposure,¹⁴ EPA promulgated a rule in 1989 prohibiting the future manufacture, importation, processing, and distribution of asbestos in almost all products. Some manufacturers of asbestos products filed suit against EPA, arguing, in part, that the rule was not promulgated on the basis of substantial evidence regarding unreasonable risk. In 1991, the Fifth Circuit Court of Appeals ruled for the manufacturers and returned parts of the rule to EPA for reconsideration. In reaching this conclusion, the court found that EPA did not consider all

¹²GAO-05-458.

¹³TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States, which is called the TSCA inventory. Of the over 84,000 chemicals currently on the TSCA inventory, approximately 8,000 chemicals are produced at annual volumes of 25,000 pounds or greater.

¹⁴EPA came to this conclusion after reviewing over 100 studies of the health risks of asbestos, as well as public comments on the proposed rule.

necessary evidence and failed to show that the control action it chose was the least burdensome reasonable regulation required to adequately protect human health or the environment. Since the court's 1989 decision, EPA has only exercised its authority to ban or limit the production or use of an existing chemical once—for hexavalent chromium, a known human carcinogen widely used in industrial cooling towers—in 1990.¹⁵

Disclosure of Chemical Data

EPA has limited ability to publicly share the information it receives from chemical companies under TSCA. Specifically, as we reported in 2005, EPA has not routinely challenged companies' assertions that the chemical data they disclose to EPA under section 14—disclosure of chemical data—are confidential business information, citing resource constraints. TSCA requires EPA to protect trade secrets and privileged or confidential commercial or financial information against unauthorized disclosures. When information is claimed as confidential business information, it limits EPA's ability to expand public access to this information—such as sharing it with state environmental agencies and foreign governments, which potentially limits the effectiveness of these organizations' environmental risk programs.

Because EPA has not routinely challenged these assertions, the extent to which companies' confidentiality claims are warranted is unknown. We recommended, in June 2005, that EPA revise its regulations to require that companies periodically reassert claims of confidentiality.¹⁶ EPA did not disagree with our recommendation but has not revised its regulations. EPA has explored ways to reduce the number of inappropriate and over-broad claims of confidentiality by companies that submit data to EPA.

¹⁵However, EPA officials said that they had started the process for promulgating the rule for hexavalent chromium years prior to the asbestos decision.

¹⁶GAO-05-458.

EPA Has Made Progress to Implement Its New Approach to Managing Chemicals, but Some Challenges Persist

In March 2013, we reported on progress EPA has made implementing its new approach to manage toxic chemicals under its existing TSCA authority—particularly by increasing efforts to (1) obtain toxicity and exposure data, (2) assess risks posed by chemicals, and (3) discourage the use of some chemicals.¹⁷ However, the results of EPA's activities, in most cases, have yet to be realized. We also reported that it is unclear whether EPA's new approach will position the agency to achieve its goal of ensuring the safety of chemicals.

EPA Has Increased Efforts to Collect Data on Toxicity and Exposure, but It May Take Several Years to Produce Results

EPA has increased its efforts to collect toxicity and exposure data, but because rules can take years to finalize and additional time for companies to execute, these efforts may take several years to produce results. Even with these efforts, EPA has not pursued all opportunities to obtain chemical data.

We reported, in March 2013, that EPA has made progress by taking the following actions but continues to face challenges in collecting such data, specifically:

- Since 2009, EPA has proposed or promulgated rules to require chemical companies to test 57 chemicals. Specifically, EPA has required companies to test 34 chemicals and provide EPA with the resulting toxicity and other data. In addition, EPA announced, but has yet to finalize,¹⁸ plans to require testing for 23 additional chemicals.¹⁹ However, requirements under TSCA place the burden of developing toxicity data on EPA. Because rulemaking can take years, EPA has yet to obtain much of the information it has been seeking. According to EPA officials, it can take, on average, 3 to 5 years for the agency to

¹⁷GAO-13-249.

¹⁸Final rules are located at 40 C.F.R. §§ 799.5087 and 799.5089 (2012). The proposed rule is located at 76 Fed. Reg. 65580 (Oct. 21, 2011).

¹⁹By comparison, EPA required testing for fewer than 200 chemicals from the time TSCA was enacted in 1976 until 2009 when the agency undertook its new approach to managing chemicals. The 57 chemicals that are part of EPA's current and proposed testing requirements were identified but not sponsored as part of the agency's 1998 voluntary effort to obtain testing data from companies on chemicals produced or imported at high volumes (i.e., amounts of 1 million pounds or more a year).

promulgate a test rule and an additional 2 to 2 ½ years for the companies to provide the data once EPA has requested them. In addition, the toxicity data eventually obtained on the 57 chemicals may not be sufficient for EPA to conduct a risk assessment (i.e., characterize risk by determining the probability that populations or individuals so exposed to a chemical will be harmed and to what degree). Specifically, EPA may obtain data that are considered to be "screening level" information. Screening level information is collected to identify a chemical's potential hazards to human health and the environment, but it was not intended to be the basis for assessing whether a chemical poses an unreasonable risk of injury to human health or the environment, according to agency documents describing the program.

- In August 2011, EPA revised its periodic chemical data reporting requirements to obtain exposure-related information for a greater number of chemicals. Under the revised requirements, EPA (1) lowered the reporting thresholds, in some cases,²⁰ which will allow it to look at exposure scenarios for a larger number of chemicals than in the past and (2) shortened the reporting cycle from every 5 years to every 4 years. In addition, starting in 2016, the revised requirements for reporting will be triggered when companies exceed applicable production thresholds in any year during the 4-year reporting cycle.²¹

Even with the increased efforts EPA has taken to collect toxicity and exposure data, in March 2013, we reported that EPA has not pursued all opportunities to obtain such data. For example, EPA has not sought toxicity and exposure data that companies submit to the European Chemicals Agency on chemicals that the companies manufacture or

²⁰For example, the production threshold for providing processing and use information went from 300,000 pounds or more to 100,000 pounds or more in 2012 and will be reduced to 25,000 pounds thereafter.

²¹Previously, the reporting requirement was triggered only if production levels were exceeded during the reporting year. According to EPA officials, this change was important because, under the previous requirement, production volumes of chemical substances fluctuated above and below reporting thresholds in different reporting periods, resulting in a change of approximately 30 percent in the composition of the chemical substances reported as being produced from one reporting period to the next.

process in, or import to, the United States.²² Under the European Union's chemicals legislation, the European Chemicals Agency may share information it receives from chemical companies with foreign governments in accordance with a formal agreement concluded between the European Community and the foreign government, but EPA has not pursued such an agreement. In addition, EPA has not issued a rule under section 8 of TSCA requiring companies to provide EPA with the information provided to the European Chemicals Agency. EPA officials told us that the agency has not sought to obtain chemical data—from either the European Chemicals Agency or companies directly—because it does not believe that this would be the best use of EPA or industry resources. They also said that it is unclear whether these data would be useful to EPA. EPA officials believe it is a more effective use of resources to gain access to data, as needed, on a case-by-case basis from chemical companies. As a result, we recommended that EPA consider promulgating a rule under TSCA section 8, or take action under another section, as appropriate, to require chemical companies to report chemical toxicity and exposure-related data they have submitted to the European Chemicals Agency. In its written comments on a draft of our March 2013 report, EPA stated that it intends to pursue data submitted to the European Chemicals Agency from U.S. companies using voluntary or regulatory means as necessary but did not provide information on its planned approach to pursue such data. Consequently, the extent to which EPA plans to continue to rely on voluntary efforts to obtain the needed data is unclear.

EPA Has Begun Assessing Chemical Risks, but It Is Too Early to Tell What, If Any, Risk Management Actions Will Be Taken

EPA has increased its efforts to assess chemical risks, but because EPA does not have the data necessary to conduct all risk assessments, it is too early to tell what, if any, risk management actions will be taken. Even with these efforts, it is unclear how EPA is going to obtain the data necessary to continue to conduct all risk assessments.

We reported, in March 2013, that EPA has made progress to assess chemical risks by taking the following actions but continues to face

²²The European Chemicals Agency implements the European Union's chemicals legislation. The European Union's chemicals legislation requires companies to develop information on chemicals' effects on human health and the environment before entering commerce, while TSCA does not require companies to develop such information absent EPA rulemaking requiring them to do so.

challenges. Specifically, in February 2012, EPA announced a plan that identified and prioritized 83 existing chemicals for risk assessment—known as the TSCA Work Plan.²³ From this list of 83 chemicals, EPA's Office of Pollution Prevention and Toxics—the office responsible for implementing TSCA—initiated risk assessments for 7 chemicals in 2012—5 of which were released for public comment—and announced plans to start risk assessments during 2013 and 2014 for 18 additional chemicals.²⁴ EPA officials told us that they expect that all 7 risk assessments will be finalized early in 2014. However, it may be years before EPA initiates regulatory or other risk management actions to reduce any chemical risks identified in these assessments. Before EPA can determine such actions are warranted, the agency would need to consider other factors—such as costs and benefits of mitigating the risk, technological information, and the concerns of stakeholders—which could require additional time and resources. Moreover, assuming EPA meets its 2014 target for completing these 7 assessments and initiating new assessments, at its current pace, it would take EPA at least 10 years to complete risk assessments for the 83 chemicals in the TSCA Work Plan.

As we reported, in March 2013, even with these increased efforts, it is unclear whether EPA can maintain its current pace given that it currently does not have the toxicity and exposure data it will need to conduct risk assessments for all of the 83 chemicals in its TSCA Work Plan. According to EPA officials and agency documents, the agency has started or plans to start risk assessments on the 25 chemicals for which it has well-characterized toxicity and exposure data. However, before EPA can initiate risk assessments for the remaining 58 chemicals, the agency will need to identify and obtain toxicity and exposure data. According to agency officials, to obtain the toxicity data needed, EPA may need to promulgate rules to require companies to perform additional testing on some of these chemicals. However, EPA has not clearly articulated how or when it plans to obtain these needed data. Moreover, without exposure-related data, such as those potentially available from chemical processors, EPA may still be missing the data necessary to conduct risk

²³In 2011, EPA convened a stakeholder meeting to discuss proposed screening criteria and data sources and took public comment over a 35-day period. Based on the input received, EPA devised and executed a protocol that used a combination of risk factors and other criteria. Using this protocol, EPA winnowed an initial group of 1,235 chemicals down to 83.

²⁴78 Fed. Reg. 1856 (Jan. 9, 2013).

assessments. To better position EPA to ensure chemical safety under existing TSCA authority, in our March 2013 report we recommended that EPA develop strategies for addressing challenges associated with obtaining toxicity and exposure data needed for risk assessments. However, based on EPA's written response to a draft of our 2013 report, it is unclear what action, if any, EPA intends to pursue.

EPA Has Taken Actions That May Discourage the Use of Certain Chemicals, but It Is Too Early to Tell Whether These Actions Will Reduce Chemical Risk

EPA has taken actions that may discourage the use of certain chemicals, but because many of these actions have yet to be finalized, it is too early to tell whether they will reduce chemical risk. We reported in March 2013 that, given the difficulty that EPA has faced in the past using section 6 of TSCA to ban existing toxic chemicals or place limits on their production or use, the agency generally considers using this authority only after exhausting all other available options. Since 2009, EPA has made progress by increasing its use of certain options, including (1) making greater use of significant new use rules under section 5 and (2) proposing actions that use its TSCA authority in new ways as follows:

- EPA is making greater use of significant new use rules under section 5 to control new uses of existing chemicals. Our analysis of TSCA rulemaking from 2009 to 2012 shows that EPA has quadrupled its issuance of significant new use rules since 2009. From 2009 to 2012, EPA issued significant new use rules affecting about 540 chemicals, about 25 percent of all 2,180 chemicals subject to significant new use rules issued by EPA since 1976. EPA officials told us that EPA typically recommends that companies submit testing information when they notify EPA of their intent to manufacture or process chemicals, which enables EPA to better evaluate the potential risks associated with the new use. According to EPA officials, this approach allows the agency to "chip away" at chemicals that may pose risks to human health and the environment. Such recommendations may discourage companies from pursuing new uses of existing chemicals that may pose health or environmental risks either because testing itself can be expensive, or because the testing recommendation suggests that the agency may consider banning or limiting the manufacture or production of the chemical on the basis of that testing.
- EPA has also proposed actions that use its TSCA authority in new ways including the following:
 - *Creating "chemicals of concern" list.* In May 2010, EPA announced that it intended to create a list of chemicals that present or may present "an unreasonable risk of injury to health or

the environment.” EPA has had the authority to create such a list under section 5 of TSCA since its enactment in 1976 but has never attempted to use this authority. EPA submitted the list, which consists of three groups of chemicals, for review by the Office of Management and Budget (OMB) in May 2010, and as of May 2013, EPA’s proposed “chemicals of concern” list has been under review at OMB for over 1,000 days and remains listed as pending review by OMB.²⁵

- *Pairing of test and significant new use rules.* In December 2010, EPA submitted to OMB for review a proposal to pair testing rules with significant new use rules for the first time. Specifically, EPA has proposed single rules that combine provisions requiring companies to develop toxicity and other data with provisions requiring companies to provide data for new uses of chemicals. EPA has proposed using this approach in two cases. In one case, for example, EPA proposed this approach for certain flame retardants that are being voluntarily phased out, effective December 2013. Under the proposed rule, any new use of the chemical after it has been phased out would qualify as a significant new use, triggering a testing requirement. According to EPA officials, the pairing of these types of rules is intended to discourage new uses of certain chemicals that may pose a risk to human health or the environment and create a disincentive for companies to continue current use of the chemical—something EPA has not done before. OMB’s review of this proposal took 422 days and was completed on February 15, 2012.
- *Extending significant new use rules to articles.* Since 2009, EPA has made increasing use of its ability to subject chemicals contained in certain products, or “articles,” such as furniture, textiles, and electronics, to significant new use rules. Generally, those who import or process a substance as part of a product are

²⁵These three groups are: (1) a category of eight phthalates, (2) a category of polybrominated diphenylethers (PBDE), and (3) bisphenol A (BPA).

exempted from compliance with a significant new use rule. EPA's proposals would eliminate this exemption for certain chemicals.²⁶

However, it is too early to assess the impact of EPA's proposed actions because they have yet to be finalized. In addition, in some cases, OMB has not met the established 90-day time for reviewing EPA's proposed actions—which has increased the time frames for formally proposing and finalizing them.²⁷ In particular, the period for OMB review is generally limited by executive order to 90 days, although it can be extended.²⁸

It Is Unclear Whether EPA's New Approach Will Position the Agency to Achieve Its Goal of Ensuring the Safety of Chemicals

As we reported in March 2013, it is unclear whether EPA's new approach to managing chemicals within its existing TSCA authorities will position the agency to achieve its goal of ensuring the safety of chemicals. EPA officials have said that the agency's new approach, initiated in 2009 and summarized in its 2012 *Existing Chemicals Program Strategy*, is intended to guide EPA's efforts to assess and control chemicals in the coming years. However, EPA's strategy, which largely focuses on describing activities EPA has already begun, does not discuss how it will address challenges discussed earlier associated with obtaining toxicity and exposure data and banning or limiting the use of chemicals as follows:

- *Obtaining toxicity and exposure data.* EPA's strategy does not discuss how the agency will meet the challenge we described related to obtaining the toxicity and exposure data it will need to conduct all risk assessments. In particular, as discussed previously, EPA has not broadly sought toxicity and exposure data that companies submit to foreign governments; instead EPA plans to obtain these data on a

²⁶In spring 2012, EPA proposed three significant new use rules that would require companies to report new uses of five groups of chemicals, including in domestic and imported articles. EPA has used this approach before but infrequently. EPA first eliminated the article exemption for a chemical substance in 1991, when it promulgated a significant new use rule for erionite fiber, and it used the same approach for a significant new use rule pertaining to the use of elemental mercury in certain switches in 2007.

²⁷Any rules that EPA plans to issue under TSCA that are considered significant regulatory actions, as defined by Executive Order 12866, are subject to review by the Office of Information and Regulatory Affairs, an office within OMB, prior to being proposed in the *Federal Register*. Among other things, a significant regulatory action may have an annual effect on the economy of \$100 million or more or raise novel legal or policy issues.

²⁸Under Executive Order 12866, the review period may be extended by the head of the rulemaking agency, and the OMB Director may extend the review period once for no more than 30 days.

case-by-case basis from chemical companies. However, the agency's strategy does not discuss how EPA would execute these plans or how the data obtained would be used to inform the agency's ongoing or future risk assessment activities, if at all.

- *Banning or limiting the use of chemicals.* EPA's strategy does not articulate how the agency would overcome the regulatory challenges it experienced in the past. In particular, EPA officials told us that, even if EPA has substantial toxicity and exposure data, the agency is challenged in meeting the statutory requirement under section 6 of TSCA to limit or ban chemicals.

Further, EPA's strategy does not identify the resources needed to meet its goal of ensuring chemical safety. For example, EPA's strategy does not identify the resources needed to carry out risk assessment activities, even though risk assessment is a central part of EPA's effort to manage chemicals under its new approach. Specifically, EPA does not identify roles and responsibilities of key staff or offices—for example which office within EPA will develop the toxicity assessments needed to support its planned risk assessments—or identify staffing levels or cost associated with conducting its risk assessment activities. Without a clear understanding of the resources needed to complete risk assessments and other activities identified in its strategy, EPA cannot be certain that its current funding and staffing levels are sufficient to execute its new approach to managing chemicals under existing TSCA authorities.

When developing new initiatives, agencies can benefit from following leading practices for federal strategic planning.²⁹ Of these leading practices, it is particularly important for agencies to define strategies that address management challenges that threaten their ability to meet long-term goals. In our March 2013 report,³⁰ we stated that without a plan that

²⁹The strategic planning elements established under the Government Performance and Results Act (GPRA) of 1993 and associated OMB guidance and practices we identified, taken together, can serve as leading practices for strategic planning at lower levels within federal agencies, such as planning for individual divisions, programs, or initiatives. Leading practices in federal strategic planning include defining mission and goals, involving leadership and stakeholders, developing performance measures, and developing strategies to address management challenges and resources needed, among others. See GAO, *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011); see GAO, *Environmental Protection: EPA Should Develop a Strategic Plan for Its New Compliance Initiative*, GAO-13-115 (Washington, D.C.: Dec. 10, 2012).

³⁰GAO-13-249.

incorporates leading strategic planning practices—particularly a plan that clearly articulates how EPA will address management challenges—EPA cannot be assured that its new approach to managing chemicals, as described in its *Existing Chemicals Program Strategy*, will provide a framework to effectively guide its efforts. Consequently, EPA could be investing valuable resources, time, and effort without being certain that its efforts will bring the agency closer to achieving its goal of ensuring the safety of chemicals. As a result, we recommended that the EPA Administrator direct the appropriate offices to develop strategies for addressing challenges that impede the agency's ability to meet its goal of ensuring chemical safety to better position EPA to ensure chemical safety under its existing TSCA authority. In its written response to our March 2013 report,³¹ EPA's Acting Assistant Administrator stated that change is needed in every significant aspect of the program, and, while strategic planning is a useful exercise it cannot substitute for the basic authorities needed for a modern, effective chemicals program. Moreover, the Acting Assistant Administrator stated that it is EPA's position that, absent statutory changes to TSCA, the agency will not be able to successfully meet the goal of ensuring chemical safety now and into the future.

Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee, this concludes my prepared statement. I would be happy to respond to any questions that you or Members of the Subcommittee may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff members have any questions about this testimony, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions include Diane LoFaro, Assistant Director; Diane Raynes, Assistant Director; Elizabeth Beardsley; Richard Johnson; Alison O'Neill; and Aaron Shiffrin.

³¹GAO-13-249.

Related GAO Products

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Mr. SHIMKUS. Thank you.

The chair now recognizes Beth Bosley, President of Boron Specialties, LLC. You are recognized for 5 minutes.

STATEMENT OF BETH BOSLEY

Ms. BOSLEY. Good morning, and thank you for inviting me here today. I am the President of Boron Specialties. We are a small fine-chemical manufacturer. We are passionate about making our products here in the United States, and we currently invest every dollar we make into accelerating our growth. We are very small, only six people altogether. We are also committed to responsible operation of our business including environmental stewardship and regulatory compliance, very important to me personally as a business owner. It is in the spirit of running a globally competitive business while protecting health and safety of our employees and the public that I speak to you today about TSCA.

At the outset, I would like to make three general points on my perspective on how to update TSCA. First, TSCA is a law regulating chemical substances, not food, not drugs, and not pesticides. TSCA gives EPA the regulatory authority to regulate unreasonable risk to human health and the environment. It also regulates a broad range of chemicals. Many of those chemicals are industrial chemicals, and by that, I mean chemicals that are sold between chemical companies but not necessarily part of consumer products and not necessarily with any exposure to the public.

The second point to bear in mind is the concept of risk. Risk is a combination of two things. It is both hazard and exposure, and one of EPA's jobs under TSCA is to do risk assessments and to make judgments about whether reasonably anticipated uses of chemicals would present sufficient probability of harm to people or the environment, and if so, then they are to restrict those uses.

Finally, smart regulation can and should achieve its objectives without inhibiting innovation. American companies like mine are on the cutting edge of chemical innovation. TSCA has allowed us to lead the world in this regard. Any amendments to TSCA must preserve time frames and flexibility but allow this innovation to continue. They must also protect confidential business information that is at the heart of all innovation.

It is really easiest to look at TSCA in terms of existing and new chemicals, and you have heard a little bit about that already this morning. New chemicals are any that are not in commerce currently, and prior to manufacturing those new chemicals, companies like mine must submit what it is called a Premanufacture Notice, or PMN, and submitted PMNs must provide all the data that they have or that they can reasonably ascertain about a chemical substance, and while it is true that upfront testing is not required, EPA is able to employ predictive technologies which interprets quite conservatively to help decide if a new chemical raises concern. Through the new chemicals program, EPA reviews roughly 2,000 chemicals every year, and that really reflects the state of innovation in the United States. It is also worth considering that new chemicals are often greener than those that they are replacing since minimizing a company's eco footprint is really a driver for innovation.

Existing chemicals are those, as you have heard, that are already on EPA's inventory. The inventory consists of chemicals that were in commerce in the late 1970s plus the chemicals that EPA has reviewed through the new chemicals program. It is often referred to as over 80,000 substances. However, EPA's 2012 survey concluded that fewer than 8,000 chemicals are actively in commerce, and that is defined as being manufactured at a rate of 12½ tons per year at any single site in the United States. While the current TSCA regulation grants EPA the authority, the Agency has no mandate to assess existing chemicals, as I think you have heard from every person on the panel so far. Not surprisingly, non-mandated programs lose out in the competition for budget resources.

Furthermore, when EPA does identify existing chemicals on which it needs more data, it has to go through a time-consuming rulemaking process to request testing, even when companies might be in full agreement with that testing. EPA has developed work-around mechanisms to collect the information that it needs, and those are voluntary programs and consent agreements, which industry participates in.

Section 6 authorizes EPA to restrict chemicals that present an unreasonable risk, and this authority has seldom been used and is at the center of the debate over TSCA. EPA's ability to restrict existing chemicals that do not meet a safety standard could be improved by eliminating some of these significant procedural burdens. While this section certainly needs improvement, and it is true that few chemicals have been restricted under it, be mindful that chemicals may be regulated under other sections of TSCA as well. As a matter of fact, most chemicals can be and are used safely. This is why rather than banning substances outright, EPA has opted to restrict their uses instead.

The provision on confidential business information in Section 14 has historically worked well to protect trade secrets and promote innovation. However, many of the claims have gone unchecked, creating a negative stigma around the concept of CBI. Protecting information regarding chemical identity and process technology are essential to maintain a competitive edge for innovative U.S. manufacturers but there are improvements that can absolutely be made to the CBI process. And please bear in mind that EPA staff sees all information, whether or not it is labeled as CBI.

As a specialty chemical manufacturer and a small business, I can say unequivocally that protection of chemical identity can be critical. Given the narrow application for which specialty chemicals are used and the niche markets they serve, disclosure of chemical identity may be all it takes to give away a competitive advantage to an offshore manufacturer. The majority of Freedom of Information Act requests to EPA come from companies, many of which are overseas, not curious members of the public. This Act underscores the real threat of losing America's innovative advantage.

That concludes my oral testimony, and I would be happy to take any questions.

[The prepared statement of Ms. Bosley follows:]



Testimony
of
Beth D. Bosley

President
Boron Specialties, LLC

Before the

U.S. House of Representatives

Energy and Commerce Committee
Subcommittee on Environment and the Economy

On

“Title I of the Toxic Substances Control Act: Understanding its History
and Reviewing its Impact”

June 13, 2013

Good morning, Chairman Shimkus, Ranking Member Tonko, and members of the Subcommittee. My name is Beth Bosley, and I am the President of Boron Specialties in Pittsburgh, Pennsylvania. Boron Specialties is a specialty chemical manufacturer and a small business. I am passionate about making our products in the United States, and about job creation. We currently reinvest every dollar we make (and more) in accelerating growth. We are also committed to responsible operation of our business, including environmental stewardship and regulatory compliance. It is in the spirit of running a globally competitive business while protecting the health and safety of our employees and the public that I speak to you today about the Toxic Substances Control Act (TSCA).

At the outset, I'd like to make three general points that the subcommittee should bear in mind as it thinks about whether and how to update TSCA.

First, TSCA is a law about products, not pollution. And it covers almost all products -- it gives the EPA authority to regulate "unreasonable risk" to humans and the environment from all chemicals and uses that aren't covered by some other more targeted statute. Contrast this approach with the laws that regulate those more narrow universes of products -- pesticides, drugs and food additives. The chemicals used in these specialized products have specific characteristics and exposure pathways. Pesticides are designed to kill pests, drugs are intended to be bioactive, and food additives are intended to be eaten. Congress created exclusions from TSCA for these separately-regulated chemicals and certain others, making it the default statute for everything else -- an enormous variety of chemicals and uses.

Over the years, TSCA has been criticized on many fronts, largely due to the emergence of international chemical control regulations, a growing patchwork of state and local laws, and de facto "retail regulation." Advances in the ability to detect chemicals at extremely low concentrations have also helped raise awareness of the pervasiveness of chemicals in the environment, although it is important to understand that a detectable presence of a chemical does not equate to harm, as the Centers for Disease Control (CDC) has regularly noted. The EPA has had trouble implementing some parts of the statute, and some have attributed this to shortcomings in TSCA (excessively so, in my view).

The second overarching point to bear in mind is the concept of risk. By definition, risk is a function of two things: (1) a chemical's intrinsic properties and (2) the degree to which anyone is exposed to the chemical through the ways it is used. Risk, in other words, requires both hazard and exposure. EPA's job under TSCA is to assess both of these and make a judgment about whether the reasonably anticipated uses of a chemical would present a sufficient probability of harm to people or the environment that we should limit those uses.

Last -- but perhaps most important -- smart regulation can and should achieve its objectives without inhibiting innovation. This isn't an abstract issue - American companies like mine are on the cutting edge of chemical innovation, regularly developing new chemicals for themselves or on a contract basis for other companies. TSCA has allowed us to lead the world in chemical innovation, and has done so without jeopardizing our nation's health or the environment. Any

amendments to TSCA must preserve the timeframes and flexibility that allow this innovation to continue. They must also protect the confidential business information that is at the heart of innovation. The specific chemical identities of new molecules, and the details of the processes by which we make them, are our competitive advantages and the way we support innovation across the economy.

On balance, much of TSCA has worked, some areas have not worked as intended, and some areas fall in between.

It is easiest to look at TSCA in terms of new chemicals and existing chemicals. The new chemicals program I believe has done its job admirably. The existing chemicals program, on the other hand, has not worked quite as intended and could be improved. Reporting requirements and the treatment of US intellectual property, or Confidential Business Information (CBI), are areas that fall in between.

As a general matter section 5 of TSCA and the EPA's new chemicals program have been a success.

New chemicals are any that are not on the TSCA inventory of chemicals "in commerce." Prior to manufacturing or importing a new chemical substance, a company must submit to EPA a pre-manufacture notice or PMN. PMN submitters must provide all information on that substance that is known or reasonably ascertainable. While upfront testing is not required, EPA is able to employ predictive technology or models – which it interprets quite conservatively – to help decide if a new chemical raises a concern. It can also use available data, and look to similar substances for comparison. EPA has 90 days to review a PMN, but it can and frequently does request an extension pending regulation or collection of more information. Most chemical reviews are completed by EPA within three weeks and conclude that the chemical will not present an unreasonable risk.

The new chemicals program also offers exemptions to full PMN requirements that can allow for reduced reporting and shorter review. Among others, several important examples are the polymer exemption and low volume exemption. The polymer exemption requires an annual report to EPA and the low volume exemption allows manufacturers to get "low volume" (production at less than 10MT annually) chemicals to market within 30 days.

Another important exemption is the R&D exemption. Under the R&D exemption, companies are able to perform research on the production of the chemical and, in fact, may produce it at a small quantity to assess the hazards, the market, and the economics of commercial manufacture. However, no production for any commercial purpose is permitted until a PMN is submitted and approved. Defined recordkeeping and notification requirements are in place to ensure control of R&D chemicals.

Through the new chemicals program, EPA reviews roughly 2,000 chemicals every year. This reflects the rate of chemistry innovation in the U.S., and it is a prevailing view in our industry

that the regulatory process must continue to support this level of throughput in any future program to avoid a serious economic impact and competitive disadvantage for U.S. business. To date, EPA has reviewed about 52,700 new chemical PMNs and exemption notifications, dwarfing other industrial nations. EPA has a lot of experience here.

Only about half of the new chemical notifications reviewed are ever marketed commercially. Since not all of the R&D needed has been completed before a PMN must be filed, there can be any number of reasons a company chooses not to move forward with commercial production – the market may not develop as estimated, technical problems may be encountered with the downstream process, or pending regulation may make the product economically unfeasible.

At the early stage of product development, it is not surprising that detailed studies have not been conducted. Companies often test the market at small scale to determine if a substance is commercially viable and has the potential to recoup investment. I believe the EPA understands this and, as such, developed these state of the art tools and put programs in place that facilitate innovation, while protecting human health and the environment based on the relative scale of risk as commercialization proceeds. Conversely, the cost of blanket testing requirements without consideration of scale would discourage many new chemicals from ever being developed.

It's also worth considering that new chemicals are often "greener" than those they would replace, since minimizing a company's eco or health footprint is a powerful driver for innovation. The new chemicals program and exemptions are critical to American competitiveness and to my ability to stay in business. They have also helped EPA manage its workload successfully.

Information on the universe of chemicals known as existing chemicals is misleading.

Existing chemicals are those that are on EPA's TSCA inventory. The inventory consists of chemicals that were in commerce in the late 1970s when TSCA was first implemented, plus chemicals that have since been reviewed by EPA's new chemicals program and subsequently manufactured. The inventory currently has about 84,000 chemicals. The TSCA inventory is not, however, an accurate reflection of chemicals in commerce. In fact, it is highly misleading – EPA's 2012 survey concluded that fewer than 8,000 chemicals are actively in commerce, defined as being manufactured at the rate of 12.5 tons/year at a single site somewhere in the U.S. (This does not include exempted substances.) The inventory could be improved by dividing it into an "active" and "inactive" list, where EPA could focus its resources on active chemicals in commerce. This would also improve transparency and the public's understanding of the list.

EPA's efforts to evaluate chemicals in commerce have been inconsistent and time-consuming.

Another shortcoming with TSCA is the lack of a mandate for EPA to screen chemicals in commerce for potential data needs, and to do so in a timely manner (though the current TSCA

does give EPA this authority). Most stakeholders agree that EPA should be required to prioritize chemicals in commerce in a comprehensive, transparent and risk-based fashion, but EPA has not been required to do this by law. As a consequence, various administrations have put different programs in place over the years, all of which have tended to lose out in the competition for budget resources to programs that have mandates. This has hampered progress on the review of existing chemicals. A prioritization scheme for existing chemicals is particularly important to optimize federal resources during a time of budget challenges such as sequestration.

Furthermore, when EPA does identify existing chemicals on which it needs more data, it has had to go through time-consuming rulemaking via section 4 of TSCA to request testing even when companies might be in agreement. EPA has developed work-around mechanisms to collect the information it needs, such as voluntary programs and consent agreements, but procedurally, EPA's regulatory efforts for testing have been unnecessarily slow and could be improved.

EPA's ability to restrict existing chemicals that present an "unreasonable risk" has also faced procedural burdens.

Section 6 of TSCA authorizes EPA to restrict chemicals that present an "unreasonable risk." This authority has been seldom used and is at the center of debate over TSCA's effectiveness. EPA and critics of TSCA have pointed to the infamous *Corrosion Proof Fittings* case (*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991)), which EPA lost when trying to ban asbestos. Despite previously successful use of this authority on other substances, EPA has been reluctant to use it since. Regarding the asbestos case, it may have been a better approach if EPA had considered regulation of critical, very low exposure uses, rather than an outright ban. It is also essential that EPA fairly consider the substance of all comments before proceeding with a ban.

Nevertheless, EPA's ability to restrict existing chemicals that do not meet a safety standard could be improved by eliminating significant procedural burdens. I suggest that EPA should be permitted to:

- Act through conventional informal rulemaking; and
- Limit its obligation to consider the burdens of alternative approaches to those approaches that are identified by commenters on the proposed rule.

If EPA has to evaluate alternatives identified by commenters on a proposed rule and choose between the least burdensome of those, instead of it having to identify them, much of the burden on EPA in the future could be alleviated.

While this section could certainly be improved, and it is true that few chemicals have been restricted under it, be mindful that many chemicals may be regulated under other sections of TSCA. As a matter of fact, most chemicals can be and are used safely. This is why, rather than banning substances outright, EPA has opted to restrict their uses instead.

EPA continues to improve its ability to collect information on chemicals, but more could be done.

Generally speaking, section 8 of TSCA, the record keeping and reporting provision, meets EPA's need to collect information on chemical substances. EPA continues to enhance, through existing authority, its ability to gather basic information on chemicals in commerce. It gathers information such as production and import volumes and industrial worker exposures, through its periodic chemical data reporting requirements, which apply to manufacturers and processors. The primary remaining problem is EPA's inability to collect use and exposure information from downstream entities. Oftentimes, manufacturers and processors are not privy to information on exposures and uses downstream of them. In many cases, their customers are also their competitors and want to keep this information confidential. TSCA could thus be improved by authorizing EPA to require reporting from distributors and nonconsumer end users of chemicals. These entities are likely to have much more accurate information about use and exposure scenarios than upstream manufacturers like myself.

TSCA section 8(e) requires companies to submit data they receive on any substance when the data supports a conclusion that it presents a substantial risk of harm to human health or the environment. There are no exemptions from 8(e) reporting – it is considered an early warning mechanism for adverse effects. Most companies err on the side of caution and submit data that suggests *any* risk. Through June 2012, EPA had received about 19,000 8(e) submissions. EPA can leverage this data to guide its regulatory decision-making when evaluating other chemicals that may be similar. The problem now is that this section is biased – it only calls for submission of adverse data. Many companies have test data demonstrating a lack of adverse effects. EPA's understanding of chemical hazards could be substantially improved by authorizing submission of non-adverse data and requiring EPA to consider such data during risk assessment efforts.

Protection of confidential business information is crucial to small businesses' and America's competitiveness, but over-claiming and lack of EPA oversight have created problems.

The ability to innovate is what enables my company to remain competitive and protection of trade secrets is essential to guard companies' valuable innovations from unfair competition.

The provision on confidential business information, section 14, has historically worked well to protect trade secrets and promote innovation. However, over many years claims have gone unchecked, creating a negative stigma around the concept of CBI. Furthermore, the statute is less clear than it could be about when the specific identity of a chemical should be protected as a trade secret. EPA's current interpretation creates uncertainty about whether chemical names are confidential when they are contained in health and safety studies

Bear in mind that EPA staff sees all the data that are submitted to them – CBI restrictions do not bar them from access to data. As for publically available information, health and safety studies are not allowed to be claimed CBI, and that is as it should be. But, strictly speaking, detailed

chemical identity is not an essential element of health and safety studies. That is, you do not need to know the precise name of a molecule to understand a study of that chemical and whether, based on that study, a chemical should be restricted. This should be clarified in the law and robust generic names guidance should be developed.

Consideration should also be given to requiring for up-front substantiation, and periodic re-substantiation, of CBI to avoid claims that remain in place longer than necessary. EPA should be permitted to share CBI with other Federal agencies and with state and foreign governments that, in practice, provide protections equivalent to those provided by EPA.

As a specialty chemical manufacturer and small business, I can say unequivocally that the protection of chemical identity can be critical. Given the narrow applications for which specialty chemicals are used and the niche markets they serve, disclosure of chemical identity may be all it takes to give away a competitive advantage to an offshore manufacturer. Simply stated, the incentive to develop greener chemicals largely disappears if prospective manufacturers know the risk is high of having their good idea being revealed. The majority of Freedom of Information Act requests to EPA come from companies, many of which are overseas, not curious members of the public. This fact underscores the real threat of losing a trade secret. The subcommittee must consider the issue of CBI in this context.

A federal effort to improve TSCA's shortcomings is appropriate, but the approach should not overlook or undermine the many ways in which TSCA has worked effectively for over three decades.

This subcommittee's review of TSCA should consider potential impacts on small businesses and the unique nature of the U.S. specialty chemical industry. Decisions must always be driven by sound science. Congress should also look at other statutes that regulate chemicals, and international efforts, as it assesses what might be improved. Regular oversight by Congress will help assess where TSCA currently demonstrates effectiveness, where it could be implemented better, and where revision is necessary.

Thank you for this opportunity to share my perspective on TSCA, and I look forward to your questions.

Mr. SHIMKUS. Thank you very much.

Now the chair recognizes Mr. Daniel Rosenberg, Senior Attorney under the Health and Environment Program of the Natural Resources Defense Council. Sir, you are recognized for 5 minutes.

STATEMENT OF DANIEL ROSENBERG

Mr. ROSENBERG. Thank you, Chairman Shimkus and Ranking Member Tonko and members of the committee. Thank you for the opportunity to testify today. It is good to see the committee re-engaging on this issue.

To be blunt, TSCA is widely recognized as a failure. It has not enabled EPA to protect the public or even to assess the risks the public may face from many commonly used chemicals. It has not provided the confidence that chemical manufacturers desire from their consumers and retailers. It is no wonder the EPA, the GAO, scientists, health advocates, doctors and business leaders are all calling for reform.

TSCA is riddled with fundamental structural flaws. Other environmental laws, though controversial, have been fair more effective. Perhaps the greatest original sin under TSCA was to grandfather the 62,000 chemicals on the market in 1976. There was no requirement for EPA to review those chemicals or to hold them to any safety standard. In nearly 35 years, EPA has managed to require testing of only about 200 of those substances, and has partially regulated only five. That is a problem because it means that chemicals that are known to cause harm including cancer, learning disabilities and reproductive problems in animals or humans remain in widespread use.

And many chemicals are in use for which we don't have sufficient information to know whether or not they are safe. This is a public health concern, particularly considering the rising rates of cancer, mental illness and other chronic diseases in our country. One in two men develop an invasive cancer and one in four die from cancer—one in four men in the United States. One in three women develop invasive cancers, and one in five die. Roughly 1.5 million people in the United States are diagnosed with cancer each year. The CDC just released a study of mental illness in children and found 13 to 20 percent, 7 to 12 million, have mental health disorders including ADHD, mood and anxiety disorders, and autism spectrum disorders. Those rates are rising.

EPA's ability to fully assess and regulate chemicals is not much better for the approximately 22,000 chemicals that have been brought to market since TSCA was enacted. The law gives EPA only a brief period—3 to 6 months—to review new chemicals and makes it hard for EPA to get the needed data. Most Premanufacture Notices are submitted to the Agency without any data on health or environmental effects. EPA has taken steps to fill the gaping holes in its authority and clear the high hurdles set by the statute, but that is not an adequate substitute for a protective system for reviewing new chemicals.

But even beyond timing and data requirements, TSCA stacks the deck against EPA and public safety. The statute places the burden on EPA to prove that a chemical poses a risk and then sets a high threshold for making such a finding. This is markedly different

from other effective health and safety laws. Makers of pharmaceuticals and pesticides have to show affirmatively that their products are safe, and the food quality law, the Food Quality Protection Act, that was passed unanimously by a Republican Congress, had a more protective risk or safety standard.

The experience with TSCA teaches the unsurprising but essential lesson that laws without enforceable deadlines and strong safety standards don't result in action and don't protect the public.

The impotence of TSCA has left a vacuum that has been filled by States and retailers. Nineteen States are currently regulating chemicals with policies ranging from bans on specific uses to disclosure requirements. This does not include mercury product bans and other policies adopted in 34 States to limit exposure to mercury. In addition, large retailers have stopped stocking some products or excluded chemicals from their supply chains. While these important actions have increased public protection in a piecemeal fashion, they are a supplemental but are no substitute for a working federal system. States and retailers have had to act, though, because of mounting scientific evidence and increasing public concern.

Scientists know more about the impact of chemicals than in 1976. There are greater concerns now about the effect chemicals can have on our endocrine system and about the potential impacts of even small doses of certain chemicals. We also have more information about ongoing exposure of hundreds of substances due to the development of biomonitoring. The public understands this.

NRDC has commissioned a number of polls to survey public opinion on the question of chemical reform. In both our poll and those of others, we see strong public support for real TSCA reform. Among the findings of our national poll, which is about a year old now, over two-thirds of voters, 68 percent, support "stricter regulation of chemicals produced and used in everyday products." This support cuts across every political group including majorities of GOP voters—57 percent; independence—66 percent, and Democrats—79 percent. The support was even stronger for specific legislation to reform TSCA. A description of legislation that would require all chemical manufacturers to show that their chemicals are safe in order to sell them and that EPA would be able to limit some or all uses of a chemical that may harm public health or the environment yielded 77 percent support with 50 percent strongly supporting. Support, again, cut across all political, ethnic, gender and regional lines. This is an issue where Washington is way behind the people it represents.

I think TSCA's one clear success has been the phase-out of PCBs that was mandated in the original law in 1976. Representative Dingell led the fight to include the PCB provision in the law, and while PCBs are still very much with us and in us, it at least did what the title of the law promises: it controlled a toxic substance.

Congress should learn from that vision and take steps to really repair TSCA and protect the public, for example, requiring the phase-out of other persistent bioaccumulative and toxic PBT chemicals. There are many ways in addition to phasing out PBTs to reform TSCA in a way that protects the public and also allows the chemical industry to thrive and innovate. We would welcome the

chance to work with the committee and all interested parties to develop such reform.

Thank you very much for the opportunity to testify.

[The prepared statement of Mr. Rosenberg follows:]

STATEMENT OF

DANIEL ROSENBERG
SENIOR ATTORNEY
NATURAL RESOURCES DEFENSE COUNCIL (NRDC)

BEFORE
THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

AT A HEARING ON

TITLE I OF THE TOXIC SUBSTANCES CONTROL ACT; UNDERSTANDING ITS HISTORY
AND REVIEWING ITS IMPACT

13 JUNE 2013

Thank you for the opportunity to testify at this hearing on the topic: "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

As you know, the Toxic Substances Control Act (TSCA) was enacted in October, 1976 – the end product of attempts to enact a statute over five years. The initial proposal for the law that ended up becoming TSCA came from the Council of Environmental Quality (CEQ) under the Nixon Administration. In 1971, the CEQ issued a report on the state of regulation of toxic chemicals in the U.S. and found there was "a high-priority need for a program of testing and control of toxic substances....We should no longer be limited to repairing damage after it is done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory."

TSCA is focused on the manufacturing, processing, distribution, use and disposal of industrial chemicals, including those used in many commercial and consumer products. Excluded from the jurisdiction of TSCA are substances whose uses are otherwise regulated including pharmaceuticals, pesticides, nuclear materials, tobacco, and radioactive materials.

Whether or not it was widely understood at the time, the final enacted version of TSCA contained several major flaws that have contributed to the law's ineffectiveness and overall lack of success. These flaws include:

- grandfathering of the 62,000 chemicals then in use without a mandate for EPA to require testing and review chemicals to meet a safety standard,
- placing the burden of proof on EPA to prove the harm of a chemical, rather than on the chemical industry to prove its safety (as is required for pesticides and pharmaceuticals);
- failure to require a minimum data set sufficient for the evaluation of new chemicals;
- limitations on EPA's ability to require testing other than via a rulemaking,

- a safety standard of “unreasonable risk,” further burdened and weakened by the “least burdensome” test;
- allowing Confidential Business Information (CBI) to be claimed without upfront justification (and review by EPA) and without a nominal sunset date absent re-justification.

Taken together, these elements have led to a program that has done almost nothing to regulate or protect the public from existing chemicals; and has approved the use of thousands of new chemicals, based on estimates of their safety that have relied on incomplete information.

The law did contain at least one positive element: a specific Congressional phase-out of the production and distribution of poly chlorinated biphenyls (PCBs) a persistent, bioaccumulative toxin. PCBs have been classified as probable human carcinogens by EPA, the U.S. National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). They have been shown to cause cancer in humans as well as non-cancer effects including effects on the immune system, reproductive system, nervous system and endocrine system. It was Congressman John Dingell who led the successful effort to add the ban on PCBs on the floor of the House in 1976.

In the years after enactment, EPA established the “TSCA inventory” a list of chemicals manufactured, imported or processed in the United States. The inventory of existing chemicals in 1982 was approximately 62,000 substances. Over the past 30 years, approximately 22,000 additional chemicals have been added to the inventory through the new chemicals program, for an approximate total of 84,000 chemicals on the inventory.

On balance, both the assessment and regulation of existing and new chemicals over the life of TSCA has been extremely limited – a point made repeatedly by the Government Accountability Office, as well as many other commentators, including EPA.

Existing chemicals

As noted above, TSCA grandfathered all of the chemicals in use, or available for use, at the time it was enacted, -- roughly 62,000 chemicals, without requiring that they meet a safety standard, or that EPA require testing of those substances. The law contained no general mandate for EPA to review the safety of those chemicals, and no minimum performance requirements or deadlines for performing such reviews. With a few exceptions, TSCA's existing chemicals program has been almost a dead letter since the day it was enacted. Since 1976, EPA has taken Section 6 action on only 5 substances. In addition to the steps taken to implement the phase out of PCBs required by Congress, these include: prohibiting the transfer of dioxin waste from a facility in Arkansas and requiring notice of disposal of TCDD wastes, phasing out the non-essential use of fully halogenated chlorofluoroalkanes as propellants in aerosol spray containers, banning the use of hexavalent chromium in comfort cooling towers, and an attempted ban on new and existing uses of asbestos.

EPA's attempt to ban asbestos and the subsequent overturning of its ban on existing uses is perhaps the central historical moment of TSCA, and one that remains the subject of dispute more than 20 years later. Asbestos is a known cause of several types of deadly illness including lung cancer and mesothelioma. As little as one single day of exposure to asbestos has been associated with deadly cancer which may not manifest itself for decades. The threat is not only posed to those industrial workers who are exposed on the job, but also to family members exposed when the fibers come home on a worker's clothes. Approximately 10,000 people are estimated to die each year in the United States from asbestos-related illnesses.

EPA spent ten years on its asbestos rulemaking, building an administrative record of more than 45,000 pages, demonstrating that asbestos posed an unreasonable risk to human health and the environment.

EPA concluded that only a phase-out of most uses of asbestos would be sufficient to protect the public, and the agency finalized a rule mandating such a phase-out.

EPA's final rulemaking was challenged in court and heard by the U.S. Court of Appeals for the Fifth Circuit in a decision known as the *Corrosion Proof Fittings* case. In that decision, the court ruled that EPA had not sufficiently demonstrated that it had chosen the "least-burdensome" approach to regulating asbestos, to meet the "unreasonable risk" standard. The court also criticized EPA from not considering the safety and cost of proposed alternatives to asbestos. The court rejected EPA's ban on existing uses of asbestos, and upheld its ban on any future new uses and any past but not current uses.

Since the court's decision in *Corrosion Proof Fittings* in 1991, EPA has not attempted another regulatory action for an existing chemical under Section 6 of TSCA. The court imposed a strict requirement for cost-benefit analysis, -- including an analysis of the costs and benefits of each of the regulatory options that are articulated in the law -- which commentators believe is the primary reason no additional regulatory actions under Section 6 have been attempted¹.

There are a range of views on the merits of court's decision in *Corrosion Proof Fittings*. What is clear though is that more than three-and-a-half decades after TSCA was enacted EPA has taken no regulatory action on virtually the entire inventory of 62,000 chemicals that were grandfathered, including existing uses of asbestos. Products containing asbestos are still imported into the U.S., and people continue to be exposed. Meanwhile, more than 50 other countries have adopted asbestos bans.

There are hundreds of chemicals besides asbestos that we already know are unsafe, or that are subject of ongoing study and concern. These include known and probable carcinogens, neurotoxicants, and

¹ See Testimony of Lisa Heinzerling before the Subcommittee on Environment and Hazardous Materials of the Committee on Energy and Commerce, U.S. House of Representatives, Hearing on "POPs, PIC, and LRTAP: The Role of the U.S. in Draft Legislation to Implement These International Conventions" July 13, 2004 and Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 Tex. L. Rev. 525, 541-49 (1997).

reproductive toxicants. It is astounding to many people to learn that EPA has taken no action to regulate the use of these and other chemicals under TSCA. TSCA needs to be amended to make it easier to take regulatory action on chemicals of concern – ranging from requiring labeling, use limitations, record retention, disposal limits up to and including bans and phase outs.

New Chemicals

Although the new chemicals program has managed to function better than the program for assessing and regulating existing chemicals, it has been hindered by key constraints that have limited its ability to ensure the safety of new chemicals entering the marketplace. These include the short period allowed for EPA to review pre-manufacture notices, , EPA's lack of authority to designate a minimum data set necessary for assessing the safety of new chemicals, and its inability to require testing by order rather than rulemaking or voluntary consent. In addition, the burden is on EPA to prove that a proposed new chemical may pose an unreasonable risk to human health or the environment rather than the burden being placed on chemical manufacturers to demonstrate the safety of their products. EPA has done its best with these limitations of the law to assess the safety of new chemicals and protect the public. In a limited number of cases EPA has imposed conditions of use on new chemicals, or raised concerns that have led to a company to withdraw its pre-manufacturing notice and forego production of the chemical. EPA has also developed methods for reviewing new chemicals for safety in the absence of easy access to the underlying data they might otherwise have. This includes comparing proposed chemicals with other known chemicals for structural similarities to help predict how they might behave in the environment and in people. While these methods can be useful for determining certain characteristics like persistence, bioaccumulation and ecotoxicity, they fall short in other areas including anticipating harmful impacts on mammals such as reproductive and developmental toxicity. Unlike under TSCA,

virtually all other industrial countries require potential manufacturers of a chemical to provide a minimum set of data up front with which the reviewing government can assess the chemical.

A further limitation under TSCA is that once a new chemical is added to the TSCA inventory – unless a Significant New Use Rule (SNUR) has been adopted at the outset – anyone may then produce the chemical, in whatever quantity, and for any number of uses – which may or may not have been considered under the original pre-manufacturing review by EPA – and with no notice to EPA required. This is one reason we now are in a situation where we don't have a clear picture of how many chemicals are actually in use in commerce, at what volumes, and for what uses. While the EPA's newly revised Chemical Data Reporting (CDR) requirements for periodically updating the TSCA inventory will provide some additional information, it is still very much an incomplete picture.

One other significant aspect of TSCA that must be mentioned is the current protections for Confidential Business Information (CBI). Let's stipulate up front that there is a category of information that most people agree should be considered CBI, at least for a reasonable period of time, and a category of information that does not qualify as CBI. There is a third category where there is less agreement, and is subject to debate. Unfortunately, under the existing TSCA, the CBI provisions are written and implemented in a way that allows information from all three categories to be swept into the protection of CBI, with no sunset for those information protections – resulting in the public having less access to information about chemicals, their uses, and their potential health effects than they should. The identity of some 16,000 chemicals on the TSCA inventory remains protected as CBI.

While EPA is thus severely constrained from regulating either new or existing chemicals under the current TSCA, the Administrator does have the authority to publish a list of chemicals of concern, based on a finding that such chemicals present or may present an unreasonable risk of injury to health and the environment. This provision allows EPA to inform the public, even when no regulatory action is

contemplated. However, the so-called “chemicals of concern” provision (which, in the early days of TSCA was also referred to as the “risk list”) has never been exercised by EPA. The previous Administrator of EPA was the first to attempt to use the provision, but EPA’s proposed rule to initiate notice and comment on a proposal has been “under review” at the Office of Management and Budget for three years.

These and other problems with TSCA have led the Government Accountability Office (GAO) to issue more than a dozen reports and testimony on the problems and ineffectiveness of TSCA since its enactment, culminating in its 2009 designation of EPA’s programs to assess the safety of chemicals as being at “high risk” of failure.

Science has not stood still

Meanwhile, over the 35 years that virtually no regulation of chemicals has taken place, the science raising concerns about the potential health effects of individual chemicals, as well as classes of chemicals, has exploded. Since 1976, scientists have linked exposure to toxic chemicals to a wide array of health risks. It is increasingly understood that exposure to low doses of certain chemicals, particularly in the womb or during early childhood, can result in irreversible and life-long impacts on health. It is now commonly known that some toxic chemicals persist in the environment, sometimes for decades, and build up in the food chain and in our bodies. It is now well-recognized that some chemicals are able to disturb our hormonal, reproductive, and immune systems and that multiple chemicals that individually may be at low levels considered to be “safe” can act in concert to harm health.

This broadening in understanding of the scope of possible health effects, as well as exposures, has occurred amidst increased public concern over the rising rates of a number of chronic illnesses and disabilities including certain types of cancer, types of mental illness and learning disabilities, asthma and Parkinson’s disease. At the same time, in the past few years the National Academies of Science (NAS)

has issued several reports containing recommendations on how EPA (and other agencies) can conduct better risk assessments of chemicals.

The explosion of science, coupled with the rise in chronic illness and disease has prompted growing calls for reform of our federal program for assessing and regulating chemicals by medical and health organizations, including the President's Cancer Panel (appointed by George W. Bush), American Medical Association, the American Academy of Pediatrics, the National Medical Association, the American Nurses Association, the American Congress of Obstetricians and Gynecologists, the Endocrine Society, the Bladder Cancer Advocacy Network, the Learning Disabilities Association, the American Fertility Association, and others.

Legacy of TSCA

Although other laws have been controversial, and battles over their implementation and reauthorization have been hard fought, there are undeniable accomplishments – with real- world benefits for public health and the environment – that can be ascribed to most of our other major environmental laws including the Clean Air Act, the Clean Water Act, Food Quality Protection Act, Safe Drinking Water Act, Superfund, and The Resource Conservation and Recovery Act (RCRA). Virtually nobody makes any such claims for TSCA. The chemical industry had long viewed TSCA as a success. However, starting around 2009, the industry position shifted and concerns began to be raised about the effectiveness of TSCA and its failure to ensure a needed level of consumer confidence in the safety of chemicals, particularly those used in commercial and consumer products. What caused the shift?

In the absence of any meaningful regulation, and little by way of disclosure of uses or potential concerns about chemicals used in hundreds or thousands of products, action devolved to the state level, and to the marketplace, where a combination of state legislative and administrative actions, and consumer pressure on major retail companies as well as some chemical processors has led to a sustained, and

growing, upheaval across the country. Public dissatisfaction with the lack of a coherent and effective federal regulatory system for chemicals is being expressed in manifest ways, in dozens of states, with hundreds of chemicals as targets for concern. This movement has had concrete results – including:

- Announcements from major chemical processors that it will stop using specific chemicals in certain products – for example, Johnson and Johnson removing formaldehyde from baby shampoo, and Procter and Gamble removing 1,4 dioxane from Tide laundry soap.
- Big box retailers refusing to carry products on their shelves containing certain chemicals – for example, Wal-Mart’s ban on products containing PBDE flame retardants.
- States across the country have acted to ban the use of certain chemicals in specific products, particularly those marketed for children, including bans of Bisphenol A (bpa) in 12 states, as well as phthalates, cadmium, PBDEs (and Tris) and lead among others. These are in addition to more than 175 policies addressing mercury in 34 states.
- At least 10 states have adopted green cleaning policies – leading school districts around the U.S. to use less toxic cleaning supplies.
- Several states have also adopted programs requiring the public disclosure of chemicals used in specific products, and the development of lists of chemicals of concern which might then be regulated by individual states.

The success of these diverse activities – usually with the support of largely bi-partisan votes by state legislatures – which are both a sign of the high degree of public concern, and lack of consumer confidence in the safety of products in their homes, automobiles, workplaces and schoolrooms – have contributed to two phenomenon dreaded by chemical processors and consumer products companies: (1) an increasingly complex “patchwork” of state-level (and, in some cases local) regulation of chemicals,

(2) so-called “retail regulation” in which companies are forced to modify their products to comply with the requirements of large-scale retailers.

And it is these developments that have led the chemical industry to reassess its own satisfaction with the way TSCA has operated for 35 years.

At least some chemical companies are now of the view that reform of TSCA is necessary to stem the tide of state and retail-level activity and to restore consumer confidence in chemicals and the everyday products which contain them. This shift has led to more discussion of potential reform of TSCA in the past few years than at any time since it was enacted. But reform of TSCA must entail serious and timely review of the safety of chemicals based on sufficient data, and allow EPA to impose restrictions as necessary to protect the public. Revisions to TSCA that won't ensure real action is taken by EPA, while at the same time preempting action at the state level, will not protect the public nor re-instill consumer confidence. Such legislation would not constitute real reform. It is possible to establish a federal program to review the safety of chemicals, and establish controls on those chemicals necessary to protect public health and the environment, while protecting the role of states and maintaining the continued success of the chemical manufacturers, processors and downstream users – and create a market for innovative companies producing safe and effective chemicals. And after more than three decades since TSCA was enacted, it is long past time that we do so.

Mr. SHIMKUS. Thank you.

The last person on the panel is Ms. Jeanne Rizzo, President and CEO of the Breast Cancer Fund, and you are recognized for 5 minutes.

STATEMENT OF JEANNE RIZZO

Ms. RIZZO. Good morning. Thank you, Chairman Shimkus and Ranking Member Tonko and the members of this committee for the opportunity to testify and to bring a public health perspective to this panel and discussion today.

At the Breast Cancer Fund, we work to prevent breast cancer by eliminating exposure to toxic chemicals and radiation linked to the disease. So I am here today on behalf of the 3 million breast cancer survivors who are living in this country at the moment, 40,000 women and, increasingly, men who will lose their lives to breast cancer this year, and I am also here on behalf of the millions who are suffering from diseases and conditions that have been linked to chemical exposure—birth defects, asthma, early puberty, learning disabilities, infertility, cancers including breast and prostate—and I am here to state from our perspective that in no uncertain terms, the 1976 Toxic Substances Control Act is hurting us. As a matter of fact, it is killing us but not protecting us, and we have manifestation of that in the fact that there are chemicals that are transferring into our bodies, into our food, our water, our air and even into the umbilical cord of babies.

That is not what Congress intended back in the 1970s when the country was grappling with the public health disaster wrought by better living through chemistry. That paradigm, the attempt was to fix that. There was really good intention, and disease rates were skyrocketing. Scientific evidence was mounting. Congress knew then as it does now, I believe, that it had to act. So it passed TSCA with great hope that that legislation would indeed protect public health. We now, as you have heard, have had 37 years of proof that the legislation has failed us.

Look at breast cancer today. Two hundred and twenty-seven thousand women will be diagnosed with breast cancer this year, and 2,200 men. Women have a one-in-eight lifetime risk of breast cancer. That is a 40 percent increase since TSCA's passage. We know that only 5 to 10 percent of breast cancer can be traced back to inherited genetic factors. There is a volcanic amount of scientific evidence that points to environmental causes including chemical exposure. We know that our genes and our environment collude together to result in positive or negative health outcomes.

We now have to acknowledge TSCA's failure and figure out how to design that better, like the fact that the 84,000 chemicals that are in the TSCA inventory, the 62,000 that were grandfathered in. We heard a lot about that today. So chemicals could continue to be sold without having to be looked at for their long-term impact on health and the environment. The EPA under TSCA has only been required to test a certain number of those grandfathered chemicals. They have only been able to restrict or ban five of them. If TSCA makes it so difficult to regulate a chemical that the EPA couldn't even ban asbestos, a very well-known carcinogen with a disease named after it, then clearly we have not accomplished the goal.

So we have to take seriously our new knowledge that timing of exposure to chemicals matters, that low dose of chemical exposures matters, and that mixtures matter, and that is our real-life experience. So there is emerging science, the growing consensus that TSCA must be reformed.

In my written testimony, I refer to three major federal reports that I encourage reading as well as the 2009 GAO report that talked about the fact that although TSCA is authorized to ban or limit chemicals, the threshold is prohibitively high. And we see States around the country, as you have heard before today, taking action. They feel they have the right and the responsibility under their 10th amendment to protect and police the safety of their residents, and they are doing that, and that is creating the kind of action that is protecting people in some States but not in all States.

So we have a growing chorus urging Congress to strengthen the way we regulate chemicals and the way the American people are protected from those chemicals. We even hear businesses want that protection. So the women of this country are looking to you for your leadership. People in our military, our armed services, want assurances that their military bases will not be contaminated as Camp Lejeune was. People in polluted communities want to know that action will happen and that workers are safe. Parents want to know their 6-year-old daughters will not enter puberty and have a later lifetime risk of not only breast cancer but social, sexual issues, drug abuse as well as high-risk behavior. So our children and our grandchildren want to know that they won't face that burden.

It is a burden then for Congress to take on the awesome responsibility of dealing with TSCA in an urgent manner with safety standards, the best available science, data on all chemicals, the ability to act on the worst, the right to know reasonably and responsibly navigated and maintain the States' rights to protect citizens in the absence of federal action.

Thank you very much.

[The prepared statement of Ms. Rizzo follows:]



Testimony of Jeanne Rizzo, R.N.
President and CEO
Breast Cancer Fund

Title I of the Toxic Substances Control Act:
Understanding its History and Reviewing its Impact

Environment and the Economy Subcommittee
House Energy and Commerce Committee

June 13, 2013

Good Morning. I would like to thank Chairman Shimkus, Ranking Member Tonko and the members of the Committee for this opportunity to testify at today's important hearing.

The Breast Cancer Fund is the only national organization focused solely on *preventing* breast cancer. We do that by eliminating our exposure to toxic chemicals and radiation linked to the disease. We all know someone who has had breast cancer. Although detection and treatment methods have improved, our odds have not: today 1 in 8 women in the United States will be diagnosed with breast cancer in her lifetime. This represents a 40% increase over the 1 in 10 risk women faced in 1973.ⁱ Globally, breast cancer affects more women than any other type of cancer. In 2012 about 227,000 women and 2200 men in the United States will be diagnosed with breast cancer and 40,000 women die each year from this terrible disease. We know that most people with breast cancer have no family history and only 5 to 10% can be traced back to inherited genetic factors including the "breast cancer genes", or BRCA1 and BRCA2.

Researchers have long known that genetic and environmental factors individually contribute and interact with each other to increase breast cancer risk. Studies show that breast cancer rates can vary with environmental circumstances. Furthermore, a large majority of cases occur in women with no family history of breast cancer. Environmental factors, including chemical exposure, are more readily identified and modified than genetic factors and therefore present a tremendous opportunity to reduce the risk of and prevent breast cancer.ⁱⁱⁱ

Most Americans assume that the industrial chemicals used in the United States have been tested for safety. Sadly, this is not the case. In our daily lives we are exposed to hundreds, perhaps even thousands, of chemicals from a wide range of sources, including cleaning and personal care products, plastics, children's toys, furniture, food, air, water, our workplaces and our neighborhoods. A strong and rapidly growing body of evidence is showing that some of those chemicals are toxic and can increase our risk for breast cancer and a number of other diseases and conditions, from asthma and learning disabilities to prostate cancer and both female and male infertility. The Toxic Substances Control Act (TSCA) has utterly failed to protect the American public from these toxic chemicals, which are contributing to a worsening public health crisis of chronic diseases.

In talking about the intricacies of federal chemical policy, we sometimes lose track of the real-life impacts of these chemicals. The child with a learning disability or asthma. The young couple struggling to conceive a child. The women – and men – who have faced the life-changing impact of a breast cancer diagnosis. I want to bring those people and those voices into the room and our discussion today – the faces of your mothers and fathers and daughters and sons – and remind us that what we do, or don't do, to ensure that new *and* existing chemicals used in commerce are safe will have a direct impact on them and on future generations.

The Science

The Breast Cancer Fund bases our work on a strong foundation of science. We review the peer-reviewed scientific literature, then compile and translate that science to be accessible to the public. We have issued six editions of our report, *State of the Evidence: The Connection Between Breast Cancer and the Environment*, and we continually update that science on our website. As the science of toxicology evolves we have learned a number of important lessons:

- **Timing of exposure matters:** Exposure to toxic chemicals can be particularly harmful at certain stages of life, including prenatally, in early childhood and during puberty. Developing bodies are more sensitive to some chemical exposures, and the body's ability to protect itself is not fully developed. These exposures can have profound impacts on later-life risk of breast cancer and many other diseases.
- **Low doses matter:** Some chemicals – particularly those that disrupt our endocrine system – can have a more profound impact at lower exposure levels. No longer is the old principle that “the dose makes the poison” necessarily applicable.
- **Chemical mixtures matter:** We are exposed to a bewildering variety of chemicals every day, and we may be exposed to a single chemical from a variety of different pathways. As little as we know about most individual chemicals, we know almost nothing about how they interact with each other.
- **Your occupation and where you live matters:** While all of us are exposed to chemicals all around us, those on the front line, either as workers or as communities living next to chemical plants or other sources of background exposures, are even more at risk for increased risk of breast cancer or other diseases.

Chemicals can impact and interfere with our bodies in a number of ways. Some chemicals, called mutagens, actually change the DNA of our cells. Some do not change the DNA, but rather interfere with how the genes are expressed through a process called epigenetics. Both of these alterations can be passed down to the next generation, increasing our children's risk of negative health impacts. Two of the leading authoritative lists of carcinogens come from the World Health Organization's International Agency on Research for Cancer, or IARC, and the U.S. National Toxicology Program, or NTP, an interagency program housed at the National Institute of Environmental Health Sciences (NIEHS). Both programs maintain and update lists of chemicals identified as carcinogens. An attached chart lists breast carcinogens identified by one or both of these authorities, along with the uses of those chemicals.

A class of chemicals that has been causing increased concern, for breast cancer and numerous other diseases, is endocrine-disrupting compounds. These substances look like our body's natural hormones and can interfere with the very sensitive and critical endocrine system that controls our development and homeostasis. This interference can happen in a number of ways, including mimicking hormones or blocking their actions. EDC's, especially chemicals that mimic estrogen, are particularly concerning for breast cancer, as increased lifetime exposure to estrogen is known risk factor. EDC's can also interfere with the thyroid system, which regulates metabolism and reproductive health. Much more needs to be known about these substances, but without strong testing requirements in TSCA, we will continue to be exposed to these chemicals without fully understanding their impacts.

We urgently need to accelerate progress toward understanding the role of these environmental chemicals. In the face of scientific uncertainty, however, we cannot wait to act. We must prioritize protecting public health and investing in safer alternatives, while intensifying the study of how chemicals impact our health. That can only be accomplished with the full force of a strong chemicals management system.

The Failings of TSCA

Numbers effectively tell the story of our failed chemical policy: Of the over 84,000 chemicals on the TSCA inventory, 62,000 were grandfathered in when the law passed in 1976, meaning chemical companies could keep selling them without safety testing. And in the 35 years since TSCA became law, the EPA has been able to require testing for only a few hundred of the grandfathered chemicals—and only five chemicals overall have been restricted. In fact, TSCA makes it so difficult to regulate a chemical that the EPA has not even been able to restrict asbestos, a well-established human carcinogen.

The TSCA framework and requirements tie the EPA's hands in a number of ways, resulting in a regulatory system that fails to protect the public's health:

Lack of Safety Data – To make sound decisions about the safety of a chemical, EPA needs adequate information looking at the range of possible health impacts. Unfortunately, TSCA makes it extremely hard for EPA to get that necessary data by placing the burden on the EPA to show they need the data rather than on the industry to prove their chemical is safe.

For existing chemicals, EPA is in a Catch 22 of having to show that a chemical poses an unreasonable risk of injury to health or the environment before the agency can require testing to find out if the chemical actually poses such a risk. Even once the agency has gone through the costly and time-consuming process of obtaining the necessary data showing the risk, they must go through a lengthy rule making process to get the additional data from the manufacturer.

For new chemicals, EPA has 90 days to review the chemical before it goes into production but it cannot compel manufacturers to submit any safety data and very few companies do so voluntarily. This leaves EPA reliant on sometimes inaccurate models to predict the toxicity of a chemical based on similarities to other chemicals that have been tested for safety. And if the EPA fails to act, the chemical goes onto the market at the end of the review period.

Confidential Business Information – Much of the limited data that the EPA receives is designated by the chemical companies as confidential business information, or CBI. A CBI designation prohibits the EPA from sharing the data with the public, or even with state and local health and environmental agencies. States often want this information to assist them with emergency planning and alerting emergency response personnel about potential threats from toxic chemicals in local manufacturing facilities. Ironically, while available safety data cannot be designated as CBI, the identity of the chemical associated with that safety data can be withheld. EPA estimates that in about 95% of new chemical notices, manufacturers claim some portion of that submission as CBI. EPA has the authority, but not the resources, to challenge CBI designations, although this is one area where EPA has made some recent strides in requiring manufacturers to better justify their claims.

Threshold for Regulation – Even once the EPA has obtained the requested safety data, the bar set by TSCA to implement actual regulations to reduce risk is impossibly high. Not only must the agency show that the chemical exposure presents “an unreasonable risk of injury to health or the environment”, but it must also demonstrate that the proposed restriction is the “least burdensome requirement” available. In proposing a restriction on a chemical, the EPA must also consider factors beyond the health impacts, including a cost/benefit analysis of the regulation. We need look no further than the agency's inability to restrict asbestos, a known carcinogen with an entire

disease named after it, to understand how impossibly high the bar is for EPA to act to protect public health.

The overall effect of this system is to place the burden to prove that a chemical is harmful on the EPA, instead of having chemical manufacturers bear the burden of proving that a chemical is safe.

Fixing Our Broken System

There is broad consensus that TSCA must be reformed. From the EPA to the public health community to the environmental health movement, voices are calling for swift Congressional action on this critical issue. A number of recent federal reports have also called for TSCA reform. The 2010 President's Cancer Panel report *Reducing Environmental Cancer Risk, What We Can Do Now*, the 2011 CDC's *National Conversation on Public Health and Chemical Exposures*, and most recently the 2013 Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) report *Breast Cancer and the Environment: Prioritizing Prevention* have all called for TSCA to be strengthened to give the EPA the information and tools needed to protect the health of American families.

I had the honor of serving as one of the co-chairs of the committee that wrote the groundbreaking *Prioritizing Prevention* report. IBCERCC was housed at the National Institutes for Health, specifically the National Institute of Environmental Health Sciences and the National Cancer Institute, and was comprised of federal agency staff, medical and scientific experts, and breast cancer advocates. The report includes the largest to-date survey of peer-reviewed science on breast cancer and the environment, finds that environmental factors like toxic chemical exposure increase breast cancer risk, and identifies the gaps in research and policies. It concludes that "prevention is the key to reducing the burden of breast cancer," and calls for a national, comprehensive, cross-governmental breast cancer prevention strategy.

The IBCERCC report cites the 2009 GOA report^{iv} which found that although TSCA authorizes the EPA to ban, limit or regulate chemicals, the threshold to take action requires meeting a prohibitively high level of risk after conducting a lengthy and expensive cost-benefit analysis. Based on deficiencies identified in the report, the GAO added TSCA reform to its high-risk list (See 8.23 IBCERCC report). The EPA's own analysis in 2012 led to six principles for reforming TSCA that addressed safety standards, timely assessment and action on priority chemicals, encouragement of green chemistry, greater transparency regarding chemicals, including public access to information, and a sustained funding source.

Any effort to mitigate the environmental causes of breast cancer, or other diseases linked to exposure to environmental chemicals, must include a plan to reform TSCA.

To be true reform and to accomplish the goal of protecting America's families and workers, any effective chemicals management system must include:

A safety standard that is health-protective, particularly of vulnerable populations.

The safety standard must explicitly protect vulnerable populations. Pregnant women, children, workers and communities living in areas of high chemical exposures all need and deserve our protection. We are not exposed to one chemical at a time, or even just one source of a particular

chemical, so it is essential to consider aggregate exposures when determining safe levels of a chemical.

Use of the best science available. TSCA reform should ensure the use of the best available science by incorporating suggestions from the National Academy of Science reports on reforming the EPA's risk assessment process. Legislation must also protect the integrity of scientific review from undue industry influence and incorporate sound science from all sources, including academia.

Require data on all chemicals. The EPA should require chemical manufacturers to demonstrate via sound scientific data that their chemical is safe. The absence of data should not default to assuming the chemical is safe.

Action on the worst chemicals. There is a lot we do not know about most chemicals, but for some, we know enough to act now to reduce exposures. TSCA reform must allow for the Environmental Protection Agency to take fast action on the worst chemicals, including PBTs: chemicals that are persistent in the environment, bioaccumulate in organisms, including humans, and are toxic.

Protecting the public's right to know about the health hazards of specific chemicals. Reform should require that the public have access to information regarding the safety of chemicals, including the identity of hazardous chemicals. State and local agencies also need chemical identity and safety data to allow them to do their job of protecting citizens from hazardous exposures.

Allow the states to continue to protect their citizens. Finally, TSCA reform must respect the right of states to protect their residents if the federal government fails to do so or is slow to act. The inability of the federal government to regulate industrial chemicals for the last 30 years left a huge gap that states from around the country have stepped up to fill. States must continue have that ability.

Congress has a moral imperative to pass legislation strengthening the way chemicals are regulated in this country and providing the public real protection from those chemicals that are causing harm to human health. The Breast Cancer Fund and others in the public health arena stand ready to help make TSCA reform a reality.

Thank you again for the opportunity to testify, and I look forward to answering questions from the Committee.

Breast Carcinogens in Our Daily Lives

The chart below lists some of the carcinogens that have been linked to breast cancer or to mammary tumors in animal studies. In addition to these carcinogens, endocrine-disrupting compounds like bisphenol A (BPA), phthalates, alkylphenols and halogenated flame retardants also raise concerns based on data linking them to breast cancer risk.

Chemical	Carcinogenicity	Used in
Benzene	IARC: Known; NTP: Known	Chemical, rubber, shoe-manufacturing, oil and gasoline refining industries
Organic solvents other than benzene (toluene, formaldehyde, methylene chloride)	IARC: Probable; NTP: Reasonably Anticipated	Computer components, cleaning products, cosmetics
Vinyl chloride	IARC: Known; NTP: Known	Food packaging, medical devices, appliances, cars, toys, rain jackets, shower curtains
1,3-butadiene	IARC: Probable; NTP: Known	Synthetic rubber, fungicides; created via internal combustion engines, oil refinement; found in tobacco smoke
Ethylene oxide	IARC: Known; NTP: Known	Sterilization of surgical instruments and in some cosmetics
Styrene	IARC: Possibly; NTP: Reasonably Anticipated	Plastics, e.g. to-go coffee lids
PCBs (banned in 1976)	IARC: Probable; NTP: Reasonably Anticipated	Insulation fluids, plastics, adhesives, paper, inks and dyes made prior to 1976. Many of these are still in use today. PCBs are persistent and bio-accumulative, meaning that they still exist in the environment and in people's bodies today

¹ Howe HL, Wingo PA, Thun MJ, Ries LA, Rosenberg HM, Feigal EG, Edwards BK (2001). Annual report to the nation on the status of cancer (1973 to 1998), featuring cancers with recent increasing trends. *J Natl Cancer Inst*, 93: 824-42.

² Horner MJ, Ries LAG, Krapcho M, et al. (2009). SEER Cancer Statistics Review, 1975-2006. National Cancer Institute. Bethesda, MD. http://seer.cancer.gov/csr/1975_2006/, based on November 2008 SEER data submission, posted to the SEER web site, 2009.

³ Interagency Breast Cancer and Environmental Research Coordinating Committee (2013). Breast Cancer and the Environment: Prioritizing Cancer. http://www.niehs.nih.gov/about/assets/docs/ibcercc_full_508.pdf (6/11/13).

⁴ Government Accountability Office (GAO). Chemical Regulation—Options for Enhancing the Effectiveness of the Toxic Substances Control Act [Internet]. Washington, DC: U.S. Government Accountability Office; 2009 [cited 2013 Jan 7]. Available from: <http://www.gao.gov/assets/130/121612.pdf>.

Mr. SHIMKUS. Thank you.

Mr. Auer, I am going to start with you and so I will give you that opportunity. Your testimony mentions that you consider the combination of “unreasonable risk” and “the least burdensome requirement,” which is what we are going to talk a lot about over the next couple months, in TSCA to be largely unworkable. From an intuitive standpoint, it makes a lot of sense to me that regulation should not be more than appropriate and necessary to address the risk. Do you agree?

Mr. AUER. Yes.

Mr. SHIMKUS. Is your concern with the wording suggesting extreme analysis?

Mr. AUER. Yes. The least burdensome and the way that it has to be squared with the to extent necessary to protect against the risk standard, I believe makes it unworkable, or largely unworkable.

Mr. SHIMKUS. Since you agree that it makes sense that regulation should not be more than is appropriate and necessary to address the risk, do you think there is a role for the basic concepts that underlie least burdensome to be included in future chemical legislation?

Mr. AUER. Yes. The concept needs to be included per my previous response. We will need to take care with the wording to ensure that it does not become a straitjacket, however. Thank you.

Mr. SHIMKUS. Ms. Bosley, the same to you. Do you think TSCA should have a least burdensome requirement for regulations?

Ms. BOSLEY. Certainly. I think that that is helpful for small businesses, especially like mine, but it should be much more workable than it is today.

Mr. SHIMKUS. How would you have it operate?

Ms. BOSLEY. So right now, EPA has to discover all the avenues themselves and then decide between the least burdensome. That is a lot of analysis. I think if you opened it up to public comment and let the public and industry and NGOs, give them the options which are out there, then they can decide among those which are least burdensome.

Mr. SHIMKUS. How easy is it to have a chemical’s production stopped or curtailed in the early going?

Ms. BOSLEY. Oh, it is much easier in the early going. If we are going to fail, we would rather fail early before too much investment has been spent. So we very much appreciate when EPA tells us before a chemical is in full production that they are going to regulate it.

Mr. SHIMKUS. And how critical—and you mentioned this in your opening statement, but can you again talk about how critical it is to your business for the protection of confidential business information and what do you believe that the public should be entitled to?

Ms. BOSLEY. Sure, sure. So especially for new chemicals and once again for small businesses like mine, our chemicals and our uses are very focused and so our competitors, mostly offshore competitors, know what we are doing, and if we are to put in a PMN, Premanufacture Notice, with chemical identity right out there, then they know what we are researching, which gives them a leg up on us. They are just a lower burden in other countries. So I

think protection of CBI is very important. I know that it has been overused, though. I used to work for people who would check every box as CBI on a PMN, and that is much overused. I would be happy if there was upfront substantiation and re-substantiation maybe every 5 years but the initial protections are very, very, very important.

Mr. SHIMKUS. And Mr. Gomez, when your testimony refers to characterizations about EPA's inability to meet its goal of ensuring the safety of chemicals, does this mean that chemicals are unsafe or that EPA is having an administrative problem prioritizing chemicals and reviewing them under the law?

Mr. GOMEZ. So just to clarify, in our testimony we make characterizations about EPA's efforts to manage toxic chemicals consistent with the agencywide strategic goal of ensuring the safety of chemicals. We didn't evaluate whether chemicals were unsafe so we were looking again at the new approach that EPA has in place and the different things that they are doing and then we are drawing questions about whether they are going to realize the results that they have taken on.

Mr. SHIMKUS. Thank you. Mr. Auer, the Government Accountability Office and Mr. Rosenberg have been critical of TSCA and EPA's implementation of it for almost 30 years from a quantitative standpoint. Do you believe that only looking at the program from this view is appropriate?

Mr. AUER. I do believe you need to take a broader view. TSCA tools can be hard to implement and use in a regulation. There are many important voluntary efforts, the high-production volume challenge program, the PEFO, a stewardship program, use of SNURs to regulate PBTs, the flame retardant tris and other very well known chemicals. I do believe you need to take a broader view. On the new chemicals, you need to look at what EPA stops as well as the effect of EPA encouraging the industry to go in the direction of safer and greener chemicals.

Mr. SHIMKUS. This is a great panel. Thank you very much. And now I will yield 5 minutes to the ranking member, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

Mr. Gomez, you identified three main challenges for TSCA implementation in your testimony. First, the fact the Act does not require companies to generate or provide adequate information on chemical toxicity and exposure to EPA. Can you elaborate on what the obstacles are to getting that information?

Mr. GOMEZ. Sure. So we noted that EPA has had difficulty obtaining adequate information on chemical toxicity, and the reason being that TSCA does not require that companies test chemicals before they are manufactured. TSCA requires EPA to demonstrate that chemicals pose certain risks before it can ask for such testing.

Mr. TONKO. OK. And Ms. Rizzo, what are the public health impacts and specifically the impacts on cancer risks from the lack of information that you cited?

Ms. RIZZO. Thank you. There have been several reports issued. The President's panel on cancer and the environment, the national conversation on chemicals and public health as well as a recent federal advisory committee on breast cancer and the environment,

an interagency committee of 21 scientists, academics, agency people, that got together to look at this issue of the impact of chemicals and cancer, breast cancer in particular, not just looking at those that are named carcinogens but endocrine-disrupting chemicals. They really have an impact in utero, in early childhood, in puberty, during lactation to trigger cells to believe that they have been exposed hormonally and to react accordingly, increasing the risk of breast cancer. We see this in animal studies and we see it in the human manifestation of the increase in breast cancer and other hormonally related cancers.

Mr. TONKO. Thank you. Mr. Gomez, the second challenge you identified is that even when EPA has obtained information about the risk from chemicals, the Agency has had difficulty banning or limiting the production or use of those chemicals. Can you explain why this happens to be the case?

Mr. GOMEZ. Sure. So we have noted that EPA had difficulty proving that chemicals posed unreasonable risk and has regulated few chemicals under TSCA. EPA has a high legal threshold to meet so EPA must demonstrate unreasonable risk, which EPA tells us that they believe that it requires them to extensive cost-benefit analyses to ban or limit chemical production. And so as I noted, since 1976 only five existing chemicals have been controlled. We have previously recommended that Congress amend TSCA to reduce the evidentiary burden EPA must meet to control toxic substances and continue to believe that such changes are warranted.

Mr. TONKO. Thank you. Mr. Rosenberg, what are some of the environmental and health impacts of this inability to ban or limit these chemicals?

Mr. ROSENBERG. Well, you are faced with ongoing exposure both in the health and the environment to all kinds of substances, particularly I mentioned PBTs, things that persist in the environment and bioaccumulate into our bodies, so those are, by definition, around for a long time, and as long as they are not controlled, more are produced, more are released into the environment, not just in the environment like out in the forest but in our homes and, you know, our workplaces and places we are. So if you are not controlling the exposure to the substances of concern and they are still being manufactured, even if they are not still being manufactured, they might still be in products. Once they are in there, they can get out of the products, whether during the natural life of the product, as it were, or during disposal or at other times.

Mr. TONKO. Thank you. Ms. Rizzo, who bears the worst effects of these avoidable hazardous exposures?

Ms. RIZZO. I am sorry, sir. I didn't hear that.

Mr. TONKO. Who bears the worst effects of these avoidable hazardous exposures?

Ms. RIZZO. Well, I think there are vulnerable—those that are most vulnerable amongst us. We see it for children, we see it for women, we see it for communities that are disproportionately affected because of where they live, what their legacy exposures are to these toxic chemicals. So you see people that live on toxic dump sites, essentially, you know, their build environment didn't consider their chemical exposure. You see it in poor people whose access to healthier foods, healthier products is just not there so they are

going to get more exposure through whether it is personal care products they use or the air pollution, the freeway they live next to, the water that isn't as safe and as healthy. So I think if we look at breast cancer, there is a dramatic increased risk in premenopausal breast cancer amongst African American women, so the vulnerable populations need the greatest protection.

Mr. TONKO. Thank you. I note, Mr. Chair, my time has expired so I will yield back.

Mr. MURPHY [presiding]. Thank you. I will now turn to the gentleman from Pennsylvania and chair of the Health Subcommittee, Mr. Pitts, for 5 minutes.

Mr. PITTS. Thank you, Mr. Chairman.

Ms. Roberts, some argue that TSCA does not encourage green chemistry. Does the TSCA structure discourage U.S. companies from innovating, including the creation of green chemistry?

Ms. ROBERTS. Thank you for the question. No, I don't believe TSCA discourages development of green chemistry. In fact, I think as Ms. Bosley had mentioned in her testimony, given the way that Section 5 new chemical notification processes are set up, U.S. companies can develop new chemicals, have them reviewed by EPA and get them to market faster, and that ability to innovate in particular helps those companies that are trying to develop greener chemicals and get them on the market. So absolutely, I think that the way the TSCA framework is set up right now, it in fact is encouraging of innovation. I don't have the numbers in front of me but I do believe that there have been reviews showing that U.S. companies have higher patents on chemical products, on polymers and the like, again showing and proving that U.S. innovation is stronger than an other parts of the world.

Mr. PITTS. We hear a lot of claims about chemicals not being tested, Ms. Roberts. Is there a requirement for new chemicals to have test data provided to EPA before they hit the market?

Ms. ROBERTS. It is a very interesting question. Actually, there is not a requirement for new chemicals to be tested before they go on the market although, again, as Ms. Bosley mentioned, there is a requirement if data is available that it be submitted with the PMN. But EPA has developed a very useful and scientifically sound program where they have predictive models where they look at molecularly similar chemicals and they can make judgments on how an analog chemical would act so they can make some considerations of hazard exposures or hazard profiles. They can look at the information that is included in the PMN and determine how this particular material might be exposed to the general public or releases to the environment. EPA staff must be given great kudos because they have taken these models that they use internally and they have made them available to companies so that companies can use these models and determine whether there are going to be issues of concern with chemicals before they even send them to EPA for market, and again, I think that helps companies pursue those areas where they are going to be developing safer and greener chemicals.

Mr. PITTS. Thank you. Mr. Auer, are many new chemicals safer and greener than their chemical predecessors?

Mr. AUER. That is my personal opinion and experience. I was the chair of the Structure Activity Team in the new chemicals process for over a decade. I have seen thousands of new chemicals. I know what they are competing against. My personal view is yes. There has also been some EPA work showing that these structure activity predictions can work effectively. The chemicals are also more energy efficient, more product efficient. Oftentimes they substitute for known toxic chemicals. So as elaborated in an annex to my testimony, I believe that the New Chemicals Program has been very effective in encouraging the development and introduction of safer and greener new chemicals.

Mr. PITTS. To follow up, the EU with more demanding requirements to market entry has seen dramatically fewer numbers of new chemicals introduced into commerce than the United States. Are these U.S. chemicals more risky than the EU chemicals?

Mr. AUER. You know, my guess is they are pretty much the same chemicals. I am sure some are unique to the United States or the EU but my guess is, most are the same, and as elaborated in my annex, looking at the same period of time and the same rules, if you will, the EU with a base set saw 3,000 new chemicals introduced. The United States saw 17,000—maybe my numbers are wrong—six times as many over the same period in time. I believe that is a profound driver for innovation, given the safer and greener answer I gave previously.

Mr. PITTS. Thank you. Mr. Gomez, some argue that companies overclaim confidential business information under TSCA. Is it EPA's responsibility to challenge claims that they think are not appropriate?

Mr. GOMEZ. We believe so, but they have not done that.

Mr. PITTS. Why hasn't EPA challenged companies on CBI claims?

Mr. GOMEZ. That is a good question, sir. I would have to get to you if we have the answer but I don't know.

Mr. PITTS. Ms. Bosley, Mr. Rosenberg's testimony suggests that chemicals under TSCA should be treated like pesticides, foods and drugs. Do you agree with this view, and why or why not?

Ms. BOSLEY. I don't agree with that view. Pesticides are meant to be bioactive and to kill bugs. Foods and drugs are also meant to be consumed and thus real chemicals are not meant to be consumed. I think as part of the risk assessment for EPA, it would certainly look at the exposure pattern that industrial chemicals are having and they are able to collect data on that. They do that every 4 years now. So EPA knows what the exposure patterns are, and based on that exposure pattern, they can decide to look at a chemical more closely, something close to what FDA might do, but only when the exposure pattern makes it necessary.

Mr. PITTS. My time is expired. Thank you, Mr. Chairman. I yield back.

Mr. MURPHY. The gentleman yields back and now I turn to the gentlelady from Colorado, Ms. DeGette, for 5 minutes.

Ms. DEGETTE. Thank you very much, Mr. Chairman, and I think it is great that we are having this hearing on TSCA. I have been interested in this bill since I came to Congress in 1997, and I have probably said this before: TSCA was enacted over 30 years ago and it is the only major environmental law in this country that has not

been reauthorized. I think we can hear from the panel today there may be differences in nuance but pretty much everybody agrees, the industry as well as the environmental community, that TSCA really needs to be updated to keep pace with modern technology and to augment the EPA's resources and authority.

Now, in the 111th Congress, two Congresses ago, this committee had significant hearings on TSCA, and one of the results of those hearings was legislation that created a process for the EPA to select and review high-priority chemicals against a minimum safety standard. We have other laws that have been effective at reducing risks related to pesticides, food and drugs but TSCA has not been effective at prioritizing action on chemicals that pose a high risk. So I want to ask some questions around these issues.

The first thing I want to ask is, under Section 6 of the current law, if the EPA suspects exposure to chemicals puts people at a serious risk, something I have been looking at is, can the EPA take action in a timely manner, because, of course, there has only been six Section 6 actions. All of them took 3 to 5 years. And in my opinion, none of us those were timely. Ms. Roberts, I am wondering what you think about that. Do you think that currently Section 6 of TSCA, if there is something that puts people at a serious risk, can that really operate to help the EPA make a decision in a timely way?

Ms. ROBERTS. Thank you for the question. There is another section under TSCA, Section 7, which I didn't review, and I apologize, but it relates to imminent hazard. So if EPA were to find a situation where there was exposure and there was clear hazard, that they could take action under Section 7 and then proceed with the Section 6 rulemaking.

Ms. DEGETTE. But that is if there is an imminent risk, but the next level down I am talking about is something that is a serious issue. Those are the ones that are taking 3 to 5 years. Do you think that that is adequate? Because that is a big gap between Section 7 and Section 6.

Ms. ROBERTS. I would agree. I just wanted to point out that there was that option in Section 7, but I would also agree that a 3- to 5-year rulemaking is something that is absolutely burdensome. I am not sure that is a deficiency of TSCA, however.

Ms. DEGETTE. OK. But if we could remedy it, certainly that would be preferable, correct?

Ms. ROBERTS. I would agree.

Ms. DEGETTE. Let us just go down right down the row.

Mr. AUER. I would agree, it would be very difficult to regulate within 3 to 5 years, probably a few years longer because of the complexities of TSCA as well as the problems that you encounter in implementing a rulemaking proposal, consider comments, finalize.

Ms. DEGETTE. Right.

Mr. GOMEZ. Yes, we have noted in our report that that is a long time for EPA to do that, and it would take them, just for the 83 chemicals that they have chosen right now, over 10 years to go through them.

Ms. DEGETTE. Right.

Ms. BOSLEY. We favor a less burdensome rulemaking process for EPA as well.

Ms. DEGETTE. Thank you.

Mr. ROSENBERG. It definitely takes too long for the Agency to be able to do almost anything, certainly under Section 6 under TSCA, and the 3- to 5-year rulemaking in probably many instances is actually optimistic. The asbestos rule took 10 years, I believe, and lately even other authorities under TSCA EPA has tried to use including their publishing a Chemicals of Concern list. They haven't even been able to formally propose a Chemicals of Concern list because that has been sitting at OMB for 3 years. So the hurdles EPA faces in taking any action go far even beyond the structure of the statute, which is pretty much what we are focused on today. There are bigger challenges even than that.

Ms. DEGETTE. Thank you. Not but not least.

Ms. RIZZO. Thank you. I would agree with that, and I would say the problem goes before we even get to having to make a rulemaking that we are not looking at the proof of safety first before we balance out the cost-benefit analysis or any other decision making. We should be looking at the safety of the chemical proven first with industry providing that information to the EPA so that we don't have to deal with this rulemaking lag.

Ms. DEGETTE. Right. And I wanted to ask you, Ms. Rizzo, because in your testimony you talk about endocrine-disrupting compounds as a chemical of increased concern, and of course, it is not just pesticides that can alter genes. It can also be compounds as well. I am wondering if TSCA enables the EPA to test and evaluate the impacts of those compounds.

Ms. RIZZO. Not adequately on human health and the environment, and I think that that is the real challenge of how we look at the classes of chemicals and what we do with them and how much time it takes, so no, we have not adequately evaluated EDCs for their impact on health.

Ms. DEGETTE. Thank you. Finally, I want to take for a minute about the confidential business information. Mr. Murphy, although he is pretending he is the chairman right now, he is actually my chairman of the Oversight and Investigations Subcommittee, I am the ranking member on that, and we both know that good oversight requires open government and access to information, not just for the committee but for everybody, and I am cognizant about protecting confidential business information. I do it in other legislation that I am sponsoring. But if a government agency is going to manage an effective confidential business information claim program, it needs three processes: substantiation by the company seeking protection, Agency verification of CBI status, and opportunity for public challenge. And TSCA's CBI claims process is absent of that framework.

So Mr. Gomez, I know that GAO has studied this issue extensively. Can you tell me what happens when there are overbroad CBI claims in terms of the EPA process and decision making? Very briefly, because I am almost out of time.

Mr. GOMEZ. We have noted that EPA's ability to share data collected under TSCA is limited when you are dealing with confidential business information. Now, EPA has made some progress re-

cently, so we just reported in our March 2013 report, which I wanted to clarify from earlier, that EPA has expanded public access information. So since 2009, EPA has made 617 formerly confidential chemical identities public because they have gone through a review process where they have looked at previous CBI claims and came to the conclusion that they could be released. EPA has also made 783 previously unavailable health and safety findings available to the public after reviewing approximately 15,000 such filings.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. SHIMKUS. The gentlelady yields back her time. The chair now recognizes the gentleman from Pennsylvania, Mr. Murphy, for 5 minutes.

Mr. MURPHY. Thank you, Mr. Chairman.

Ms. Roberts, first of all, can you just tell me what other federal environmental laws contain the regulatory reach of TSCA that allows regulation of manufacturing, processing, interstate and foreign commerce, use and disposal of chemicals and mixtures of chemicals and what are the law governing chemicals? Is TSCA the only one?

Ms. ROBERTS. Absolutely not. TSCA—well, the chemical industry I think is probably one of the most regulated industries out there. In addition to TSCA, you have the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. You have got regulations looking at food, drug, and cosmetics. There is the Clean Air Act, Clean Water Act, RCRA, Hazardous Materials Transport Act. There are numerous ones that are out there. I think the uniqueness of TSCA is recognizing that there are these other regulatory statutes that cover these particular special use or applications of companies and that TSCA is really to capture those that remain, the industrial chemicals, as I think Ms. Bosley appropriately pointed out.

Mr. MURPHY. As a sum total of all those, do TSCA and other bills prevent the EPA from evaluating chemicals of concern in any way that causes EPA to ignore or stops them from evaluating health risk?

Ms. ROBERTS. No, sir, there is nothing in TSCA that would hinder EPA from going through that. I think what has been noted in the testimonies of most of us is, the fact that there is not a specified prioritization process for existing chemicals. There has been plenty of opportunity and programs where the Agency has started up such programs but for whatever reason they did not sustain momentum.

Mr. MURPHY. Mr. Auer, is pollution prevention or other steps that would have reduced emissions a component of judging this unreasonable risk?

Mr. AUER. There is a Pollution Prevention Act, and as I interpret the meaning of “unreasonable risk” under TSCA, I interpret “pollution prevention” for substitutes, et cetera, et cetera all to be important components which go into that meaning of “unreasonable risk,” so, yes, pollution prevention is encompassed.

Mr. MURPHY. OK. Someone told me that water may not meet the standards of passing TSCA. Is that true?

Mr. AUER. I think it is listed on the inventory. I don't know that we have assessed it.

Mr. MURPHY. I know in certain amounts if inhaled it can be lethal.

Mr. AUER. Well, it can. There is water intoxication.

Mr. MURPHY. And I am not making light of that, but I do want to find out health effects, and I want us to focus on science, and that is critically important.

Ms. Bosley, welcome here from western Pennsylvania. You mentioned that the cost and practicality of blanket testing requirements for chemicals would discourage new chemicals from coming to market. So generally speaking, how much would a well-characterized study on a new chemical cost your company?

Ms. BOSLEY. So if we were to do what is called a base set of testing as maybe is required in Europe, a single chemical could cost between a half a million and three-quarters of a million dollars, which is more than the profit my company makes in 5 years' time. So we certainly wouldn't—especially on a new chemical when we don't know the markets, so when we submit a PMN, we back up 90 days from when we think there will be commercial manufacture and usually more than that because we want to give ourselves time. We haven't fully assessed the market yet or the economics yet or even the final product form so we would never undertake that testing if it were to cost that much under such an unknown market analysis.

Mr. MURPHY. If you had to receive regulatory approval prior to developing and selling any of your products, similar to the REACH program that they have in the European Union, what would happen to your customers and your business?

Ms. BOSLEY. They would be gone. They would go overseas where you don't need those sorts of protections before you enter into a market. I can say that because there is not testing when we first put in a PMN, it doesn't mean that we have stopped testing. EPA has another provision within TSCA called TSCA AD where when we do have new test data, we are required to submit it to EPA but only if it is adverse. So if we have predicted a certain toxicity and our chemical actually comes back less toxic than that, we have no provision to give that information to EPA.

Mr. MURPHY. So the EPA does not get that information?

Ms. BOSLEY. They do not.

Mr. MURPHY. Do you take any steps at your location to deal with reducing any potential human hazards?

Ms. BOSLEY. Oh, of course. We assess all the hazards that we can when we are first making a chemical. EPA does allow us to go into the lab and start making a chemical under an R&D exemption before we file that PMN. So we are able to assess a broad range of hazards before we are interested in entering to market, and every step we take, there is a risk assessment done within my own company, and we reduce the risk of that chemical exposure to humans and to the wastes that we generate. That is all part of our new chemical process.

Mr. MURPHY. Beyond that of what the EPA requires?

Ms. BOSLEY. Oh, much beyond what EPA requires, yes.

Mr. MURPHY. Why?

Ms. BOSLEY. It is good business sense. We are a small chemical company. We have limited resources. We don't want to spend our

money getting rid of waste. We want to spend our money on new product development and innovation.

Mr. MURPHY. And taking care of your employees?

Ms. BOSLEY. That is right.

Mr. MURPHY. Thank you. I yield back.

Mr. SHIMKUS. The gentleman yields back his time. The chair now recognizes the gentlelady from California, Ms. Capps, for 5 minutes.

Mrs. CAPPS. Thank you, Mr. Chairman.

It is so easy to focus on all the details of this statute and miss the big picture of why we are here, in my opinion. I would like to focus on one of the most important reasons for this law. Increasingly, researchers tell us that environmental exposures are a key factor in the onset of cancer. That means we need an effective Toxic Substance Control Act reform to fight cancer. According to the President's Cancer Panel in May of 2010, 41 percent of Americans will be diagnosed with cancer at some point in their lives, and about 21 percent will die from cancer. The panel also found that the true burden of environmentally induced cancer has been grossly underestimated and that the American people do not have sufficient information about harmful chemical exposures or how to prevent them.

In February of this year, the interagency Breast Cancer and Environmental Research Coordinating Committee released a new report called "Breast Cancer and the Environment: Prioritizing Prevention." We are fortunate to have with us here today a member of that committee who was involved in crafting that work. Ms. Rizzo, based on your work on that report, can you briefly describe the emotional, physical and financial burden of breast cancer? And that is a huge question to ask you in a very short time.

Ms. RIZZO. Thank you. We talked about the fact that 3 million women in this country are living having been diagnosed with breast cancer and 40,000 families will deal with death. Friends, families, when you think about the total number of people impacted by this disease in this country, it is overwhelming. The report did an analysis of the amount of money spent on the diagnosis and treatment of breast cancer, and that is about \$17.5 billion a year. That doesn't relate all the additional costs—the human cost, the cost of childcare, the cost of getting to your treatments, the loss of work. So it is a tremendous burden on the country and a burden on the economy, a burden on the contribution of women to our world, to our social justice as mothers. We have lost mothers, lost school teachers. So the burden is quite dramatic, and the report addressed that pretty significantly. Thank you for asking.

Mrs. CAPPS. What can we do as policymakers to lessen that that burden or to prevent this terrible disease altogether?

Ms. RIZZO. What actions do we need to take?

Mrs. CAPPS. What can we do as policymakers?

Ms. RIZZO. As policymakers, to look at the exposures to chemicals that have evidence of harm and to navigate the science, weigh the evidence. If you are making a decision for or against an exposure, as for proof of safety rather than unreasonable risk of harm. I think we have the wrong paradigm, and it is demonstrated in the

fact that there are so many people with chronic illnesses and that we are finding these toxic chemicals in our bodies.

Mrs. CAPPs. So is there a role, and would you describe what it might be, the TSCA reform can play in preventing breast cancer?

Ms. RIZZO. Absolutely. I think one of the key issues in TSCA reform is to look at the science. The National Academies of Science gave a report on how to look at doing the science, giving authority to the EPA to look at the science that isn't just good laboratory practices but to look at the academic science that could inform their decision making. So I think the safety standards have to be met on that. I think we also have to look at the way TSCA can look at the regulatory process, speeding it up, look at vulnerable populations. I think all of those contribute to the prevention of disease.

Ms. CAPPs. For so many women, men, families, communities, the fight against breast cancer is a matter of life and death. We have it in our power to limit some of the environmental exposures that can cause this disease. I thank the chair for calling this hearing, and I hope it is the start of a serious effort to address the problems in TSCA and to better protect the American public. Thank you very much, and I will yield back the balance of my time.

Mr. HARPER [presiding]. The gentlelady yields back and I now recognize Mr. Johnson from Ohio for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman, and I want to thank our panel members for being with us today.

Mr. Auer, your testimony mentions that new chemical regulations can apply to more than one company. How frequent is this practice?

Mr. AUER. Thank you for the question. It is quite frequent. There can be a toll manufacturer. There can be downstream companies that buy that chemical. When EPA negotiates a 5(a) order, a requirement can be to extend those requirements downstream. EPA also has Significant New Use Rule authority, which can apply those requirements to any other company that makes or processes that chemical.

Mr. JOHNSON. OK. Some people have critically testified before this committee in the past about the regulatory and management outcomes under TSCA. Have the regulatory and management outcomes been as limited as some suggest?

Mr. AUER. As I overelaborated in my statement as well as in my testimony, there are a lot of facts there. I am not arguing that enough has been done, but I think there has been a mischaracterization of the extent of the work. The fact that 300 or more existing chemicals are regulated under SNURs, many of those are any-use SNURs. They are basically out of the market, as well as the other requirements. They are consequential and they need to be given due account.

Mr. JOHNSON. OK. Does TSCA promote innovation, in your view?

Mr. AUER. You know, I think the way TSCA struck the balance with new chemicals in taking the tough decision not to require testing and the costs associated with that has resulted in the United States leading the world in the innovation of new chemicals which, as I indicated before, I believe to be safer and greener. That is key.

Mr. JOHNSON. All right. Ms. Bosley, you mentioned that the Existing Chemical Program faces challenges. How could EPA have

such a performance disparity between new and existing chemical programs?

Ms. BOSLEY. I think that all lies in the mandate from Congress. Frankly, the mandate and the time frames are very well laid out in TSCA for new chemicals but not so in existing chemicals. EPA has broad authority for existing chemicals to prioritize, to ban, to limit uses, but I think very few resources since there is no mandate.

Mr. JOHNSON. Well, what are your views on a strategy that relies on tailored restrictions rather than outright bans?

Ms. BOSLEY. Oh, I think restrictions are generally a better idea. So even in the asbestos case, let us just say, there are zero exposure but very critical uses of asbestos today in aerospace, space shuttle operations, some firefighting operations that a ban of asbestos would have eliminated and there was no clear alternative. So if you can demonstrate that there is a no-exposure use for even a very hazardous chemical, that use should be allowed to go on, so restrictions are much better than bans.

Mr. JOHNSON. Well, thank you, Mr. Chairman. I yield back the remainder of my time.

Mr. SHIMKUS. The gentleman yields back his time. The chair now recognizes the gentleman from California, Mr. McNerney, for 5 minutes.

Mr. MCNERNEY. Thank you, Mr. Chairman. I thank the panel for testifying today.

Mr. ROSENBERG. I understand there are some 84,000 synthesized chemicals used in the United States today. Is that about right?

Mr. ROSENBERG. There are roughly 84,000 chemicals on the TSCA inventory. They are not all in use at any one particular time, and the estimates are maybe that there is quite a bit fewer that are actually in use right now. We don't have as great a picture on that as we would under a better functioning TSCA. But any of those chemicals that are on the inventory can be used, manufactured or used at any given time. So if they are not in use now, they could be at some time in the future without additional review currently.

Mr. MCNERNEY. How many of those have been cleared for use of those 84,000?

Mr. ROSENBERG. Well, the 62,000 roughly were grandfathered in, so those made it, and I believe the bulk by volume of chemicals that are in use now are from that original 62,000. The 22,000 were reviewed. I think there is some discussion about the extent that they were reviewed but the 22,000 chemicals have some amount of review.

Mr. MCNERNEY. So in your opinion, there are many chemicals that are being used even according to manufacturer's specifications finding their way into the environment and to human bodies?

Mr. ROSENBERG. Yes, absolutely that is the case, and the one piece of evidence for that is the CDC has done its biannual biomonitoring of people and has found—the more they look for, the more they find, but they have found hundreds of chemicals widely in people's bodies and their blood. So there is no question that even chemicals used as intended, whatever that might mean, are still winding up in people's blood or in their bodies and their tissues in

ways that I assume weren't intended and are not good for people's health, presumably.

Mr. MCNERNEY. Ms. Rizzo, have you heard of the term "chemical trespass"?

Ms. RIZZO. Yes, sir, I have.

Mr. MCNERNEY. Would you explain what that means, please?

Ms. RIZZO. That is basically, I haven't given you permission to put that chemical in my body. It is trespassing into my body. That is how it is used. So I think when Mr. Rosenberg referred to bio-monitoring, when you measure in blood, urine, cord milk, other body specimens, the presence of chemicals that you did not intend to have in your body that way, you didn't ask for it, you didn't give permission, that is what the trespass is.

Mr. MCNERNEY. Thank you. Mr. Rosenberg, do you share the view that the statutory changes are needed to protect human health and the environment from unsafe chemicals, or is the EPA going to be able to do this without statutory changes?

Mr. ROSENBERG. No, they won't be able to do it without statutory changes, and it is interesting, if you go back and look, GAO has been saying essentially that for 20 or 30 years. They wrote their first report on TSCA in 1980. They identified very much the same problems then that they are identifying now and it is really up to Congress to step up and take this effort seriously, and at this point the law is such a failure that, you know, a broader range of stakeholders is recognizing that it is causing problems—I talked about this a little bit in my testimony—as a result of this vacuum that is left by EPA's inability to take action, even when they have tried to. States are adopting all kinds of different use restrictions and other bans and activities, and the marketplace is also taking action. I don't think any of that is a bad thing but it is a sign that TSCA is really not working. I mean, there is some preemption authority under TSCA but it has never been exercised as far as I know because they have never been able to accomplish anything that would even hint at preemption. So it is a nonfunctioning law to a great extent, not a total extent but a large extent.

Mr. MCNERNEY. Well, is bureaucratic delay in clearing chemicals part of the problem in protecting our safety? Does anyone want to answer that on the panel?

Mr. AUER. The New Chemicals Program takes 90 percent of its decisions within 90 days. The remaining chemicals, there can sometimes be a bit of delay but, you know, within months or sometimes longer everything is decided.

Mr. ROSENBERG. It would be absolutely critical for Congress to seriously look at streamlining EPA's ability to do different things including getting data from companies and taking actions, both regulatory action and assessment actions, and there is, in addition to whatever hurdles EPA faces, one hurdle is that they are underresourced significantly and particularly in this program, so that is a problem, and then I mentioned this earlier, OMB has been sort of roadblock for even things that EPA has tried to do, particularly in the last few years, with their existing authority. They have taken a number of steps to try to get more information out to the public and assess chemicals, and every step of the way

they have been bogged down by OMB, and that a whole other major problem.

Mr. MCNERNEY. Thank you, panel members, and thank you, Mr. Chairman.

Mr. SHIMKUS. The gentleman's time is expired. The chair now recognizes the gentleman from Mississippi, Mr. Harper, for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman, and thank each of you for being here and giving us your insight. We have many things we need to look at as we go back and review this and see where we are, and I would like to start with Ms. Roberts, if I could.

Thank you for your earlier presentation. I tried to squint as best I could to read the slide and follow that, but thank you for your time on that. Can you tell me what the practical difference is between the authority in Sections 4 and 8 to develop information?

Ms. ROBERTS. Sure. My apologies for the small print on the slides, but I did want to try to fit everything into one slide so that people could sort of reference it back. So under Section 4, EPA has the authority to require testing, and I am trying to find the exact wording, but if there is concern of an unreasonable risk for a chemical, that is one finding that EPA can make to issue a test rule, or if the chemical is produced or released into the environment in substantial quantities, that is the second finding that EPA would have to make in order to issue a test rule. It seems to me that the Section 8 provisions that currently exist give EPA that opportunity to collect that information. Section 8(e) requires companies to immediately inform EPA if there is a substantial risk on a chemical. Section 8(c) requires companies to provide EPA upon request information that they gather from their companies. So I think that would make that first finding the significant risk. The second finding of production volumes are already collected under the chemical data reporting, which occurs every 4 years, or under Section 8(a) should EPA decide they want to gather that information.

Mr. HARPER. OK. Can EPA gather enough information under Section 8 to justify a test rule under Section 4?

Ms. ROBERTS. It is my belief that they could, yes, sir.

Mr. HARPER. Now, I know Mr. Rosenberg had argued that CBI should be protected less and re-substantiation required for these claims. What are the issues that come with it?

Ms. ROBERTS. I think we need to recognize that TSCA covers a huge gamut of different industries and different businesses, and so while the idea of re-substantiation on a certain periodic time may make sense for some companies, it may not for all. So for certain companies, for example, Coca-Cola comes to mind. They are not going to share their formulation ever. So if they had to re-substantiate that every year, and I realize it is not covered under TSCA but it is the first example that came to mind, that would be very problematic for them. And again, keep in mind the type of information that is required under TSCA under New Chemical Notification. You have to tell the EPA what the byproducts are, what the impurities are. That could be very meaningful information for a competitor because now they know what you are using to manufacture that. Volumes produced, again, could be very meaningful to a competitor to get a better understanding of what your market

share is so that they may be able to glean into it. So again, CBI is extraordinarily important and really should not be taken lightly.

Mr. HARPER. Thank you for that.

Ms. ROBERTS. My pleasure.

Mr. HARPER. Mr. Gomez, if I may ask you, the Acting Administrator of EPA's Chemical Office told you that the law makes it impossible for EPA to assess and regulate chemicals. How will EPA use its requested \$67 million for this office in fiscal year 2013?

Mr. GOMEZ. That is a very big question, and a good question, and that is something that we will have to get back to you on since EPA is not here, who could probably better answer it. But EPA, one thing that I do want to mention though, EPA has this new approach that I talked about in my statement, and so in this new approach, they are doing new things using the existing TSCA authority. So one of the things that we talked about earlier already is they are extending those Significant New Rule uses where they have added a lot more chemicals that they are looking at, so they are trying different things to try and get more information. We noted that basically it is too early to tell whether that is going to be achievable or not, especially since in their strategy they haven't laid out some key elements that we think are needed for them to succeed.

Mr. HARPER. Do you agree with that assessment, that the resources are not there, that \$67 million is not sufficient to do this?

Mr. GOMEZ. Sure. That is what the Agency has told us also that it is a reason because of resources but it is not something that we have looked at specifically to see if they have the resources.

Mr. HARPER. And you will have to give me a quick answer on this, but your testimony mentions the EPA creation of a Chemicals of Concern list under Section 5(b)(4) and the delay of this list at OMB. Could you please explain in very short order for me the specific understanding of and maybe the criteria for the "may present" clause which either gets a chemical on or off the list?

Mr. GOMEZ. Well, very briefly, that is something I will have to get back to you on, but that list is still at OMB. It has been there for a while. So—

Mr. HARPER. I would appreciate it if you could give me a detailed answer to that.

Mr. GOMEZ. We will do that.

Mr. HARPER. Thank you very much. I yield back my time.

Mr. SHIMKUS. The gentleman yields back. The chair now recognizes the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman. I appreciate your holding this timely hearing on the Toxic Substance Control Act. Over the years—and again, some of you may not know I represent a district that is heavy petrochemical, the biggest petrochemical complex in the country, second in the world. There is nearly universal consensus among all stakeholders that we need to have TSCA reform, and it is necessary to provide greater regulatory certainty for the industry while giving EPA the necessary authority to protect human health and the environment from hazardous chemicals, and I know the Senate just before the death of Senator Lautenberg, he and Senator Vitter had introduced legislation that had been put together as a compromise. We have had TSCA reform legislation in

the House and Senate for it seems like my whole career here, and it has never gotten anywhere. So maybe we need to see what we can do to bring the parties together which the Senate has been doing and work across the aisle.

My first question is for the whole panel. In 2008, I introduced a bill that would have banned the import, manufacture and distribution of asbestos in response to a 1991 court hearing that the EPA's attempted ban of the substance did not follow the least burdensome requirement clause under TSCA. My question for everybody on the panel: If the least burdensome requirement were removed from TSCA, would EPA have a strong authority to protect human health and environment and be able to uphold future bans on known dangerous substances like asbestos before a court trial? If you could do yes or no, obviously we have a big panel. In fact, we have more panel than we do members.

Ms. ROBERTS. Although I am not a lawyer, I think I am going to say it depends. I think I would be concerned if there was not a least burdensome aspect in the regulation simply because banning an entire chemical versus picking certain applications that are high risk could be problematic, and so I think there is some good reason for least burdensome, and I leave that as my answer.

Mr. AUER. I think the "the" in "the least burdensome" is a big part of the problem. I do think that those concepts are important and need to be accommodated in any such determination.

Mr. GREEN. Mr. Gomez?

Mr. GOMEZ. Sure. That is something that really is a policy call, I believe. I mean, GAO has gone on record to say that it is a high legal threshold for EPA to meet and has had difficulty meeting that, and if that is changed, whether or not that results in different outcomes.

Mr. GREEN. Anyone else on the panel?

Ms. BOSLEY. I agree with Charlie that "the least burdensome" is probably too high a threshold but "least burdensome" should be in the mix there as far as the risk-making decision.

Mr. ROSENBERG. "Least burdensome" is definitely a problem, and EPA would be better able to regulate without it. TSCA contains a bunch of options that EPA has to use, and there is no reason that they should or would always go to the maximum option that they have but in certain instances that is the most health protective, and since the statute is intended to be health protective, that should have priority.

Ms. RIZZO. Yes, I would just add that the burdensome part is also the burden on public health that should be weighed evenly with the burden on business in making that decision.

Mr. GREEN. OK. Ms. Roberts, in your testimony you state that the EPA has been constrained when using its rulemaking authorities. Why is that, and what are the ramifications of that constraint?

Ms. ROBERTS. In my view, the reason that they are constrained is because rulemakings in general take a long time. There is a lot of administrative procedures that are required under rulemakings so that, I believe, is the problem. The ramifications are that they can't gather information in a timely manner and therefore can't make decisions as far as risk management or the needs for testing.

Mr. GREEN. Also in your testimony, you note that EPA could implement a prioritization process which specifies timelines for Existing Chemical Review. Could you elaborate on the benefits of a prioritization process and how it would improve TSCA?

Ms. ROBERTS. Sure. Again, because under the New Chemical Review there is a certain statutory deadline that is associated with that, if there were a specific deadline or at least for a prioritization of existing chemicals that EPA will go through during a review, I think that would keep EPA sort of on the straight and narrow. They would get some work accomplished. As I had said before, there are programs that have started and stopped. I think what we need is to maintain momentum under one particular prioritization program.

Mr. GREEN. Mr. Chairman, in my last 14 seconds, I guess, Mr. Gomez, and you might have to get back with me on this. In your testimony, you note that EPA has difficulty in obtaining adequate information on chemical toxicity and exposure. Has GAO provided recommendations to EPA on how to improve information gathering so that the status of EPA's actions on these recommendations, and also in your professional opinion, does EPA have sufficient resources—staff, funds—to effectively run TSCA?

Mr. GOMEZ. Certainly. We have noted and have commented on the first part of your question and talked about the SNURs that we mentioned earlier, that that is the way that EPA is getting additional information now. The second part of the question we will have to get back to you on.

Mr. GREEN. Thank you. Thank you, Mr. Chairman.

Mr. SHIMKUS. The gentleman's time is expired. The chair now recognizes the gentleman from Louisiana, Mr. Cassidy, for 5 minutes.

Mr. CASSIDY. Thank you all.

Mr. ROSENBERG, just a couple things. You listed the statistics for cancer, how prevalent it is in our society, but you did not mean to suggest those are all due to chemical exposure, I presume?

Mr. ROSENBERG. That is correct.

Mr. CASSIDY. I will just say, your testimony kind of gave way to that. Secondly, let me ask you, you are not also suggesting that when you say that even minimal exposure can cause cancer that there isn't a threshold effect? Anyone who has ever had a hangover has had formaldehyde in their body, and yet—formaldehyde as a metabolite of alcohol—but yet it is not known to cause cancer in that low level or probably half the room wouldn't be here. And so again, you are not suggesting there is not a threshold effect, which is a fairly well documented scientific concept.

Mr. ROSENBERG. Yes. The most recent National Academy of Sciences studies actually recommend EPA's methodology for assessing chemicals not to assume a threshold. They traditionally have not assumed a threshold but—

Mr. CASSIDY. They haven't, but the Native American of Sciences criticized the EPA for not doing so in their methodology on their formaldehyde sort of regulation. As a doctor, I will acknowledge that aflatoxin is something we are all exposed to. It is well known as a carcinogen for liver cancer but it is only over a certain threshold that risk poses itself, not the amount that we get opening up

a little bit of an old jar of peanut butter. If you will send that to me, I would like to see where they deny that there is not that threshold effect.

Mr. ROSENBERG. Absolutely. I would be happy to send that to you.

Mr. CASSIDY. Ms. Rizzo, it turns out my wife is a breast cancer surgeon, and so we were on vacation recently, and you may think we don't have a life, but we were actually looking up the literature on chemical exposure and breast cancer, so it just so happens and serendipitously—

Ms. RIZZO. On your vacation, sir?

Mr. CASSIDY. What is that?

Ms. RIZZO. Was that on your vacation?

Mr. CASSIDY. It was on our vacation, believe it or not. Again, get a life, huh?

Now, I was struck, though, when I looked at the literature that really if you look at the top nine things that are associated with breast cancer, chemicals are not on that top nine or top eight or top seven, and when they speak—unless you include estrogen or hormonal therapy, and then they attribute that overwhelmingly to the metabolic syndrome with high rates of obesity and low rates of physical activity. While we were speaking, I loaded the document that you have in reference 3, the recent IB whatever, and they again emphasize the role of obesity and the metabolic syndrome, absence of physical activity, but don't give the prominence to chemicals except insofar that rat mammary tissue is affected but they admit that it is unclear how well that would translate to human studies. Any comments on that? Because from your data, from your presentation, I get a sense that chemicals are the etiology, and my wife has just told me you have to reassure women as to what—rightly reassure them as to what the real risk is because they can modify cigarettes and alcohol and weight and physical activity. If you add the existential concern of chemicals, which is very unproven as to their role, then that makes it harder for the physician to provide that reassurance. What are your thoughts on that?

Ms. RIZZO. Well, we are sympathetic with the uncertainty and with the difficulty that it provides. If you look at all of the known risk factors, you can account for maybe half of breast cancer. I will give you an example that might be working looking at—

Mr. CASSIDY. Well, no, not if you include estrogen because obviously women—my wife always says, and believe me, if I could channel my wife here, I would be a much better man. My wife would say that the primary risk factor for breast cancer is being a woman, and she would then say that it clearly is related to hormones because it happens after menarche, and that the earlier the menarche, i.e., the longer the exposure to estrogen, the higher the risk, and then you go into cigarette smoking and alcohol. Now, we do know the risk factor, and it is estrogen exposure.

Ms. RIZZO. Well, it is also estrogen-mimicking exposure, and that is where the toxic chemicals come in.

Mr. CASSIDY. Now, that literature, though, is very thin. I have looked at it, and it is principally among rat mammary tissue, and it is unclear from the scientists, and that article that you ref-

erenced points this out, that it is unclear how well you can translate rat data to human data. Do you dispute that?

Ms. RIZZO. I don't think that was the conclusion of the report. The animal-to-human paradigm was an essential factor in this issue. The hormonal factor, the chemical exposure factor—I will give you another example.

Mr. CASSIDY. Those are two different issues, though. The hormonal factor again is related to physical activity and obesity. The more physical activity, the less obesity, and the more obesity, the earlier the age of menarche, that is so well established, and my wife is always preaching that gospel, so that is why I want to make sure that we acknowledge what we know to be the strongest risk factors and also acknowledge that the role of chemicals is really not as well defined.

Ms. RIZZO. Which part of that would you like me to challenge back?

Mr. CASSIDY. The very last one, because all the studies I have read were all on rat data, so unless the rat data is—

Ms. RIZZO. No, there is also human data. We are in the middle of a human experiment, and I will give you a couple examples of that. Camp Lejeune, the military base, where these military men were exposed to solvents in the water. We have over 100 cases now of male breast cancer as a result of that exposure to that toxic chemical. Male breast cancer is not an ordinary occurrence. You wouldn't expect a cluster of it. Very highly associated to a chemical exposure. So that is one factor that I wanted to point out.

Mr. CASSIDY. I have read about this 3 years ago so I am a little rusty but the Army takes some issue with that epidemiology, as I recall. I am not saying you are wrong. I am just saying that before we accept it as totally unchallenged, I think I remember that the Army does challenge that. Is that fair? Oh, I am sorry, the Marines. I don't want to offend anybody.

Ms. RIZZO. No, it was Marines. The ATSDR is looking into that at the CDC, and I am more than happy to follow up with some additional information on that. And the second part has to do with the BRCA gene and—

Mr. CASSIDY. That is purely genetic.

Ms. RIZZO. Yes, that is genetic, but there is a four- or five-fold increased risk of breast cancer in women with the BRCA gene than there was back in the 1940s.

Mr. CASSIDY. But then also if you look at the mean body weight of women from now relative to the 1940s, the mean body weight is significantly higher than it formerly was, again supporting the fact that obesity and the estrogens produced by adipose tissue, or fat tissue, is a stronger risk factor as your paper promotes.

Ms. RIZZO. I would also look at obesogens, sir, and I am happy to send you some on the chemicals that act as obesogens that are contributing to early childhood obesity and early puberty.

Mr. SHIMKUS. The gentleman's time is far expired. I have enjoyed the questioning. Now the chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman. I want to continue to pursue that issue because there are a lot of different causes for dis-

ease and we can isolate some but we can't know all the factors that are happening.

Every day American people come in contact with a wide range of chemicals in their food packaging, in their furniture, in their workplace. They believe these chemicals have been found to be safe, that they have been tested, but this is a mistaken impression. In many cases, chemicals simply aren't tested, and in some cases, even chemicals that we know pose substantial risk remain in the products that we use every day. As cancer rates and the rates of other serious health issues arise, we have an obligation to do more.

So Ms. Rizzo, what are some of the carcinogenic chemicals that have been linked to breast cancer or to mammary tumors in animal studies?

Ms. RIZZO. Well, I think you can look at some of the—you know, we have benzene, we have the solvents, we have some of those chemicals, organochlorines, the persistent bioaccumulative chemicals. Then we have those chemicals that disrupt the endocrine system that we were speaking about earlier that are provocative, that act like estrogen, that trick your body into believing you have been exposed to estrogen, which we know a woman's lifetime exposure to estrogen increases her risk. So if your body is exposed to chemicals that act like estrogen, they provoke in the same way. We saw that with hormone replacement therapy. I don't think anybody can forget years ago when the Women's Health Initiative study came out, and millions of women stopped taking hormone replacement therapy, which was increasing risk between 26 and 40 percent, and we saw a drop in breast cancer incidence at that point because women exposed to that hormone for 4 years or more had a dramatic increased risk. So we know that hormonally active chemicals, biologically active chemicals are connected to breast cancer.

Mr. WAXMAN. Are those the same as carcinogens?

Ms. RIZZO. They are not categorized as carcinogens. They provoke in a different way. They can set us up for other exposures that provoke rapid cell C invoice or interfere with periods of time when our cells are in rapid cell development.

Mr. WAXMAN. Have adequate restrictions been imposed on these chemicals that you are discussing to prevent human exposure to the extent possible?

Ms. RIZZO. I would say no, they are not.

Mr. WAXMAN. What are some of the ongoing uses of those chemicals that might lead to dangerous exposures?

Ms. RIZZO. Those chemicals, I will give you—there are chemicals in our food can linings. There are chemicals in personal care products. They are not all under the control and auspices of the Environmental Protection Agency. But that which EPA and TSCA does to assess risk, to look at chemicals has an influence across the broad spectrum of uses. So if we don't test chemicals that we are exposed to in a real way every day in real time, in mixtures, in accumulation and over time, then we will never fully understand, as was raised, what their contribution is but we know that if in cell studies they are making cells turn into cancer, if they are giving mammary tumors in animals, then we should expect a similar impact on humans. We do that to test pharmaceuticals. We like animal testing when we are trying to approve a pharmaceutical for

clinical trial. We don't like it so much when it tells us the chemical may harm us.

Mr. WAXMAN. My colleague was talking about other factors—obesity, cigarette smoking. I would assume that gene that would make a woman more susceptible or more likely to have breast cancer would be another factor. If those factors are serious factors, does that negate the impact of these chemicals?

Ms. RIZZO. Not at all, and 5 to 10 percent of breast cancer is associated with the breast cancer gene. Smoking is a chemical, so let us not forget, tobacco smoke and secondhand smoke are chemicals. When you look at the obesity and you look at the contributing factors to obesity and you look at some of the chemicals in food packaging and in food, then we have to ask the question, what are the other exposures that are contributing to that. It is not simply a matter of eating too much.

Mr. WAXMAN. Let me ask you about these endocrine disruptors because you seemed to single them out as the most serious. Have those chemicals been adequately restricted or banned, and what are some of their ongoing uses to which we might be exposed?

Ms. RIZZO. Endocrine disruptors have not been, and I think there is an effort—the endocrine disruption panel that should be working on this is, I don't know, 10 years behind time, I think. We can certainly get more information for the committee. I don't want to mistake that time frame. But that is not an insignificant effort that needs to be made to look at the impact of endocrine-disrupting chemicals, and we are not talking just about breast cancer. We are talking about testicular cancer, prostate cancer. These are hormonally responsive cancers, and it is demonstrated in cell and animal studies. So I think it is very important that we look at those, that we study them adequately and that where we don't need them, we shouldn't be using them when they are non-essential. There are things that we essentially need but we don't need to have some of those chemical exposures, and I think it will spur innovation if we say we are concerned about them, come up with an alternative to bisphenol-A or to phthalates or to some of the others. And I am sure our American industry can do it. We are smart. I am confident in them.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. SHIMKUS. The chair thanks the ranking member. The chair wishes to thank you all for a really productive and educational hearing. I want to advise you that you will be receiving written questions as were posed, and your answers will be included for the record. I want to advise members that there will be five legislative days for members to submit opening statements for the record. Finally, with all the interest in this subject, we are going to leave the record open to receive helpful comments on this subject. Without objection, so ordered.

The hearing is now adjourned.

[Whereupon, at 12:14 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (209) 225-2827
Minority (203) 225-3641

July 22, 2013

Mr. Charles Auer
President
Charles Auer and Associates LLC
17116 Campbell Farm Rd.
Poolesville, MD 20837

Dear Mr. Auer,

Thank you for appearing before the Subcommittee on Environment and the Economy on Thursday, June 13, 2013, to testify at the hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Monday, May 13, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Kirby.Howard@mail.house.gov and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy
Attachment

130



Charles Auer & Associates, LLC
17116 Campbell Farm Rd
Poolesville, MD 20837

Sent by email

September 20, 2013

The Honorable John Shimkus
Chairman, Subcommittee on Environment and the Economy
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Mr. Shimkus:

As requested, please find below my responses to the "questions for the record" posed to me in your letter of July 22, 2013.

I appreciate having had the opportunity to testify before the Subcommittee.

Regards,

/s/

Charles M. Auer, President

Questions for the Record**The Honorable John Shimkus****1. Why do you think EPA has been more successful assessing and regulating new chemicals than existing chemicals?**

Assessing and regulating new chemicals under TSCA is in general a less complex undertaking and involves a regulatory standard which is more easily satisfied than is the case for regulating existing chemicals. Specific advantages generally held by the new chemicals effort include the fact of the 90-day clock, an assembled "case file" in the form of the Premanufacture Notification, the existence of a generally limited set of information and facts to be reviewed, the fact that EPA is dealing with a single company working to establish a new market (rather than working to protect existing investment and markets as is the case for existing chemicals), and most importantly the more workable and easily satisfied §5(e) regulatory standard that is implemented via a consent order negotiated with the notifier. Other advantages include the fact that the use of §5(a)(2) SNUR authority to regulate a new chemical is a relatively straightforward alternative or complement to a Consent Order for a new chemical. The §5(h)(4) exemption procedure has been used to regulate thousands of new chemicals and has proven to be an effective and valuable regulatory tool for eligible new chemicals.

Existing chemicals assessment and regulation is much more difficult to realize. The §6 regulatory standard and requirements have proven difficult and complex to satisfy; EPA often lacks use or exposure information needed for assessing risk and, in order to obtain such information, EPA would need to propose and promulgate a §8(a) reporting rule; given the nature of existing chemicals, the hazard, exposure, and risk aspects of the cases are often considerably more complex to sort out and assess; and the regulatory proceeding generally involves multiple manufacturers as well as established processors and users of the chemical. SNUR authority can be useful for regulating existing chemicals but the conditions have to be in place (i.e., manufacture or uses must have ceased) for the authority to be applied. These combine to make assessment and regulation of existing chemicals a much more difficult undertaking with the result that EPA has not been successful in dealing with existing chemicals.

2. Please compare the success of the Agency in getting chemical information under voluntary efforts versus under test rules or enforceable consent agreements?

Test rules and enforceable consent agreements (ECAs) have proven difficult and cumbersome to use in obtaining needed testing with the result that only about 200 chemicals have been handled using these approaches. EPA has tried various approaches in applying §4 authority, including actions on individual chemicals and on multiple chemicals (e.g., based on a chemical category-type approach (brominated flame retardants, e.g.), an endpoint approach (neurotoxicity), or regulatory need (e.g., "OSHA dermal" chemicals, Hazardous Air Pollutants under the Clean Air Act), but success was very limited. While ECAs were useful in a few instances to obtain needed testing, on multiple occasions it proved difficult to reach final agreement on the testing; §4 rulemaking was not generally seen as a credible backstop which contributed to this result.

When EPA, working with industry and environmental groups, developed the concept of obtaining screening level testing on large numbers of High Production Volume (HPV) chemicals in 1998, EPA,

recognizing the scale of the HPV effort and the issues encountered historically with use of test rules and ECAs, decided to rely on a voluntary "challenge" program. According to EPA's website,

As of June 2007, companies sponsored more than 2,200 HPV chemicals, with approximately 1,400 chemicals sponsored directly through the HPV Challenge Program and over 860 chemicals sponsored indirectly through international efforts. (<http://www.epa.gov/hpv/>)

While the voluntary HPV Challenge Program was quite successful in obtaining new information, including new testing, on HPV chemicals, EPA still had to deal with "orphan" HPV chemicals that were not voluntarily sponsored as well as with HPV chemicals where sponsors were not willing to voluntarily conduct needed tests. In these cases the weaknesses evident in the rulemaking and ECA approaches have meant that, some 15 years after the start of the HPV Challenge, actions are yet to be concluded and some HPV data needs remain unmet.

3. If EPA's legal ability to obtain more test data were strengthened, and there were no other changes in law, what would be the practical effect for the program office and TSCA implementation?

In my view, TSCA's inability to obtain needed testing on existing chemical was the Act's central failing. Statutory changes that would allow for these data needs to be met would greatly strengthen the program's ability to assess the hazard and environmental fate issues presented by existing chemicals. While this would represent a significant improvement and one that would be useful and valuable to EPA, industry, and other stakeholders at many levels, the continued weaknesses in TSCA's authority to promptly obtain exposure and use information needed to inform risk assessment and to undertake and conclude needed control actions would prevent EPA from realizing TSCA's goal of managing unreasonable risks.

4. Please explain how a data call-in works under Section 8(c) and why EPA has not used this authority in some time?

Under TSCA §8(c), companies are required to record and retain, and in some cases report to EPA, "allegations of significant adverse reactions" to any substance/mixture that they produce, import, process, or distribute. EPA's TSCA §8(c) rule includes provisions whereby producers, importers, and certain processors of chemical substances and mixtures are required to report §8(c) allegations to EPA upon notice in the Federal Register or upon notice by letter. EPA last required companies to submit §8(c) allegations some time in the 1990s and, as I recall, EPA did not find the information submitted to be particularly helpful in identifying possible new issues or improved understanding concerning the subject chemicals. Given what I recall to be the limited value of the information received as well as the burden of the effort to collect and evaluate the information, EPA has not used such call-ins since then. I understand that EPA has recently identified a possible interest in using §8(c) as one of the tools in assessing certain Work Plan chemicals and more information on this question may be available from the Agency.

5. TSCA Section 5 encourages EPA to regulate new chemicals that are a "potential problem" and led EPA to develop and rely on Structure Activity Relationships (SAR) analysis as a tool to assess and identify potentially hazardous new chemicals. Do you believe that these predictive assessment tools have worked to identify potential problem chemicals?

Yes, I believe based on my experience while at EPA that these tools and approaches have been used effectively and successfully to identify potentially problematic new chemicals. The Annex to my testimony notes several efforts that EPA has undertaken to "check its work," and over the past several

years other jurisdictions (including Canada and the European Union) have come to rely on SAR approaches for identifying possible concern chemicals, all of which speaks to the growing recognition of its value for this purpose.

6. The Committee received testimony that EPA is in a “Catch-22” situation about needing to show “unreasonable risk” before it can require testing. Is that true?

No, this “Catch 22” statement is not accurate. TSCA §4(a)(1) provides authority for EPA to require testing via rulemaking that relies on, among other findings, a finding that the chemical “may present an unreasonable risk” or a finding that the chemical is produced in substantial quantities and has substantial or significant exposure/release. Risk does not factor into making the latter (exposure based) finding.

7. EPA has 90 days to review a new chemical before it goes into production, but some say EPA cannot compel manufacturers to submit safety data in the Pre-Manufacturing Notice and very few companies do so voluntarily. Is that true?

TSCA §5(d)(1) specifies the information that is required to be submitted in the Pre-Manufacturing Notice and, regarding safety data, requires that “any test data in the possession or control of the person giving such notice...on health or the environment” must be submitted. TSCA §5 thus requires that existing data available to the notifier be submitted in the PMN.

Thus it is not true that EPA cannot compel the submission of test data in PMNs; on the contrary, notifiers are required to submit any data in their possession. On the other hand, it is true that most PMNs do not include health and safety data in the submission; EPA states that “(T)he information included in PMNs is limited: 67% of PMNs include no test data and 85% include no health data.”

(<http://epa.gov/oppt/pubs/oppt101-032008.pdf>)

8. Is the exposure-based standard a suggestion to EPA to obtain greater scientific certainty on higher volume/higher exposure new chemicals?

Yes, I read the exposure-based finding as encouraging EPA to obtain testing on such chemicals, be they new or existing chemicals, regardless of the Agency’s ability to support hazard or risk concerns for such chemicals.

a. Do you think this authority can help improve EPA’s approach as a check on “false negative” new chemicals?

In this context, a “false negative” new chemical is one for which EPA, using its SAR approach, does not identify health or environmental hazard concerns. Because the exposure-based authority does not rely on hazard or risk issues as a basis for requiring testing, every new chemical for which testing is required based on this authority provides a check on the accuracy of EPA’s initial assessment of “low concern,” and thus can serve as a check on such false negatives.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

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Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2327
Minority (202) 225-3641

July 22, 2013

Mr. Alfredo Gomez
Director
Natural Resources and Environment
Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Gomez,

Thank you for appearing before the Subcommittee on Environment and the Economy on Thursday, June 13, 2013, to testify at the hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

**GAO Responses to Questions for the Record
Hearing before the Subcommittee on Environment and the Economy
Committee on Energy and Commerce, U.S. House of Representatives
On June 13, 2013**

Member Requests for the Record

The Honorable John Shimkus

1. What prevents EPA from concluding an agreement with the European Chemicals Agency to obtain data pursuant to REACH?

- As we stated in GAO's report: *Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemical but Could Strengthen Its Approach* (GAO-13-249, March 22, 2013), under the European Union's chemicals legislation, the European Chemicals Agency may share information it receives from chemical companies with foreign governments in accordance with a formal agreement concluded between the European Community and the foreign government, but EPA has not pursued such an agreement. According to EPA, it has an informal agreement or Statement of Intent, for cooperation and sharing of information with European Chemicals Agency, and had hoped that such an agreement would allow for the sharing of detailed studies, beyond the summaries made publically available by European Chemicals Agency.

a. Could EPA issue a section 8 rulemaking requiring information collecting of the same data provided by U.S. companies to the European Chemicals Agency?

- EPA could issue a rule under section 8 of TSCA requiring companies to provide EPA with the information provided to the European Chemicals Agency, but as we reported in GAO-13-249, EPA officials told us that the agency has not sought to obtain chemical data—from either the European Chemicals Agency or companies directly—because it does not believe that this would be the best use of EPA or industry resources. They also said that it is unclear whether these data would be useful to EPA. EPA officials believe it is a more effective use of resources to gain access to data, as needed, on a case-by-case basis from chemical companies.

b. Does EPA have resources to effectively and efficiently process and use these data?

- EPA's 2012 *Existing Chemicals Program Strategy*, which is intended to guide EPA's efforts to assess and control chemicals in the coming years, does not include a description of the resources needed to meet its goal of ensuring chemical safety. As such, EPA has not evaluated whether it has resources to effectively and efficiently process and use chemical data from either the European Chemicals Agency or companies directly. However, EPA officials have recognized that rules under section 8 of TSCA could be fashioned in such a way as to establish general access to information while providing EPA with the flexibility to request the information as needed.

2. Your testimony mentions EPA creation of a "chemicals of concern list" under Section 5(b)(4) and the delay of this list at OMB.

a. Please explain the specific criteria for the "may present" clause that determine if a chemical goes on or off the list.

- Section 5(b)(4)(a) of TSCA provides as follows:

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including--

the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

Mr. Auer testified that EPA is always trying something new, often coinciding with changes in Administration.

b. Do you agree, and if so, has GAO considered suggesting that new Administrations more carefully evaluate the net benefits of stopping or substantially altering existing TSCA programs?

- GAO has not looked into this issue in any of our past work.

3. We had understood that section 4(a) contains two routes by which EPA is permitted to issue rules for testing of existing chemicals: (1) the manufacture, processing, distribution, use, or disposal of the chemical substance or mixture "may present an unreasonable risk of injury to health or the environment" or (2) the chemical substance or mixture is or will be produced in very large volume, and (a) a substantial quantity may be released into the environment or (b) there is or may be substantial or significant exposure to it. Under either condition, EPA must issue a rule requiring tests if: (1) existing data are insufficient to resolve the question of safety, and (2) testing is necessary to develop the data. In the case of a chemical mixture, EPA is obligated to issue a test rule if health or environmental effects cannot be determined by looking at each component separately.

Could you please clarify what your understanding of Section 4 is on this point?

- As we stated in our testimony, to require testing under section 4, EPA must find that a chemical (1) may present an unreasonable risk of injury to human health or the environment or (2) is or will be produced in substantial quantities and that either (a) there is or may be significant or substantial human exposure to the chemical or (b) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities. We've reported that, due to requirements under TSCA that place the burden

of developing toxicity data on EPA, rather than on industry, and because EPA's past efforts to obtain these data voluntarily were not successful, EPA proposed or promulgated rules to require chemical companies to test 57 chemicals. However, because these rules can take years to finalize and additional time for companies to execute, EPA has yet to obtain much of the information it has been seeking. According to EPA officials, it can take, on average, 3 to 5 years for the agency to promulgate a test rule and an additional 2 to 2 ½ years for the companies to provide the data once EPA has requested them.

In addition, toxicity data eventually obtained on the 57 chemicals may not, in all cases, be sufficient for EPA to conduct a risk assessment (i.e., characterize risk by determining the probability that populations or individuals so exposed to a chemical will be harmed and to what degree). EPA officials told us that much of the chemical toxicity information obtained previously through its 1998 voluntary effort to obtain testing data from companies is considered "screening level" information. That is, the information was collected to identify a chemical's potential hazards to human health and the environment, but it was not intended to be the basis for assessing whether a chemical poses an unreasonable risk of injury to human health or the environment, according to agency documents describing the program. EPA's efforts since 2009 to require companies to test chemicals is based on testing parameters similar to those used under its voluntary effort and thus may produce similar basic screening level data.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
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COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (201) 225-2027
Minority (202) 225-3641

July 22, 2013

Ms. Beth Bosley
President
Boron Specialties LLC
249 Forsythe Road
Valencia, PA16059

Dear Ms. Bosley,

Thank you for appearing before the Subcommittee on Environment and the Economy on Thursday, June 13, 2013, to testify at the hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman

Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

June 13, 2013, Committee on Energy & Commerce Subcommittee on Environment and the Economy Hearing entitled: "Title I of the Toxic Substances Control Act (TSCA): Understanding Its History and Reviewing Its Impact"

Response to Questions for the Record

The Honorable John Shimkus

1) Would you say there are any evaluation deficits using current Section 5 processes for new chemicals, versus a blanket testing requirement?

No. Simply put, a blanket testing requirement is not necessary for EPA to adequately address the potential risks of a new chemical – but it would seriously limit chemical innovation.

Fundamentally, when EPA evaluates a chemical, it looks at the intrinsic characteristics of a chemical -- its hazard -- and potential exposures. This is a risk-based approach, because risk = hazard x exposure.

When EPA evaluates the potential hazards of a new chemical, it is able to compare it with similar chemicals to help guide its decisions. In almost all instances, there are such similar chemicals.

Furthermore, even if toxicity data is not available, the EPA can form reliable judgments regarding potential hazard simply based on a chemical's physical properties, such as how volatile it is or its solubility in water, for example.

During its review, EPA evaluates a chemical's exposure potential. Many industrial chemicals have limited exposures, because they are only used on the site where they are made, or are only sold between chemical companies. These facilities maintain engineering controls, personal protective equipment, and other worker protections. If a substance presents a wide exposure potential (for instance, if it is present in a consumer product), EPA has the authority to require more information before making its assessment.

The Agency also has predictive modeling tools, based on test data, that it can employ to make precautionary decisions if a new chemical does not have toxicity or exposure data. If one of these models predicts hazards, EPA can request (or order) the submitter to generate test data. Since the models are precautionary in nature, the EPA always errs on the side of safety in compelling testing in instances where hard data is not yet available.

When the Agency reviews a new chemical, it can:

- Require testing by order (typically issued on consent),

- Ban the chemical pending testing, or
- Partially approve the chemical by allowing activities indicated in the original Pre-Manufacture Notice (PMN) while requiring a new PMN if those activities change. This is called a Significant New Use Rule (SNUR). It allows EPA to reevaluate a chemical's potential risks if and when uses or exposures change – in those cases where EPA deems it warranted.

EPA can also regulate a chemical under Section 5 based solely on the potential for high releases or exposures – without any need to reach any conclusions about risk.

The EPA has reviewed approximately 52,700 new chemical notifications and exemption notices to date and has been able to evaluate those chemicals for safety. Based on this extensive experience, EPA has developed 56 categories of chemicals that each exhibit identified trends and similarities. These categories are very helpful to EPA and companies, since chemicals of potential concern can be identified early on.

The EPA typically makes a decision on a new chemical within three weeks, although by statute a company must wait 90 days prior to manufacture. (EPA can take 90 days to review a PMN, but in practice submitters usually agree to waive the time limit in cases where EPA demonstrated that it needs additional information. Alternatively, EPA can issue an order restricting the chemical until and unless it receives the information it needs.) EPA currently receives over 2000 PMNs and exemption notices a year for review. Based on about 260 business days in a year, that's roughly 8 PMNs every day, or 40 per week.

The bottom line is that a one-size-fits-all approach or minimum data set is unnecessary. It would not only overwhelm EPA, it would grind innovation to a halt.

Another thing to consider is that new chemicals tend to be "greener," as manufacturers have every incentive to reduce their – and their customers' – costs and potential liabilities by devising less hazardous chemicals wherever feasible. EPA's new chemicals program thus simultaneously promotes innovation and protection of human health and the environment. The new chemicals program should generally be maintained in any TSCA reform effort.

- 2) You call for submission to EPA to include good news about no adverse effects from chemicals regulated under TSCA. Why? Can EPA manage the volume of this information? Can they use it effectively?**

Currently, TSCA section 8(e) creates a bias towards reporting adverse data on chemicals – it only requires companies to submit adverse data, and EPA has resisted attempts by companies to submit nonadverse data, calling them "nuisance filings." This has helped paint an incomplete picture of chemical safety by making it appear as though EPA is only able to assess risks when it

evaluates chemicals. But safety determinations should be based on the weight of all the evidence, using the best available data – that is a key reform of S. 1009. A statutory authorization for companies to submit non-adverse data could help EPA comply with this obligation. While it is impossible to prove absolute safety – because the absence of evidence is not the evidence of absence - it is not clear how companies *could* demonstrate safety without review of nonadverse data.

As for EPA’s ability to manage this additional data load:

- In terms of mechanics, continuing advances in information storage should make it completely feasible.
- In terms of analysis, EPA and the toxicological community generally are steadily evolving more effective ways to compile and search databases and to do initial sorts of studies for relevance and reliability.

In any event, what we propose would be far less burdensome than a blanket minimum data set requirement for new chemicals. *That* would really burden the new chemicals office.

3) Mr. Rosenberg’s testimony suggests that chemicals under TSCA should be treated like pesticides, foods, and drugs. Do you agree with this view and why?

In his oral testimony (at 39:51-40:24), Mr. Rosenberg said that (1) the statutes governing approval of pesticides and pharmaceuticals are superior to TSCA because they place the burden of proof on the applicant, rather than the agency, and (2) the Food Quality Protection Act imposes a more protective safety standard than TSCA.

S. 1009 addresses both issues: (1) it would require EPA to determine “whether” a chemical meets the safety standard, rather than requiring it to show that a chemical may present a risk before it can restrict it; and (2) it would establish a more protective safety standard.

But it would be a gross mistake to go beyond that and to regulate industrial chemicals the way we regulate pesticides, drugs or food additives. The jurisdiction of TSCA covers the universe of chemicals and uses, but it exempts things like pesticides, drugs and food additives that are regulated under their own, subject-specific federal statutes. This is for good reason:

- These types of substances have very specific applications and are relatively few in number. By contrast, there are close to 10,000 chemicals in active commerce, and another 2,000 or so submitted for review every year. These chemicals can and often do have multiple uses.

- Pesticides and drugs are designed to be bioactive – they are supposed to kill pests and affect people’s bodies, respectively. Industrial chemicals are not designed with those intentions.
- Food-use pesticides and drugs are expected to be ingested, and as a result have very distinct exposure pathways that can be carefully modeled. Industrial chemicals are only ingested or otherwise taken into the human body incidentally, typically at very low levels. Their exposure pathways can be highly complex and more conjectural.
- At the end of their approval processes, the makers of pesticides, drugs and food additives are given federally-protected monopolies to make and sell their products. They can thus justify substantial expenditures to gain approvals. Under TSCA, both currently and as S. 1009 would amend it, once a chemical goes on the Inventory, anyone can make it. And this is a good thing, because it encourages innovation and competition. Industrial chemicals have various potential uses and limiting all approvals to identified uses would make every approval a de facto Significant New Use Rule, with debilitating impacts on innovation and competitiveness across our economy. EPA should continue to use SNURs to regulate when necessary, but broad based use of this authority does not make sense for most industrial chemicals.
- The federal programs that review pesticides, drugs and food additives are much better-funded than the TSCA program, both absolutely and – even more so – on a per-chemical-reviewed basis.

Fortunately, EPA has adequate tools to review industrial chemicals without imposing the demanding processes used to review pesticides, drugs and food additives.

4) There was a bit of discussion about protection of chemical identity and CBI.
a. Is CBI protection unique to EPA or TSCA?

CBI protection is not unique to EPA or TSCA. To the contrary, it is ubiquitous across the U.S. Code and the federal government. The Trade Secrets Act,¹ part of the federal criminal code, makes it a crime for a federal employee to divulge trade secrets and similar confidential financially-related information. The Freedom of Information Act exempts essentially the same information from its general disclosure mandate.² But since TSCA is a statute about products and their ingredients generally (i.e., chemicals), protection of trade secrets is of paramount importance.

¹ 18 U.S.C. § 1905.

² See 5 U.S.C. § 552(b)(4).

b. How can you ensure that your employees or neighbors in the surrounding community of the safety of your chemicals if you are claiming this information CBI?

We shouldn't discount the role of TSCA in protecting workers and communities: Industry provides EPA a plethora of information on chemicals, including highly proprietary information on manufacturing processes, volumes, and end uses. Protections for that CBI do not apply to authorized EPA personnel and contractors. So, even where the chemical identity of a substance is not divulged to the public, it is known to EPA, which is able – and legally obliged under TSCA – to evaluate the safety of the substance and to impose necessary restrictions. EPA evaluates worker protections during its review and, when necessary, requires that specific personal protective equipment be worn during handling.

Also, health and safety information on chemicals in commerce is required to be publicly disclosed under TSCA. Even if the specific identity is protected, the generic chemical name (as well as the trade name) of the chemical is released. Generic names can provide sufficient information to interpret the health and safety information and, more broadly, to evaluate the types of hazards a chemical may pose. Hence, TSCA currently affords the needed balance of public right to know and protection of U.S. intellectual property.

Beyond TSCA, other federal laws ensure that plant communities and plant employees are given the information they need to protect themselves and to make judgments about risks. The Occupational Safety & Health Act requires the results of any toxicity and hazard studies regarding a chemical product (including chemicals that are more than de minimis components of mixtures) to be available to workers under OSHA's Hazard Communication Standard.³ This includes labeling requirements and Material Safety Data Sheets (MSDS) – now called Safety Data Sheets – which are also readily available to the public via most companies' websites. Any and all hazards known about the substance are fully described on the MSDS, and the name on the MSDS must match the name on the label of the container in which the substance is packaged. Similarly, the Emergency Planning and Community Right-to-Know Act (EPCRA) requires facilities to provide information about chemicals onsite (including MSDSs) to local emergency preparedness committees and fire departments.⁴ Notably, both of these authorities require companies to provide treating health professionals with the specific identity of a chemical, without a previous confidentiality agreement, in

³ 29 C.F.R. § 1900.1200.

⁴ See 42 U.S.C. § 11021.

emergency situations.⁵ These authorities also provide access to specific chemical identity to medical and public health professionals (in the case of EPCRA), and to health professionals, employees and union representatives (in the case of OSHA), under confidentiality agreements.⁶

As an industry, we want anyone who has an interest to be able to assess the hazards of the chemicals we produce. We do not keep any hazard data confidential. However, specific chemical ID or formulation information, in many cases, is vital company intellectual property and must be protected.

⁵ See 29 C.F.R. § 1900.1200(i)(2), 42 U.S.C. § 11043(b).

⁶ See 42 U.S.C. § 11043(a), (c); 29 C.F.R. § 1900.1200(i)(3)-(11).

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HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2827
Minority (202) 225-3641
July 22, 2013

Mr. Daniel Rosenberg
Senior Attorney
Health and Environment Program
Natural Resources Defense Council
1152 15th Street, N.W., Suite 300
Washington, DC 20005

Dear Mr. Rosenberg,

Thank you for appearing before the Subcommittee on Environment and the Economy on Thursday, June 13, 2013, to testify at the hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Monday, May 13, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Kirby.Howard@mail.house.gov and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

Additional Questions for the Record

The Honorable John Shimkus

Should Federal agencies take public comment on methodologies underpinning the rules that they issue?

NRDC supports an opportunity for the public to comment on methodologies that underpin federal agency rules. The time allotted for such comments should be long enough to provide the public and interested stakeholders with ample time to develop meaningful comments, but not so long as to unduly delay protections for health or the environment. For example, the 2005 Cancer Guidelines were issued in draft form for public comment several times over several years, delaying the document significantly.¹ By comparison, the NIEHS Office of Health Assessment and Translation (OHAT) recently issued its draft method for systematic review and evidence integration for a 90-day public comment period that was of reasonable length and worked well for stakeholders and the public.² Public comment on methodologies underpinning rules is an important step to facilitate Agency consideration of full body of available relevant information as well as stakeholder and public perspectives. However, there is also a risk of repeated and excessive rounds of public comment that are unlikely to yield new information for the agencies, but serve to delay the agency from moving forward to meet its mandate to protect human health and the environment. It is important to strike the right balance in establishing any process that includes public comment on agency methodology. In addition, excessive rounds of inter-agency comment can unreasonably delay the regulatory process. For example, a proposal to add redundant and excessive rounds of inter-agency comment on EPA's IRIS Health Assessments was strongly criticized by the Government Accountability Office (GAO)³, leading to a more streamlined review system⁴.

The Honorable Henry A. Waxman

High incidences of cancer are often found close to industrial areas where large amounts of chemical substances are manufactured, processed or used. In fact, a 100-mile stretch along the Mississippi River that is home to hundreds of industrial facilities is sometimes referred to as "cancer alley." Populations in these areas and others like it are often composed of the poor and minorities. Environmental justice groups have been active in discussions around TSCA because low-income communities and communities of color are disproportionately burdened with environmental hazards and suffer disproportionately from environmentally related diseases.

What are some of the hazards and diseases that people in these communities face from exposures to toxic chemicals?

Many communities across the Nation are disproportionately burdened with the largest exposures to multiple hazardous industries and wastes that pollute the air, water, and land. Within breathing distance, and often within an easy stone's throw, may be chemical storage tanks, oil and gas refineries, open piles of petroleum coke, and asphalt plants, along with churches, schools, playgrounds, homes, and gardens. People living in these communities - including pregnant women, children, the elderly, and the infirm - face far greater exposure to many industrial pollutants than the average American.⁵ As a consequence of these unhealthy and poorly

¹ <http://www.epa.gov/cancerguidelines/draft-final-guidelines-carcinogen-ra-2003.htm>

² <http://ntp.niehs.nih.gov/?objectid=960B6F03-A712-90CB-8856221E90EDA46E>

³ See GAO: "Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System" (March 2008)

⁴ <http://www.epa.gov/iris/process.htm>

⁵ Linder SH, Marko D, Sexton K. Cumulative cancer risk from air pollution in Houston: disparities in risk burden and social

regulated exposures, disproportionately exposed communities often face excessive risk of pollution-related illnesses including cancer.⁶

What we don't know about our exposure to hazardous chemicals is also a problem – whether that exposure comes from living in a particularly polluted area, from workplace exposures, or through commercial and consumer products in our homes. Biomonitoring data from the Centers for Disease Control and Prevention (NHANES/CDC) has found measurable levels of 200 high-production volume chemicals in the blood and urine of virtually all Americans, including pregnant women. While the health implications of this chemical mix is not understood due to the lack of toxicity testing for most of these chemicals, their potential to disrupt fetal and infant development singly and in combination is a significant concern for health professionals wanting to diagnose and prevent disease, disabilities, and developmental abnormalities⁷

In your view, what should be done to address those risks?

Science has proved that assessing the hazards of polluting chemicals and regulating them to reduce human exposures can lead to significant improvements in health. Limiting fine-particulate air pollution – which increases risk of disease and death - is a dramatic example of how regulations and pollution controls can save lives.⁸ In 2013, Dr. Andrew Correia published “Effect of Air Pollution Control on Life Expectancy in the United States: An Analysis of 545 U.S. Counties for the Period from 2000 to 2007.” This study found increases in life expectancy with decreases in fine particulate air pollution levels. The effect was stronger “in more urban and densely populated counties.” The study concludes, “Air pollution control in the last decade has continued to have a positive impact on public health.”⁹

It is critical that Congress continue to identify and reduce toxic chemicals in the places we live, learn, work, and play. One approach that has support from environmental justice groups is directing EPA to identify some of the communities most heavily exposed to toxic chemicals from various sources and to use its existing authorities under TSCA or other laws to address and reduce those exposures. And a reformed TSCA needs a mandate for EPA to take expedited action to regulate those chemicals for which we already have enough information about hazard and safety – such as asbestos and persistent, bioaccumulative and toxic (PBT) chemicals. More broadly, a reformed TSCA that would move us away from production and use of the most dangerous chemicals, and stimulate identification and production of safer substitutes, would likely lead to a reduction of exposure to unsafe chemicals, with a particular benefit for those communities where chemicals

disadvantage. *Environ Sci Technol.* 2008 Jun 15;42(12):4312-22.

James W, Jia C, Kedia S. Uneven magnitude of disparities in cancer risks from air toxics. *Int J Environ Res Public Health.* 2012 Dec 3;9(12):4365-85.

⁶ James W, Jia C, Kedia S. Uneven magnitude of disparities in cancer risks from air toxics. *Int J Environ Res Public Health.* 2012 Dec 3;9(12):4365-85.

⁷ Landrigan PJ, Goldman LR. Children's vulnerability to toxic chemicals: a challenge and opportunity to strengthen health and environmental policy. *Health Aff (Millwood).* 2011 May;30(5):842-50.

Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: implications for policy. *Health Aff (Millwood).* 2011 May;30(5):879-87.

⁸ In 2009, Dr. C. Arden Pope published “Fine-Particulate Air Pollution and Life Expectancy in the United States,” reaffirming past studies and finding “improvements in life expectancy during the 1980s and 1990s were associated with reductions in fine-particulate pollution across the study areas, even after adjustment for various socioeconomic, demographic, and proxy variables.” <http://www.nejm.org/doi/full/10.1056/NEJMs0805646#t=article>

⁹ Correia AW, Pope CA 3rd, Dockery DW, Wang Y, Ezzati M, Dominici F. Effect of air pollution control on life expectancy in the United States: an analysis of 545 U.S. counties for the period from 2000 to 2007. *Epidemiology.* 2013 Jan;24(1):23-31.

are being produced.

Additional steps beyond the scope of TSCA itself that are necessary to address the threats to Environmental Justice and fenceline communities include restoring the polluter pays tax under Superfund to help finance clean-up of “orphaned” Superfund sites, strong enforcement of the Clean Air Act – particularly to address Hazardous Air Pollutants – and stronger permitting and enforcement of the Clean Water Act.

As this Committee considers TSCA reform, how important is it that we address risks to disproportionately burdened communities and other vulnerable populations?

The National Academy of Sciences has called for changes to risk assessment to ensure that vulnerable populations are adequately considered and protected from exposure and harm from unsafe chemicals. Vulnerability can be a result of either inherently greater susceptibility to the effects of chemicals or of disproportionate exposure. There are important variations between individuals that affect their likelihood of developing a disease or other health problem following a chemical exposure. First, the exposure level varies; some people may be exposed to higher levels than others, depending on where they work or live, or what they eat. Second, factors such as age, genetic makeup, diet, socio-economic status, and pre-existing diseases contribute to variability, making some individuals more susceptible to developing a health problem. Multiple exposure and susceptibility factors may interact to increase an individual’s risk from exposure to a particular chemical. For example, exposure at a critical age or during a critical stage of development, underlying health conditions, nutritional status, and/or genetic make-up can make it difficult to metabolize a chemical, and may increase susceptibility. Current risk assessment practices do not fully account for this variability, leaving many people inadequately protected by regulatory standards. In its 2009 report, *Science and Decisions: Advancing Risk Assessment*, NAS recommended that the types, sources, extent, and magnitude of vulnerability should be identified for each step in the risk assessment process. In addition to fully characterizing the population at risk, the NAS stated that special attention should be paid to vulnerable individuals and populations that may be particularly susceptible and/or more highly exposed.

When TSCA was passed in 1976, Congress grappled with many of the same issues that face us now. Worker exposures were a significant concern at that time. The United Steel Workers submitted a letter for the June 13, 2013 hearing record, raising significant concerns about shortcomings in TSCA. According to them, those shortcomings adversely impact workers, to the tune of 190,000 worker illnesses and 50,000 worker deaths every year. Estimates suggest that this costs businesses between \$128 billion and \$155 billion every year.

What are some of the impacts of chemical exposures for workers and their families?

Workplace exposure to chemicals is a significant cause of illness, disability¹⁰ and death¹¹, and risks from workplace exposures can also be brought home to other family members. For example workers exposed to asbestos have brought home the deadly dust on their clothing, leading not only to their own illness and deaths but sometimes also sickening their spouses and children¹². For this reason, EPA and OSHA have both issued

¹⁰ For a disturbing account of how one unregulated chemical has caused serious disabilities for workers in furniture manufacturing, see Ian Urbina, “As OSHA Emphasizes Safety, Long-Term Health Risks Fester,” *New York Times*, March 30, 2013. http://www.nytimes.com/2013/03/31/us/osha-emphasizes-safety-health-risks-fester.html?pagewanted=all&_r=0

¹¹ For one personal statement by a man whose father died prematurely due to workplace exposure to toxic dust, see this blog by Tony Iallorardo: “Labor’s Rewards and Risks: My Father’s Story” <http://blog.saferchemicals.org/2013/08/labors-rewards-and-risks-my-fathers-story.html/>

¹² For example, see “Daughters of the Dust: The Changing Face of Mesothelioma,” by Gary Cohn, on the Mesothelioma Cancer Alliance Blog, <http://www.mesothelioma.com/blog/authors/gary/daughters-of-the-dust-the-changing-face-of->

recommendations to workers that do auto brake and clutch repairs, to change out of their contaminated work clothing before going home to reduce the chances of bringing asbestos into the home environment.¹³ Contamination with the deadly fiber has been found on workers' clothing, hair, shoes, lunchboxes, and cars. Asbestos dust is a highly stable mineral fiber that does not decompose once brought into the home environment, so that hazardous conditions accumulate and become worse over time. In addition to OSHA-regulated workplace exposures, many people do their own brake repairs on their own vehicles. Although asbestos-containing brake pads are no longer made in the U.S., they continue to be imported. It was for this reason that EPA published brake repair guidance documents in 1986 and updated them in 2007.

Overall, a 1995 NIOSH Report to Congress found that the contamination of worker's homes is a global problem, with illnesses and deaths among worker's families reported in 36 states of the U.S.¹⁴ In addition to asbestos, which can affect workers engaged in the manufacturing of insulation, automobile mufflers and brakeshoes, shingles, textiles, floor tiles, boilers, and ovens, many other hazardous materials are well known to be used in the workplaces in ways that can result in contamination of worker's homes. These include: beryllium from the nuclear and aviation industries and golf club manufacturing; toxaphene; mercury vapors from thermometer manufacturing; estrogenic substances from pharmaceutical industries; lead from manufacturing bullets, lead batteries, paints, and stained glass; chlorinated hydrocarbons from manufacturing insulated wire, plastics, resins, and textiles; arsenic from mining, smelting, and wood treatments; fibrous glass from insulation used in the construction industry; and explosive compounds.¹⁵

In terms of worker health, asbestos has been a significant historical risk for workers.

Has EPA been able, given its current tools to address the risks of asbestos exposures?

No. Most exposure to asbestos has occurred in the workplace, and it is estimated that 10,000 people continue to die each year in the U.S. as a result of asbestos-related illness. There is no safe level of asbestos exposure. EPA has not been able to adequately regulate the risks of asbestos under the current law. The Reagan and Bush administrations spent 10 years developing a rule on asbestos under TSCA, concluding that there was no safe level of exposure, and calling for a ban on all current, future and past uses. EPA's ban on existing uses of asbestos was ultimately rejected by a federal appeals court for, among other things, the agency's failure to adequately account for the costs and benefits of the regulation -- to determine whether the threat of asbestos posed an "unreasonable risk" sufficient to justify the regulation. As a result of that court decision, asbestos remains in use in the U.S., despite being banned in more than 50 other countries.

As this Committee considers TSCA reform, how important is it that we address worker exposures?

Throughout the history of industrial labor, workers have been exposed to hazardous, even deadly substances -- chemicals, radiation, mineral fibers, dusts -- that irritate, ignite, explode, or damage cells and organs in ways that are invisible, irreversible, and sometimes even inter-generational. Deaths due to disease may occur long after exposure to the cause, and are often therefore not recognized as being associated with workplace exposures and are less visible than deaths due to work-related injuries. However, deaths due to disease from workplace exposures are a much greater problem. Globally, work-related deaths due to disease (1.7 million)

mesothelioma.htm

¹³ OSHA SHIB 07-26-2006 <https://www.osha.gov/dts/shib/shib072606.html>

EPA-747-F-04-004 <http://www2.epa.gov/sites/production/files/documents/brakesfinal-3-07.pdf>

¹⁴ Report to Congress on Worker's Home Contamination Study Conducted Under The Worker's Family Protection Act (29 USC 671a). 1995 DHHS(NIOSH) Publication No 95-123. <http://www.cdc.gov/niosh/pdfs/95-123.pdf>

¹⁵ Report to Congress on Worker's Home Contamination Study Conducted Under The Worker's Family Protection Act (29 USC 671a). 1995 DHHS(NIOSH) Publication No 95-123. <http://www.cdc.gov/niosh/pdfs/95-123.pdf>

occur at a rate 5 times greater than deaths due to work-related injuries (350,000). Cancer and chronic lung disease are two examples of disease associated with multiple workplace hazards. The most common occupational cancers occur in the lung, mesothelium, blood and circulatory system, bladder, skin, liver, and bone.¹⁶ Occupational lung diseases include pneumoconiosis, asthma, and chronic obstructive pulmonary disease (COPD).¹⁷ Pneumoconioses are found in up to half of workers heavily exposed to silica, coal dust, or asbestos fibers.¹⁸ Chemical hazards exist in virtually all types of work, including both industrial and non-industrial activities where metals, dyes, solvents, cleaners, pesticides, and plastics are found. Over 100,000 chemicals exist in the modern work environment, of which about 1,500-2,000 are widely used.¹⁹ A healthy workforce is a necessary asset to the economy and the sustainable development of the US. The unacceptably high number of occupational illnesses that develop each year are preventable by reducing exposure to hazards in the work place. A greater emphasis on primary prevention of illness through the health-protective regulation of hazardous chemicals would make significant and long lasting gains in both the health of the workers and the health of the economy, while reducing employer and society costs. Part of ensuring effective workplace protection in TSCA reform includes ensuring that any safety standard is explicitly based only on health protection – not cost – and that vulnerable populations, including workers, are explicitly protected under the safety standard.

How important is it that we address the aspects of the law that have limited EPA's ability to regulate asbestos?

For TSCA to be a functioning statute, EPA must be able to fulfill the purpose of the Act, to protect the public from unsafe chemicals, including asbestos.²⁰ This means that, where EPA has identified a risk to human health or the environment, the agency must be able to exercise its authority to require the various risk management measures that are outlined in current TSCA. Specifically, TSCA's safety standard should be strictly health-based and protective of vulnerable populations. Costs should not be taken into account in determining whether a chemical causes health problems. Consistent with the way pesticides and pharmaceuticals are currently regulated, the burden of proof should be on chemical manufacturers to prove that a chemical is safe, rather than on EPA to prove that it is unsafe. In addition, while cost should be an element considered in developing the risk management approach for a substance that does not meet the safety standard, the "least burdensome" requirement of current TSCA should be removed. When it comes to analyzing a chemical in terms of either hazard or exposure, asbestos is not a "close call;" it is almost universally recognized as an extremely toxic substance in microscopically tiny amounts (hence its having been banned in more than 50 other countries). The elements of TSCA that have prevented EPA from regulating asbestos must be addressed in TSCA reform if the statute is ever going to be sufficiently effective to save lives and protect the public. There are many other toxic substances besides asbestos that are still widely used in the workplace and that have been linked to illness, disability, and death including methylene chloride²¹, n-Hexane²², vinyl chloride²³,

¹⁶ World Health Organization. Global strategy on occupational health for all: the way to health at work. (1994). http://www.who.int/occupational_health/publications/globstrategy/en/index4.html

¹⁷ World Health Organization. Occupational airborne particulates: Assessing the environmental burden of diseases at national and local levels. (2004) http://www.who.int/quantifying_ehimpacts/publications/9241591862/en/

¹⁸ World Health Organization. Global strategy on occupational health for all: the way to health at work. (1994). http://www.who.int/occupational_health/publications/globstrategy/en/index4.html

¹⁹ World Health Organization. Global strategy on occupational health for all: the way to health at work. (1994). http://www.who.int/occupational_health/publications/globstrategy/en/index4.html

²⁰ <http://www.nrdc.org/health/files/asbestos.pdf>

²¹ <http://www.nrdc.org/health/files/methyleneChloride.pdf>

hexavalent chromium²⁴, and formaldehyde²⁵. While asbestos is the “poster child” for TSCA’s failure, it is just one example that illustrates the importance of EPA having authority to restrict the use of those toxic substances that pose a threat to human health and the environment. After decades of inaction by EPA due to the fundamental flaws of TSCA, EPA needs the authority and the mandate to take expedited action against chemicals we already know are unsafe, and for which widespread exposure has been established.

During the June 13, 2013, hearing, questions were raised about risk assessment methodology and specifically about the assumption of thresholds for dangerous exposures.

What has the National Academy of Sciences said about assumptions of threshold effects for cancer and non-cancer endpoints?

The current approach to evaluating risks for any health effects other than cancer is to assume that there is a ‘safe’ exposure level below which negligible or no health effects will occur (a “threshold” of response). (Note: the practice for carcinogens assumes there is no threshold unless shown otherwise.) In practice, a single chemical is usually tested in a genetically homogeneous strain of rodent, where individuals are raised in the same highly controlled laboratory environment and are healthy, and the dose of the chemical that doesn’t appear to cause any obvious health effects in the animals is used to establish a “safe” threshold. The same threshold (after application of an animal-to-human adjustment factor) is then applied to a diverse human population. This results in levels of many chemicals in food, air, water, and workplaces being declared “safe” even though they may not be.

According to the NAS report *Science and Decisions*, “[S]mall chemical exposures in the presence of existing disease processes and other endogenous and exogenous exposures can have linear dose response relationships at low doses.”²⁶ In other words, there may be no “safe” threshold in the human population for many chemicals. Newer science is finding many examples of chemicals that increase the risk of various non-cancer health effects - such as reproductive harm and neurological effects - at low doses, without any scientifically identifiable threshold.^{27, 28} Even if a threshold were to be established in an individual, when risk is assessed across a diverse population, there is a diminishing likelihood that a threshold exists at the population level because some people are more vulnerable than others.

The *Science and Decisions* report recommended that agencies use the same approach for addressing risks from both cancer and non-cancer health effects (such as developmental or reproductive effects). The committee concluded that “scientific and risk management considerations both support unification of cancer and non-cancer dose response assessment approaches.”²⁹ They called for a “unified-dose response framework” that includes a systematic evaluation of factors such as background exposures, disease processes and inherent

²² <http://www.nrdc.org/health/files/hexane.pdf>

²³ <http://www.nrdc.org/health/VinylChloride-fs.asp>

²⁴ <http://www.nrdc.org/health/files/hexavalentChromium.pdf>

²⁵ <http://www.nrdc.org/health/files/formaldehyde.pdf>

²⁶ *Science and Decisions: Advancing Risk Assessment*. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Research Council (2009). National Academies Press, Washington D.C. ISBN: 0-309-12047-0, p. 158.

²⁷ Grandjean P, Bellinger D, Bergman A, et al. The Faroese Statement: Human Health Effects Of Developmental Exposure To Chemicals In Our Environment. *Basic Clin Pharmacol Toxicol*. 2008. 102(2):73-5.

²⁸ Grandjean P, Landrigan PJ. Developmental neurotoxicity of industrial chemicals. *Lancet*. 2006. 16;368(9553):2167-78.

²⁹ *Science and Decisions*, p. 9.

vulnerabilities. This evaluation will inform the choice of the appropriate dose-response model. The NAS also pointed out that there are multiple differences in the population due to age, disease status, nutrition, and other factors. Due to these differences, and the fact that people are exposed to multiple chemicals, the science supports using a model that does not have an assumption of a “threshold” below which exposures cause zero risk in the population. The NAS recommended that a conceptual model be developed that is “from linear conceptual models unless data are sufficient to reject low-dose linearity; and nonlinear conceptual models otherwise.”³⁰

In essence, the approach recommended in Science and Decisions is to assume that all exposures, even low ones, are associated with some level of risk unless there is sufficient data to reject this assumption, after accounting for background chemical exposures, biological additivity, and population variability.

What are the most recent National Academy of Sciences recommendations for conducting risk assessments for chemical substances?

The National Academy of Sciences released three reports in 2007-09, each recommending modernization of chemical health evaluations in the United States.^{31 32 33} A 2012 NRDC Issue Paper, “Strengthening Toxic Chemical Risk Assessments to Protect Human Health” provides a concise and readable summary of the major scientific advances in chemical risk assessment recommended by the National Academy of Sciences in several groundbreaking reports over the past few years. The NAS recommended that, in order to properly focus and avoid getting bogged down, the agency should first identify the decision that needs to be made, and then focus the assessment on answering the specific questions that would most significantly inform the decision. Specifically, the NAS committee recommended identification of options to reduce identified hazards or exposures at the earliest stages of decision-making and using risk assessment to evaluate the merits of the various options, with public involvement at all stages.³⁴ Furthermore, the NAS recommended that simplified guidelines and methods be developed to allow risk assessments to be done in a timely fashion, and to facilitate community participation. The NAS reports recommended four main areas of reform: 1) Identify and incorporate variability in human exposure and vulnerability into health assessments, so that all people are better protected. 2) When information is missing or unreliable, use scientifically based default assumptions that will protect health, rather than waiting for more data, to improve the timeliness of the chemical assessment and decision-making process. There should be a clear set of criteria for when to depart from default assumptions. 3) In assessing the risk of chemicals, incorporate information about the potential impacts of exposure to multiple chemicals. In addition, consider other factors, such as exposure to biological and radiological agents and social conditions. 4) Because the population is exposed to multiple chemicals and there is a wide range of susceptibility to chemical exposures, it cannot be presumed that exposures - even low ones - are risk free. It should therefore be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to reject this assumption.

³⁰ Science and Decisions, p. 144.

³¹ Toxicity Testing in the Twenty-first Century: A Vision and a Strategy. Committee on Toxicity and Assessment of Environmental Agents, National Research Council (2007). National Academies Press, Washington D.C. ISBN: 0-309-10989-2.

³² Phthalates and Cumulative Risk Assessment: The Tasks Ahead. Committee on the Health Risks of Phthalates, National Research Council (2008). National Academies Press, Washington D.C. ISBN: 0-309-12841-2.

³³ Science and Decisions: Advancing Risk Assessment. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Research Council (2009). National Academies Press, Washington D.C. ISBN: 0-309-12047-0.

³⁴ Science and Decisions, pp. 10-12.

As this Committee considers TSCA reform, how important is it that we incorporate those recommendations?

The system in the United States for assessing chemicals for safety is broken. The vast majority of chemicals in use today have never been tested for their potential to harm human health or the environment; chemicals that have been tested have numerous data gaps and uncertainties; the range of human exposures and vulnerability is large and poorly understood; and the risk assessment process for common chemicals is “bogged down” and subject to decades of delay due to corporate interference and litigation. The above recommendations incorporate the best scientific understanding of environmental chemical risks to better protect people from toxic chemicals.

During the hearing, Charlie Auer, a former EPA official and industry consultant, called on Congress to implement international treaties on the regulation of chemicals, including the Rotterdam and Stockholm Conventions.

Do you agree that these international chemical treaties should be implemented in the United States?
NRDC does not have a position on this question at this time.

During the hearing, Beth Bosley, representing Boron Specialties, testified that claims of confidential business information should require up-front substantiation and re-substantiation every five years.

Do you agree with those recommendations?

Yes. Under current TSCA, the lack of up-front substantiation, combined with the lack of a re-substantiation requirement, has led to what amounts to permanent CBI designation for a significant amount of information, including information that should not have qualified for CBI designation in the first place. While legitimate CBI deserves protection under the law, at least for some period of time, the current system has been open to misuse and is badly need of reform. Up-front substantiation and regular re-substantiation are two of the critical elements of reforming TSCA's current CBI provisions.

As this Committee considers TSCA reform, how important is it at we incorporate those recommendations?

It is vital that information that is not legitimately CBI be available to the public. TSCA should promote as much transparency as possible so that the public knows what chemicals are in commerce, for what uses, as well as specific information about the chemical including its potential environmental and health effects.

Throughout the hearing, questions were asked about the safety of chemicals already distributed in commerce in the United States and new chemicals proposed for distribution in commerce.

Have chemicals distributed in commerce in the United States been evaluated for safety?

No, the vast majority of chemicals distributed in commerce in the United States have not been adequately evaluated for safety by the EPA. This is true for several reasons, all related to fundamental flaws in TSCA. First, as far as existing chemicals, the approximately 62,000 chemicals available for use in commerce at the time the law was enacted were grandfathered under the law, meaning that they were presumed to be safe and did not have to meet a safety standard.

For new chemicals, there is no requirement in TSCA that new chemicals be demonstrated to be safe before they can enter the market. This contrasts with the laws governing both pesticides and pharmaceuticals, which must be shown to be safe before being allowed on the market. In addition, limits placed on EPA under TSCA make an adequate evaluation of the safety of a new chemical very difficult. EPA has a limited window of 90 days (with a possible extension of 90 additional days) to evaluate the information provided by a manufacturer in its pre-manufacturing notice. However, because the current law prohibits EPA from establishing a minimum set of data required for new chemicals, most of the time EPA receives little or no information on either health or environmental impacts of a new substance. Instead, EPA must rely on methods developed to accommodate

its limited authority, which seek to compare a new chemical to the structure and available data of existing chemicals. These methods are flawed in several respects, including their inadequacy for screening for a number of potential health effects including reproductive and developmental toxicity.

Are new chemicals proposed for distribution in commerce determined to be safe before being let on the market?

No. There is no requirement under current TSCA that EPA determine that a chemical is safe, or that a chemical manufacturer provide information demonstrating the safety of a new chemical before it is allowed on the market. This is in contrast to the way pesticides and pharmaceuticals are regulated – both require an affirmative safety determination by the relevant regulatory agency and both require the manufacturer of the pesticide or pharmaceutical to provide the agency with data sufficient to demonstrate the safety of the substance. Under TSCA, for EPA to prevent a new chemical from entering the market, it must demonstrate that the substance poses or may pose an unreasonable risk to human health or the environment. This can be difficult since in most instances the agency does not have sufficient data to assess the chemical and is largely constrained from obtaining it. The burden of proof is on the agency to prove the chemical is unsafe, rather than on the manufacturer to demonstrate its safety.

For most new and existing chemicals in the United States, does sufficient data exist to evaluate their safety?

No. For most chemicals in commerce – both those that were grandfathered in when TSCA was enacted and those added since to the TSCA inventory - we do not have sufficient data on either their hazardous (or potentially hazardous) properties or about their uses and the degree (and source) of human and environmental exposures. This is a problem not only because it means we may not know about chemicals that pose a health or environmental risk to which we are being exposed, but also because we don't have sufficient information about potentially safe alternatives to those chemicals that are unsafe.

In addition, the testing provisions of TSCA are sufficiently restrictive and arduous for the agency that it has managed to require only between 200 and 300 of the grandfathered chemicals to be fully tested over the life of the law. To require testing, EPA must conduct a notice and comment rulemaking, which is itself a long and expensive step. In addition, the agency must demonstrate that a substance may pose an unreasonable risk to human health or the environment to support its action requiring testing – information which it may not have without the chemical actually having been tested, creating a Catch-22 which limits the agency's ability to evaluate chemicals in a timely, efficient and health-protective manner. For an excellent illustration of the hurdles EPA faces to obtain information on existing chemicals, I recommend Richard Denison's blog post: "A near-Sisyphian task: EPA soldiers on to require more testing under TSCA."³⁵

Requiring testing for new chemicals is also procedurally difficult under TSCA, and – in combination with the lack of a requirement for a minimum data set – has been a major impediment to obtaining needed data for most chemicals. As discussed above, EPA is significantly constrained in the amount of data and information it can require from a chemical manufacturer and by the process by which it can obtain the data and information. For a fuller treatment of the many problems with the New Chemicals program under TSCA, see Richard Denison's blog: "EPA's New Chemicals Program: TSCA dealt EPA a very poor hand."³⁶

As this Committee considers TSCA reform, how important is it that we require the generation of data, for new and existing chemicals, sufficient to evaluate their safety?

It is very important. Virtually every stakeholder who has appeared before the Energy and Commerce

³⁵ <http://blogs.edf.org/health/2011/01/05/a-near-sisyphusian-task-epa-soldiers-on-to-require-more-testing-under-tsca/>

³⁶ <http://blogs.edf.org/health/2009/04/16/epas-new-chemicals-program-tsca-dealt-epa-a-very-poor-hand/>

Committee in recent years to discuss TSCA reform has testified about the need for TSCA reform (or “modernization”), and most of those stakeholders have been supportive of a risk-based approach to analyzing the safety of chemicals. In shorthand, a risk-based approach means doing a risk assessment of a chemical to determine its potential for safe use in the marketplace. The risk assessment requires an analysis of the hazard (or potential hazard) to human health or the environment posed by the chemical, and the exposure profile of the chemical. In general, you need to have data on both the hazard and exposure of a chemical to do a risk assessment. In instances where data is not available, the standard practice is instead to rely upon conservative, health-protective default assumptions about hazard or exposure. Effective TSCA reform must ensure that EPA can obtain the data necessary to evaluate the safety of chemicals in an efficient and timely manner. For example, allowing EPA to establish a minimum set of data and information needed to evaluate new chemicals, will ensure the agency has what it needs to screen chemicals and, where necessary, conduct more thorough risk assessments. In addition, EPA should be authorized to require testing of chemicals by order rather than full notice and comment rulemaking.

Recently, new legislation to amend TSCA was introduced in the United States Senate.

Please identify any concerns you have with S. 1009 and any gaps you see in the legislation.

S. 1009, the Chemical Safety Improvement Act is a deeply flawed bill that would, in its current form, be several steps backward from even the weak and ineffective current version of TSCA. As currently drafted, the bill would continue to leave EPA with only a limited ability to take action against hazardous chemicals, while blocking states from taking actions to protect health that are now permitted. Our primary concerns are outlined in our statement on the bill,³⁷ and the written³⁸ and oral testimony³⁹ recently provided to the Senate Environment and Public Works Committee. Among the many problems with the bill, some of the primary concerns include:

Lack of deadlines or minimum requirements – the bill lacks statutory deadlines or minimum requirements for most of the key steps of chemical assessment including prioritization, assessment, safety determination, and risk management.

Low priority designations based on insufficient evidence – the bill would allow EPA to designate some chemicals as “low priority” for assessment, based on a lack of sufficient data for that chemical and with no recourse for anyone to get such a decision reviewed.

Preemption – the bill includes sweeping preemption provisions that include all chemicals designated as “low priority” by EPA (including those designated as such based upon insufficient information) and preemption of any new state action on chemicals designated by EPA as high priority even if action by the agency on those chemicals could be years away.

Hoops, hurdles – the bill imposes numerous redundant, overlapping and unnecessary procedural steps on EPA before the agency can even begin to prioritize chemicals for assessment, ensuring the agency will be paralyzed by red tape for years – and that no health protection will be forthcoming.

Bad science – the bill contains numerous directions on how EPA should assess chemicals that are inconsistent with the recommendations of the National Academy of Sciences.

³⁷ http://docs.nrdc.org/health/files/hea_13071101a.pdf

³⁸ http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=ac9ffa00-d5fe-4a02-9035-545b047ffc0f

³⁹ <http://www.nrdc.org/media/2013/130731a.asp>

Weak safety standard – the bill is not sufficiently clear that cost is not a consideration in the safety standard or that the standard must protect vulnerable populations. In addition, the bill retains the less-protective “unreasonable risk” standard of current TSCA and fails to shift the burden of proof from EPA to chemical manufacturers.

Removing existing EPA authorities – the bill removes a number of authorities EPA has under existing TSCA.

Bans and phaseouts – although the bill formally strikes the “least burdensome” requirement of current TSCA, it contains language that is likely to have a similar effect, which it applies to any EPA effort to ban or phase out a substance (such as asbestos or PBTs).

Grandfathering Confidential Business Information – all current CBI designations are grandfathered, including the identity of some 16,000 substances on the TSCA inventory.

Judicial review – retains the “preponderance of the evidence” standard of existing TSCA, which is out of step with every other environmental and public health law.

Lack of expedited action – contains no provision mandating EPA to take expedited action to curtail use and exposure of chemicals already known to be unsafe and to which people are widely exposed.

Does not include Hot Spots provision – the bill contains no provision to address the problems of communities burdened by legacy exposures.

The Senate bill can and should serve as a basis for negotiating a way to move forward. It provides an opening to discuss bipartisan TSCA reform. But the bill is unacceptable in its current form, and, because the problems mentioned above are threaded throughout the entire bill, the changes that are needed to fix it require amending language on virtually every page, not just tweaking wording in a few places.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

July 22, 2013

Ms. Jeanne Rizzo
President and CEO
Breast Cancer Fund
1388 Sutter Street, Suite 400
San Francisco, CA 94109

Dear Ms. Rizzo,

Thank you for appearing before the Subcommittee on Environment and the Economy on Thursday, June 13, 2013, to testify at the hearing entitled "Title I of the Toxic Substances Control Act: Understanding Its History and Reviewing Its Impact."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Monday, May 13, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Kirby.Howard@mail.house.gov and mailed to Kirby Howard, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

**Responses to Additional Questions for the Record
From Jeanne Rizzo, President and CEO
Breast Cancer Fund**

Regarding the June 13, 2013 Hearing:

**Title I of the Toxic Substances Control Act:
Understanding its History and Reviewing its Impact**

**Environment and the Economy Subcommittee
House Energy and Commerce Committee**

Responses to The Honorable Henry A. Waxman

Question:

High incidences of cancer are often found close to industrial areas where large amounts of chemical substances are manufactured, processed or used. In fact, a 100-mile stretch along the Mississippi River that is home to hundreds of industrial facilities is sometimes referred to as "cancer alley." Population in these area and others like it are often composed of the poor and minorities. Environmental justice groups have been active in discussions around TSCA because low-income communities and communities of color are disproportionately burdened with environmental hazards and suffer disproportionately from environmentally related diseases.

1. What are some of the hazards and diseases that people in these communities face from exposures to toxic chemicals?

As stated in the HHS's 2012 Environmental Justice Strategy, the impact of the environment on human health cannot be overstated.¹ For example, poor air quality, disproportionate exposure to hazards in the workplace, unhealthy housing conditions (e.g., mold, dampness and pest infestation), and the lack of safe areas for physical activity have been linked to chronic conditions such as asthma and other respiratory diseases, cardiovascular disease, cancer and obesity.² Developmental disabilities have been associated with prenatal and childhood exposures to environmental toxicants.³ Globally, the WHO estimates that approximately one-quarter of the global disease burden, and more than one-third of the burden among children, is due to modifiable environmental

¹ US Department of Health and Human Services (HHS). 2012 Environmental Justice Strategy and Implementation Plan. Available at <http://www.hhs.gov/environmentaljustice/strategy.html>

² Centers for Disease Control and Prevention (CDC). Health Disparities and Inequalities Report – United States, 2011. MMWR Supplement 60(2011):1-113

³ Miodovnik, A. Environmental Neurotoxicants and Development Brain. Mt Sinai Journal of Medicine 78(2011):58-77

factors⁴ In the U.S., the cost of diseases in children attributed to environmental factors (e.g., lead poisoning and asthma) was estimated at \$76.6 billion in 2008.⁵

Most polluted communities are situated near factories, waste disposal sites, agricultural areas or other pollution sources that regularly release toxic chemicals or radiation into the environment. Some, but not all, of these sources are recorded by the Environmental Protection Agency's Toxic Release Inventory (TRI) database. TRI facilities are more likely to be located near communities with higher proportions of people of color and people with lower socioeconomic status.^{6,7} In many cases, sources of pollution are clustered in a small area, meaning that communities near one toxic release site are often near several others.⁸ Research suggests that exposures to mixtures of chemicals may magnify risk. The disparities in proximity to pollution sources motivated the emergence of the environmental justice movement, which seeks to establish fair and equal access to environments free of pollutants and fair and equal participation in environmental decision-making.^{8,9}

A recent study found that African Americans, people with less formal education, and people with lower socioeconomic status were more likely to live within a mile of a polluting facility identified by the EPA.⁷ This study reaffirms findings from a number of other studies conducted in the past 20 years.¹⁰ Another study found that pregnant African American, Latina and Asian/Pacific Islander women were more likely to live in counties with higher air pollution.¹¹

For breast cancer specifically, we know that the levels of chemicals related to breast cancer in people's bodies can vary by race, ethnicity and socioeconomic status. As a group, African Americans have higher levels than whites or Mexican Americans of many chemicals, including polychlorinated biphenyls (PCBs), mercury, lead, polycyclic aromatic hydrocarbons (PAHs), dioxin, and phthalates.^{12,13} Mexican Americans as a group have higher levels of the pesticides DDT/DDE and 2,3,5,TCP.¹⁴ People with lower socioeconomic status have higher levels of Bisphenol A (BPA),¹⁵ while

⁴ World Health Organization (WHO). "Preventing Disease Through Healthy Environments: Towards an Estimate of the Environmental Burden of Disease." http://www.who.int/quantifying_ehimpacts/publications/preventingdisease.pdf

⁵ Transande, L. and Liu, Y. Reducing the Staggering Costs of Environmental Disease in Children, Estimated at \$76.6 Billion in 2008. *Health Affairs* 30(2011):863-870.

⁶ Perlin, S., Wong, D., & Sexton, K. (2001). Residential proximity to industrial sources of air pollution: Interrelationships among race, poverty, and age. *J Air Waste Manag Assoc*, 51, 406-421.

⁷ Mohai, P., Lantz, P., Morenoff, J., House, J., & Mero, R. (2009). Racial and socioeconomic disparities in residential proximity to polluting industrial facilities: Evidence from the Americans' Changing Lives Study. *Am J Public Health*, 99, 649-656.

⁸ IBCERCC Interagency Breast Cancer and Environmental Research Coordinating Committee (2013). *Breast Cancer and the Environment: Prioritizing Prevention*. http://www.niehs.nih.gov/about/assets/docs/ibcercc_full_508.pdf

⁹ Cole LW and Foster SR (2001). *From the Ground Up: Environmental Racism and the Rise of the Environmental Justice Movement*. New York, NY: New York University Press.

¹⁰ Brulle, R., & Pellow, D. (2006). Environmental justice: human health and environmental inequalities. *Ann Rev Public Health*, 27, 103-124.

¹¹ Woodruff, T., Parker, J., Kyle, A., & Schoendorf, K. (2003). Disparities in exposure to air pollution during pregnancy. *Environ Health Persp*, 111, 942-946.

¹² CDC: Center for Disease Control and Prevention. (2009). *Fourth National Report on Human Exposure to Environmental Chemicals*. Atlanta: Center for Disease Control and Prevention. <http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf>

¹³ CDC: Center for Disease Control and Prevention. (2013). *Fourth National Report on Human Exposure to Environmental Chemicals - Updated Tables March 2013*. Atlanta: Center for Disease Control and Prevention.

http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Mar2013.pdf

¹⁴ Smigal, C., Jemal, A., Ward, E., Cokkinides, V., Smith, R., Howe, H., & Thun, M. (2006). Trends in breast cancer by race and ethnicity - Update 2006. *Cancer*, 56, 168-183.

triclosan levels (used in antibacterial soaps and other consumer products) are higher among those with higher socioeconomic status.

2. In your view, what should be done to address those risks?

Chemical plants, incinerators, Superfund sites and brownfields are more often than not located in neighborhoods of the most disenfranchised of our citizens. The result is a high background level of exposure that is added to the everyday exposures to which all of us are subject. These communities are burdened with the disproportionately high chemicals exposures and the accompanying health impacts. These areas of high exposures are often referred to as “hot spots” and they result in “toxic trespass” – people being exposed to toxic chemicals without their consent. Since many of these communities are poor, the residents often do not have the option to move away.

Every American deserves to live in a community free from pollution. The federal government has an obligation to identify, understand, educate the community about and mitigate these hot spots, all in partnership with leaders within the impacted communities. The industries responsible for discharging and/or dumping unsafe chemicals into the air, water and land of our communities should be held responsible and accountable for any short-term and long-term adverse health effects that may be related to exposure to chemicals they produce. The federal government’s role should be to protect all citizens, particularly the least empowered among us.

3. As this Committee considers TSCA reform, how important is it that we address risks to disproportionately burdened communities and other vulnerable populations?

As the law that is supposed to regulate industrial chemicals,—the very chemicals most responsible for hot spots—effective TSCA reform should contribute substantially to reducing the disproportionate burden of toxic chemical exposure placed on people of color, low-income people and indigenous communities. The Safe Chemicals Act, S. 696, included a provision that requires the EPA to identify and publish a list of communities with toxic chemical exposures that are “significantly greater than the average exposure in the United States.” Once identified, the Safe Chemicals Act required the creation of action plans to reduce those exposures. Addressing hot spots is an important piece of the larger public health issue posed by ubiquitous exposure to toxic chemicals and I strongly encourage that any TSCA reform measure considered by the Committee include such a provision.

Question:

When TSCA was passed in 1976, Congress grappled with many of the same issues that face us now. Worker exposures were a significant concern at that time. The United Steelworkers submitted a letter for the June 13, 2013 hearing record, raising significant concerns about shortcomings in TSCA. According to them, those shortcomings adversely impact workers, to the tune of 190,000 worker illnesses and 50,000

¹⁵ Nelson, J. W., Scammell, M. K., Hatch, E. E., & Webster, T. F. (2012). Social disparities in exposures to bisphenol A and polyfluoroalkyl chemicals: a cross-sectional study within NHANES 2003-2006. *Environ Health*, 11, (10), art. No 10.

worker deaths ever year. Estimates suggest that this costs businesses between \$128 billion and \$155 billion every year.

4. What are some of the impacts of chemical exposures for workers and their families?

Workplace exposures contribute to a notable proportion of the burden of chronic disease in the U.S. The current best estimates suggest that 5 to 16 percent of cases of cancer, asthma, chronic obstructive pulmonary disease, heart and cerebrovascular disease,^{16,17,18} and 1 to 3 percent of neurological disease and renal diseases¹⁹ result from hazards in the workplace. These proportions are very likely to underestimate the burden of disease attributable to occupation. For instance, estimates of workplace contributions to cancer may be underestimated when they are based solely on established human carcinogens,²⁰ particularly given current data gaps in chemicals safety assessments that may overlook some carcinogens and many endocrine disrupting chemicals. Furthermore, many work-related injuries and illnesses are never reported, so disease burden estimates based upon documented cases may capture only half of all work-related illness.^{21,22}

Some groups may be uniquely vulnerable to workplace exposures either due to higher than normal exposures or due to unique vulnerabilities. Low income workers may face double jeopardy, as a result of cumulative and aggregate risks that come from both working and living in polluted environments.²³ Furthermore, 55% of children in the US are born to working mothers and 62% of the workforce is of reproductive age.²⁴ Fetal exposures to chemicals as a result of parents workplace exposures could affect the health of the population for decades to come.

Workplace exposures are high for many industries. Data from the National Health Interview Study, a nationally representative study of health suggest widespread exposure to chemicals in the workplace – 20.6 percent of workers reported frequent occupational skin contact with

¹⁶ Glorian Sorensen, Paul Landsbergis, Leslie Hammer, Benjamin C. Amick III, Laura Linnan, Antronette Yancey, Laura S. Welch, Ron Z. Goetzel, Kelly M. Flannery, and Charlotte Pratt. Preventing Chronic Disease in the Workplace: A Workshop Report and Recommendations. *American Journal of Public Health*: December 2011, Vol. 101, No. S1, pp. S196-S207.

¹⁷ Leigh J, Markowitz SB, Fahs M, Shin C, Landrigan PJ. Occupational Injury and Illness in the United States: Estimates of Costs, Morbidity, and Mortality. *Arch Intern Med*. 1997;157(14):1557-1568. doi:10.1001/archinte.1997.00440350063006.

¹⁸ Taiwo AO, Mobo BH Jr, Cantley L (2011) Recognizing occupational illnesses and injuries. *American family physician*, 82(2), 169-174.

¹⁹ Leigh J, Markowitz SB, Fahs M, Shin C, Landrigan PJ. Occupational Injury and Illness in the United States: Estimates of Costs, Morbidity, and Mortality. *Arch Intern Med*. 1997;157(14):1557-1568. doi:10.1001/archinte.1997.00440350063006.

²⁰ Leigh J, Markowitz SB, Fahs M, Shin C, Landrigan PJ. Occupational Injury and Illness in the United States: Estimates of Costs, Morbidity, and Mortality. *Arch Intern Med*. 1997;157(14):1557-1568. doi:10.1001/archinte.1997.00440350063006.

²¹ Boden LJ, Ozonoff A (2008). Capture-recapture estimates of nonfatal work-place injuries and illnesses. *Ann Epidemiol*. 2008; 18(6):500-506.

²² Rosenman, K.D., A. Kalush, M.J. Reilly, J.C. Gardiner, M. Reeves, and Z. Luo. 2006. How Much Work-Related Injury and Illness Is Missed by the Current National Surveillance System? *Journal of Occupational and Environmental Medicine* 48(4):357-65.

²³ Baron SL, Beard S, Davis LK, Delp L, Forst L. (2013). Promoting integrated approaches to reducing health inequities among low-income workers: Applying a social ecological framework *American Journal of Industrial Medicine*. Published Ahead of Print, 26 MAR 2013.

²⁴ Lawson CC, Grajewski B, Daston GP, Frazier LM, Lynch D, McDiarmid M, Muroso E, Perreault SD, Robbins WA, Ryan MA, Shelby M, Whelan EA. Workgroup report: Implementing a national occupational reproductive research agenda--decade one and beyond. *Environ Health Perspect*. 2006;114:435-441. doi: 10.1289/ehp.8458.

chemicals and 25 percent reported frequent exposure to vapors, gas, dust or fumes. Exposure to these hazards is not equitable across educational attainment, sex, ethnicity, or occupation.²⁵

Workers are frequently exposed to mixtures of hazards, which may act synergistically to impact long-term health. Common mixed exposures impact more than 15,000,000 workers, leading the CDC's National Institute for Occupational Safety and Health to conclude that "The historical one-chemical-at-a-time approach to occupational health is inadequate. Safety and health practitioners using substance-by-substance or hazard-by-hazard approaches generally make conclusions about worker risk or lack of risk without sufficient caveats about the inability to evaluate additive or synergistic effects."²⁶ Reform of the Toxic Substances Control Act should take into consideration likely worker exposures to mixtures for determining appropriate testing requirements, including risk assessment of mixtures, dose-response tests that consider synergistic effects, and unintended occupational exposures.

With regard to breast cancer specifically, women make up nearly half the workforce in the United States, but little research has explored work-related exposures and breast cancer. Women in some occupations have a higher risk of breast cancer.^{27,28} These include women who work with toxic chemicals like organic solvents, including chemists, paper mill workers, textile workers, autoworkers, and microelectronics workers,^{29,30,31,32} workers with plastics or in food canning;³³ and women who work with or around ionizing radiation, including dental hygienists and radiology technicians.^{34,35,36} In the Canadian study reference above, young women working

²⁵ Calvert GM, Luckhaupt SE, Sussell A, Dahlhamer JM, Ward BW (2013). The prevalence of selected potentially hazardous workplace exposures in the US: Findings from the 2010 National Health Interview Survey. *American Journal of Industrial Medicine*, 56(6), 635-646.

²⁶ NIOSH (National Institute for Occupational Safety and Health). 2005. *Mixed Exposures Research Agenda: A Report by the NORA Mixed Exposures Team*. NIOSH Publ No2005-106. Washington, DC:U.S. Government Printing Office.

²⁷ Teitelbaum, S., Britton, J., Gammon, M., Schoenberg, J., Brogan, D., Coates, R., ... Brinton, L. (2003). Occupation and breast cancer in women 20-44 years of age (United States). *Cancer Causes Control*, 14, 627-637.

²⁸ Brophy JR, Keith MM, Watterson A, Park R, Gilbertson M, Maticka-Tyndale E, Beck M, Abu-Zahra, Schneider K, Reinhartz A, DeMatteo R, Luginaah I (2012). Breast cancer risk in relation to occupations with exposure to carcinogens and endocrine disruptors: a Canadian case-control study. *Environ Health*. 2012; 11: 87. Published online 2012 November 19. doi: 10.1186/1476-069X-11-87.

²⁹ Thompson, D., Kriebel, D., Quinn, M., Wegman, D., & Eisen, E. (2005). Occupational exposure to metalworking fluids and risk of breast cancer among female autoworkers. *Am J Indust Med*, 47, 153-160.

³⁰ Bernstein, L., Allen, M., Anton-Culver, H., Deapen, D., Horn-Ross, P., Peel, D., ... Ross, R. (2002). High breast cancer incidence rates among California teachers: Results from the California Teachers. Study - United States. *Cancer Causes Control*, 13, 625-635.

³¹ Shaham, J., Gurchich, R., Gorel, A., & Czerniak, A. (2006). The risk of breast cancer in relation to health habits and occupational exposures. *Am J Ind Med*, 49, 1021-1030.

³² Labreche, FP, Goldberg, MS (1997). Exposure to organic solvents and breast cancer in women: A hypothesis. *Am J Ind Med*, 32:1-14.

³³ Brophy JR, Keith MM, Watterson A, Park R, Gilbertson M, Maticka-Tyndale E, Beck M, Abu-Zahra, Schneider K, Reinhartz A, DeMatteo R, Luginaah I (2012). Breast cancer risk in relation to occupations with exposure to carcinogens and endocrine disruptors: a Canadian case-control study. *Environ Health*. 2012; 11: 87. Published online 2012 November 19. doi: 10.1186/1476-069X-11-87.

³⁴ Bhatti, P., Doody, M., Alexander, B., Yuenger, J., Simon, S., Weinstock, R., ... Sigurdson, A. (2007). Breast cancer risk polymorphisms and interactions with ionizing radiation among U.S. radiologic technologists. *Cancer Epidemiol Biomarkers Prev*, 17, 2007-2011.

³⁵ Sigurdson, A., MM, D., & RS, R. (2003). Cancer incidence in the U.S. Radiologic Technologists Health Study, 1983-1998. *Cancer*, 97, 3080-3089.

in automotive and food canning factories were found to have a five times higher risk of being diagnosed with premenopausal breast cancer. Other groups disproportionately affected include teachers, librarians, social workers and journalists, although the reasons for these differences are yet to be understood.

Question:

In terms of worker health, asbestos has been a significant historical risk for workers.

5. Has EPA been able, given its current tools to address the risks of asbestos exposures?

Under TSCA, the EPA tried and failed to ban asbestos, a known carcinogen that has been credited with an estimated 2,500³⁷ American deaths per year as a result of mesothelioma and up to 7,000 more annual deaths from lung cancer, asbestosis and gastro-intestinal cancer resulting from asbestos.^{38,39,40} When the EPA issued a rule in 1989 banning the use of asbestos, industry sued to keep this carcinogen on the market. Despite an extensive scientific record of the dangers of asbestos, the court ruled that the EPA had failed to meet the regulatory bar needed under TSCA. As a result of this failure to regulate such a well documented risk, the EPA has not tried to regulate a chemical under TSCA since that court decision in 1991.

As currently written, S. 1009, the Chemical Safety Improvement Act, currently being considered by the Senate, would retain this insurmountable burden for any attempt to ban or phase out a chemical. These regulatory options would be reserved for the most toxic chemicals, resulting in this provision at the very least delaying, and in the worst case completely obstructing, EPA's ability to get the worst chemicals out of commerce and thereby reduce dangerous exposures to workers and the public.

6. As this Committee considers TSCA reform, how important is it that we address worker exposures?

Workers, particularly those manufacturing and agricultural jobs, are both the backbone of the American economy and our "canary in the coal mine" for the dangers of exposures to toxic substances. In fact, many of the human studies on the health impacts of chemicals are

³⁶ Simon, S., Weinstock, R., Doody, M., Neton, J., Wenzl, T., Stewart, P., ... Linet, M. (2006). Estimating historical radiation doses to a cohort of U.S. radiologic technologists. *Radiat Res*, 166, 174-192.

³⁷ Barg KM, Mazurek JM, Storey E, Attfield MD, Schleiff, PL, Wood JM (2009). Malignant Mesothelioma Mortality – United States, 1999-2005. *MMWR*, 58(15): 393-396.

³⁸ Centers for Disease Control, National Center for Health Statistics, Multiple Cause of Death Files, 1999-2001.

³⁹ Nicholson, W. J., G. Perkel, et al. (1982). "Occupational exposure to asbestos: population at risk and projected mortality--1980-2030." *Am J Ind Med* 3(3): 259-311.

⁴⁰ Lilienfeld, D. E., J. S. Mandel, et al. (1988). "Projection of asbestos related diseases in the United States, 1985-2009. I. Cancer." *Br J Ind Med* 45(5): 283-91.

epidemiological studies on workers. Their exposure all day, every day, to chemicals in the workplace can put them at the higher risk of adverse health impacts. In addition to their own exposures, workers can bring those chemicals home to their families on their clothes and shoes. Hugging your child after a long day at work or including your clothes in the family's laundry shouldn't put them at risk for similar higher than average exposure.

Any reform of TSCA must include protections for workers by identifying them as a vulnerable population to be considered when setting safe exposure levels. In addition, investment in green chemistry (an approach to chemistry that adds health and environmental outcomes to the criteria used to evaluate a chemical) can serve the dual purpose of protecting workers while spurring innovation to create an economy made up of safer chemicals that are more environmentally and economically sustainable.

7. How important is it that we address the aspects of the law that have limited the EPA's ability to regulate asbestos?

Asbestos is one of the best documented known carcinogens. An entire deadly disease has been identified specifically and exclusively as resulting from exposure to asbestos and there is wide agreement that there is no safe level of exposure. If the EPA is unable to ban this substance, then clearly it will be powerless to address the hundreds and possibly thousands of less studied, yet known or potentially toxic chemicals. If TSCA reform does not address the aspects of TSCA that failed the American public on asbestos, then the EPA will not be given the statutory authority it needs to regulate this extremely toxic chemical or other equally toxic chemicals.

Question:

During the June 13, 2013, hearing, questions were raised about risk assessment methodology and specifically about the assumption of thresholds for dangerous exposures.

8. What has the National Academies of Science said about assumptions of threshold effects for cancer and non-cancer endpoints?

In 2009, the National Research Council of the National Academies of Science published a major report entitled *Science and Decisions: Advancing Risk Assessment*.⁴¹ The report was requested by the U.S. Environmental Protection Agency to provide an independent study to determine practical changes that could be made in risk-analysis approaches in the relative short- (2-5 years) and long- (10-20 years) term future, and resulted in a comprehensive analysis of existing risk-assessment approaches, their strengths and limitations.

One of the two major overall recommendations of the report, and a theme that runs throughout the analysis, is the need to harmonize or make consistent the approaches for assessing risk for both cancer and non-cancer endpoints:

Scientific and risk-management considerations both support unification of cancer and non-cancer dose-response assessment approaches. The committee therefore recommends a consistent, unified approach for dose-response modeling that includes formal, systematic

⁴¹ National research Council of the National Academies (2009). *Science and Decisions: Advancing Risk Assessment*. Washington, D.C.: The National Academies Press.

assessment of background disease processes and exposures, possible vulnerable populations, and models of action that may affect a chemical's dose-response relationship in humans. (p.9)

Among the issues that underlie this recommendation is the recognition of very different assumptions currently made about the safety thresholds of exposures with cancer and non-cancer endpoints.

- For carcinogenic agents, the current assumptions include:
 - There is no lower threshold for risk; low-dose exposures continue to affect biological systems at linearly decreasing levels;
 - The most (only) important variable to account for in addressing human variability in susceptibility to exposures is possible enhanced susceptibility in early life;
 - Chemical exposures that lead to increased risk for developing cancer do so through direct or complete mutagenesis, "ignoring contributions to ongoing carcinogenesis processes and the multifactorial nature of cancer. Chemicals that may increase cancer risk by contributing to an ongoing process are handled essentially as non-carcinogens even though they may be integral to the carcinogenic process." (p. 131)
- For non-carcinogenic agents, the current assumptions include:
 - Above a threshold dose for increased disease risk, dose responses are linear or sigmoidal in shape;
 - Below that threshold, biological systems are able to effectively detoxify the system, thereby minimizing potential physiological damage and precluding influence on disease occurrence;
 - Interactions with other chemicals with similar mechanisms of actions that might alter threshold analyses need not be considered.

By unifying or harmonizing approaches to risk-assessment for both cancer and non-cancer endpoints, it is hoped that these assumptions will be carefully re-evaluated and appropriate new guidelines will be created.

It seems clear from the recommendations in the NAS report and extensive evidence that continues to amass that these assumptions are sorely outdated and do not reflect current scientific understanding of the many ways that chemicals impact human health.

9. What are the most recent National Academies of Science recommendations for conducting risk assessments for chemical substances?

In establishing a unifying framework for conducting risk assessments for exposures to chemical substances, including both cancer and non-cancer endpoints, the National Academies of Sciences report calls for an inclusion in the analyses of both direct actions of the chemicals on biological systems as well as background exposures and conditions:

An individual's risk for exposure to an environmental chemical is determined by the chemical itself, by current background exposures to other environmental and endogenous

chemicals that affect toxicity pathways and disease processes, and by the individual's biological susceptibility due to genetic, lifestyle, health, and other factors. (p. 135)

Among the features of the dose-response framework envisioned by the authors of the report are:

Dose-response characterizations that use the spectrum of evidence from human, animal, mechanistic, and other relevant studies. Whole-animal dose-response studies will continue to play an important role in establishing PODs [point of departures] for most chemicals, but information on human heterogeneity, background exposures, and disease processes and data from mechanistic in vitro and in vivo studies will be critical in selecting the approach to the dose-response analysis. Some information used in the dose-response derivation will be chemical-specific. In the absence of reliable chemical-specific information on human variability, interspecies differences and other components of the analysis, generalizations and defaults based on evidence from other chemicals and end points and theoretical considerations may be used. (p. 138)

These are important directives to scientists and risk assessors.

However, the NAS report does not explicitly address cases where chemicals exert effects below the standard threshold of safety determined by traditional high-dose toxicology tests. In particular, and as summarized in an exhaustive recent review⁴² by Vandenberg and colleagues, endocrine disrupting compounds are known to display non-monotonic (change in slope of the curve in at least one point) dose-response curves, with a weight-of-the-evidence analysis supporting the conclusions that low dose exposures to chemicals that interfere with endocrine system can have profound effects on later health (both cancer and non-cancer) outcomes in both animal models and in humans, especially when exposures are in utero or early in life. In some cases, these low-dose effects may be greater than those observed after exposures to higher doses.⁴³

The presence of these low-dose effects should not be a surprise either to research scientists or risk analysts if, as the NAS report recommends, the mode-of-action (MOA) assessment of a chemical exposure includes an exploration of

... what is known or hypothesized about the key events after chemical exposures that lead to the toxicity of the compound, including metabolic activation and detoxification, ignition interactions with critical cellular targets (for example, covalent binding with protein or DNA, peroxidation of lipids and proteins, DNA methylation, and receptor binding), altered cellular processes (for example, apoptosis, gene expression, and signal transduction) and other kinds of biochemical perturbation that may involve defense mechanisms or be considered precursor events. Background or endogenous processes that might act in concert with those events would also be considered. Any MOA information that might be considered helpful in

⁴² Vandenberg LN, Colborn T, Hayes TB, Heindel JJ, Jacobs Jr DR, Lee DH, Shioda T, Soto AM, Vom Saal FS, Welshons WV, Zoeller RT (2012). Hormones and endocrine-disrupting chemicals: low dose effects and nonmonotonic dose responses. *Endocrine Reviews* 33: 378-455.

⁴³ Angle BM, Do RP, Ponzi D, Stahhhut RW, Drury BE, Nagel SC, Welshons WV, Besch-Williford CL, Palanza P, Parmigiani S, Vom Saal FS, Taylor JA (2013). Metabolic disruption in male mice due to fetal exposure to low but not high doses of bisphenol A (BPA): Evidence for effects on body weight, food intake, adipocytes, leptin, adiponectin, insulin and glucose regulation. *Reproductive Toxicology* <http://dx.doi.org/10.1016/j.reproto.2013.07.017>

understanding dose-relationship events at both high and low doses would be considered, including dose-dependent nonlinearities in metabolic processes, depletion of cellular defenses, potential to outpace repair processes, induction of enzymes by repeat dosing, additivity and interaction with background disease processes, and additivity of the chemical and its metabolites with other chemical exposures. (p.145)

In a recent paper, "Endocrine Disrupting Chemicals and Public Health Protection: A Statement of Principles from the Endocrine Society"⁴⁴, Zoeller and colleagues examined the implications of the Society's earlier scientific white paper on endocrine disrupting compounds⁴⁵ in the context of chemical safety assessment. As the world's largest (16,000+ members) and most prestigious collective of basic and clinical researchers and practitioners in the broad field of endocrinology, the Society's decision to issue its first scientific white paper on the topic of endocrine disrupting compounds reflected its collective concerns about the growing literature demonstrating serious, and usually adverse, outcomes of exposures to synthetic endocrine disruptors, especially at low doses when exposures are early in development.

In the more recent "Statement of Principles", the authors argue cogently that the many decades of detailed research into the underlying mechanisms by which normally occurring hormonal (endocrine) exposures exert effects on biological systems, both healthy and disease-related, should serve as the basis for understanding the class of chemicals known as endocrine disruptors. After all, these synthetic, exogenous exposures are exerting their effects by interfering with the normal actions of endogenous hormones. Among the principles to be acknowledged and applied are the following well established principles of endocrinology (pp. 4099-4102⁴⁴):

- Hormones exert their effects through a variety of cellular and intercellular protein receptors and can affect various pathways in different cell types. Some endpoints are more sensitive to altered hormone exposures than are others.
- Hormones function through nonlinear, and often non-monotonic, dose-response processes. The consequence of this is that observations of responses at high doses often will not accurately predict responses at lower doses.
- Hormones exert their biologically relevant effects at very low doses. Small perturbations, through altered exposures to the primary hormone or to compounds (whether natural or synthetic) that interfere with the actions of that hormone can have profound effects.
- The effects of specific hormones on biological systems often change over the lifespan.
- The effects of some hormones early in development are permanent, exerting important effects on physiological and behavioral systems months, years, sometimes decades following early exposures.

Taking the National Academies of Sciences recommendations seriously is critical, and this includes attending to the best existing scientific models we have. In the case of risk assessment for endocrine disrupting compounds, this will mean requiring assessment of dose-response

⁴⁴ Zoeller RT, Brown TR, Doan LL, Gore AC, Skakkebaek NE, Soto AM, Woodruff TJ, Vom Saal FS (2012). Endocrine-disrupting chemicals and public health protection: A statement of principles from The Endocrine Society. *Endocrinology* 153: 4097-4110.

⁴⁵ Diamanti-Kandarakis E, Bourguignon JP, Giudice LC, Hauser R, Prins GS, Soto AM, Zoeller RT, Gore AC (2009). Endocrine-disrupting chemicals: and Endocrine Society scientific statement. *Endocrine Reviews* 30: 293-342.

relationships to reflect what has been established by thousands of researchers in the field of endocrinology over the past several decades.

10. As this Committee considers TSCA reform, how important is it that we incorporate those recommendations?

If medical professionals were to practice medicine the way they did in 1976, they would undoubtedly be sued for malpractice. The same is true for science. To conduct toxicology testing in the same way we did when TSCA was passed is irresponsible and fails to protect public health. The example of endocrine disrupting chemicals, discussed above, is an excellent case in point. Traditional toxicology testing would fail to look for, and therefore fail to identify, the risk from chemicals that can have more profound impacts at lower doses than at higher doses. And these adverse impacts, particularly when exposure is very early in life, can increase the risk of disease years and sometimes decades later. If we are not looking for the right information, we are almost assuredly not going to find it. Protecting the public from toxic chemicals depends on using today's science.

Question:

During the hearing, Charlie Auer, a former EPA official and industry consultant, called on Congress to implement international treaties on the regulation of chemicals, including the Rotterdam and Stockholm Conventions.

11. Do you agree that these international chemical treaties should be implemented in the United States?

The Stockholm and Rotterdam treaties are significant international chemicals treaties that have been ratified by most countries across the world. The United States should join these global efforts to reduce the production and global import and export of hazardous and persistent chemicals and implement these important treaties here.

The Stockholm Convention aims to eliminate or restrict the production and use of persistent organic pollutants (POPs). In the U.S., persistent chemicals such as perfluorinated compounds and halogenated flame retardants are still widely used in products and manufacturing. Both classes of compounds persist over time and biomonitoring data shows significant human exposures. For example, polychlorinated biphenyls (PCBs), which were banned when TSCA was first passed in 1976, are still in our environment and in our bodies almost four decades later and we will continue to deal with that legacy well into the future. Growing scientific evidence suggests many POPs are related to a number of adverse health concerns.

The Rotterdam Convention promotes the sharing of responsibilities in importing hazardous chemicals. The convention promotes an open exchange of information and calls on exporters of hazardous chemicals to use proper and appropriate labeling, instructions on safe handling, and inform purchasers of any known restrictions or bans.

As a major producer and exporter of chemicals, the U.S. has an obligation to address the issues raised in these treaties and should join the global community by ratifying both the Stockholm and Rotterdam Conventions.

Question:

During the hearing, Beth Bosley, representing Boron Specialties, testified that claim of confidential business information should require up-front substantiation and resubstantiation every five years.

12. Do you agree with those recommendations [that confidential business information should require up-front substantiation and resubstantiation every five years?]

The Breast Cancer Fund starts from the position that workers, disproportionately exposed communities and the public at large all have a right to know the identity and hazardous characteristics of the chemicals to which we are being exposed. One of the many failings of TSCA, and one that Ms. Bosley alluded to, is the lack of oversight and over use of the confidential business information (CBI) provision. The EPA estimates that in about 95 percent of new chemical notices manufactures claim some portion as CBI. The way the current law is written, the public may know that a particular chemical is hazardous but may not be allowed to know the identity of that chemical.

The Breast Cancer Fund does not believe that the identity of a chemical and associated safety data should ever be withheld from the public. However, if CBI provisions were to continue to allow the identity to be kept confidential, at the very least there should be clear up-front justification, substantiation and a set time period for a reapplication for CBI status. The 5 year interval proposed by Ms. Bosley should be the maximum period allowed for CBI claims before they would need to be resubstantiated. Given green chemistry and technological advances, a shorter CBI period would be preferable. The EPA must also be given sufficient resources to be able to properly and thoroughly review these CBI claims. Finally, states, localities and medical professionals should also be given access to CBI in order to protect their citizens and patients from unsafe chemical exposures.

13. As this Committee considers TSCA reform, how important is it that we incorporate those recommendations?

Any reform of TSCA should continue the current practice of never allowing safety data to be designated as CBI and if claims are allow for chemical identity, they should only be allowed under strict and narrow conditions and should be time limited. In addition, it is essential that state and localities and medical professionals be given prompt and unencumbered access to this information when it is needed to protect the public health.

Question:

Throughout the hearing, questions were asked about the safety of chemicals already distributed in commerce in the United States and new chemicals proposed for distribution in commerce.

14. Have chemicals distributed in commerce in the United States been evaluated for safety?

The overwhelming majority of chemicals on the TSCA inventory have not been tested for safety. TSCA included a provision that allowed the EPA to require testing when there was evidence for concern. This provision creates a catch-22 or “logical paralysis,” whereby evidence of concern is necessary for the EPA to be able to require testing. As a result, in the over 35 years since TSCA passed, the EPA has been able to require testing for only a few hundred of the 62,000 grandfathered chemicals, and only five chemicals overall have been restricted. The fact that, even with new chemicals, industry is only required to provide the safety data it has access to results in an incentive to NOT conduct those tests. Even for the few chemicals that do have safety data, many have NOT been adequately tested for qualities such as endocrine disruption.

15. Are new chemicals proposed for distribution in commerce determined to be safe before being let on the market?

There is no affirmative finding of safety and no baseline of safety data required before new chemicals are allowed into commerce. EPA has 90 days to review the chemical before it goes into production, but it cannot compel manufacturers to submit any safety data and very few companies do so voluntarily. This leaves EPA reliant on sometimes inaccurate models to predict the toxicity of a chemical based on similarities to other chemicals that have been tested for safety. And if the EPA fails to act, the chemical goes onto the market at the end of the review period.

16. For most new and existing chemicals in the United States, does sufficient data exist to evaluate their safety?

No. As discussed in the previous two questions, sufficient data is not available for the EPA to accurately evaluate the safety of chemicals and thereby protect public health. TSCA neither requires nor incentivizes chemical manufacturers to produce the necessary safety data. Nor does the current system account for the vast advances in scientific knowledge that was discussed previously. Finally, the fact that the bar to actually regulate a chemical, even in the presence of data, is so impossibly high may have a chilling effect on the dedication of resources to obtain the data in the first place.

17. As this Committee considers TSCA reform, how important is it that we require the generation of data, for new and existing chemicals, sufficient to evaluate their safety?

TSCA reform should include requirements that a chemical be proven safe for the most vulnerable and those with disproportionate exposures—including children, pregnant women and workers—before it can be used, or continue to be used, in commerce. In order to understand the health risks of a particular chemical, the manufacturer(s) must be required to provide adequate safety data looking at all relevant endpoints. The NAS recommendations discussed above must also be incorporated into the testing regime, including looking for the impacts of early life exposures, low dose effects and endocrine disruption. Only with this information will the EPA be able to properly assess the potential risks from exposure to that chemical

Question:

Recently, new legislation to amend TSCA was introduced in the United States Senate.

18. Please identify any concerns you have with S.1009 and any gaps you see in the legislation.

The June 2013 introduction of the Chemical Safety Improvement Act (CSIA; S. 1009) in the U.S. Senate has changed the conversation about chemical policy reform in Washington. No longer are we working to convince members of Congress of the need to reform the broken chemical management system set up 37 years ago by the Toxic Substances Control Act (TSCA). Now there is a robust debate about what that reform needs to look like to be meaningful and truly safeguard the American public, especially vulnerable populations, from exposures to dangerous chemicals.

Unfortunately, the CSIA, which was introduced by Sens. David Vitter (R-La.) and the late Frank Lautenberg (D-N.J.) falls so far short of that goal that the Breast Cancer Fund opposes the bill as it is currently written. I outline in written and oral testimony and in these supplemental responses how the bill should be strengthened so that it adequately protects public health and ensures the safety of the chemicals Americans are exposed to every day. If adopted in its current form, the legislation could roll back the few current laws protecting us from exposures toxic chemicals, particularly at the state level, without giving the U.S. Environmental Protection Agency the statutory authority, tools and resources it needs to provide real federal protection against unsafe chemical exposures. As a result, the bill would stifle progress in creating a better system for regulating chemicals. Protecting public health and the environment should be the primary and overriding goal of TSCA reform.

The CSIA needs to be strengthened in the following areas:

Vulnerable Populations: The CSIA does not adequately protect vulnerable populations, which include pregnant women, children, workers and disproportionately exposed communities. As currently written, CSIA directs the EPA to conduct safety assessments of industrial chemicals, including an exposure assessment, which is used to make a safety determination. While CSIA safety assessments would require the EPA to consider the “vulnerability of exposed subpopulations” in the *exposure* portion, the bill does not define “subpopulations,” nor does it require those vulnerable populations to be protected. Nowhere does the bill explicitly require a consideration of the health impacts of chemical exposures to our most vulnerable populations.

Safety Standard: The CSIA retains TSCA’s existing safety standard, which requires the EPA to show a chemical presents an “unreasonable risk of harm to health or the environment.” In contrast, federal safety standards have evolved over the past 30 years to a more health-protective framework, defined as a “reasonable certainty of no harm.” This “reasonable certainty of no harm” standard is used by multiple government agencies, including the EPA to evaluate the safety of pesticides; the Consumer Product Safety Commission (CPSC) to evaluate the safety of phthalates in toys; and the FDA to evaluate the safety of food-contact substances.

The continued use of TSCA’s flawed “unreasonable risk of harm to health or the environment” safety standard raises a number of unsettling questions: Who decides if a chemical presents an “unreasonable risk?” And who bears the burden of proof for meeting that standard – the EPA (and therefore the public), or industry? One of the major failures of TSCA is that the burden falls on the EPA to prove chemicals are *not* safe rather than on industry to demonstrate chemicals are safe. ***Any meaningful***

reform of TSCA must shift the burden of proof to industry to demonstrate the safety of the chemicals they manufacture and market.

While the CSIA states that the safety assessment of an industrial chemical should be based solely on health considerations, the “unreasonable risk of harm” safety standard implies a cost-benefit analysis. While the first mention of the safety standard refers to health, subsequent references do not clearly limit the standard to health-based considerations. The safety standard needs clarification to ensure it is strictly health-based.

Cost-Benefit Analysis: One of the key failings of TSCA is its required cost-benefit analysis, which mandates that the “least burdensome” regulatory option be taken, making the EPA responsible for assessing the economic consequences of several possible regulatory scenarios. The least burdensome requirement was the hurdle the EPA was unable to overcome in its effort to ban asbestos in the 1980s. The CSIA removes the explicit “least burdensome” standard for most regulatory options, an important step forward, but essentially reinstates it if the EPA attempts to phase out or ban a chemical. While a cost-benefit analysis may be appropriate to *consider* when deciding which restrictions on a chemical are most appropriate (and indeed is already required by the Office of Management and Budget for all federal regulations), the language of the bill explicitly requires that any attempt by the EPA to ban or phase out a chemical must be *based* on a cost-benefit analysis, effectively reinstating the almost insurmountable “least burdensome” requirement. Since phase-outs and bans are regulatory options the EPA would reserve for the most dangerous chemicals, this means the ***EPA could determine a chemical is unsafe through a safety assessment, but still be unable to regulate that chemical if the regulation is seen as too costly.*** In addition, the cost-benefit analysis should include as a part of the equation the costs to human health and its impact on the economy from lost productivity and health care costs.

Aggregate Exposures: To understand the true exposures to and health impacts of a chemical, and therefore to be able to correctly determine its safety, scientists and regulators must look at all of the routes of exposures to it (referred to as aggregate exposures). CSIA allows consideration of aggregate exposures, but does not require such considerations.

Intended Conditions of Use: Finally, the definition of “intended conditions of use” should include the concept of “reasonably anticipated exposure” (used in other parts of the legislation). Unintended uses or exposures may be as or more important than intended uses. Chemical manufacturers should have to account for unintended exposures because that’s the reality of how people come in contact with chemicals. For instance, when manufacturers added lead to paint, they never intended children to ingest paint chips, nor did manufactures of flame retardants intend for their chemicals to migrate out of furniture cushions into dust, which is then ingested or inhaled by consumers. Yet these are critical exposure routes that must be incorporated into any meaningful safety assessment.

Expedited Action on the Worst Chemicals: Meaningful TSCA reform must provide mechanisms for the EPA to take immediate action to reduce public exposures to the chemicals we already know are highly toxic. CSIA retains the same impossibly high regulatory burden for the EPA to meet when attempting to ban or phase out a toxic chemical. Since these actions would be reserved for the worst of the worst chemicals, it would have the exact opposite effect of what is needed – slowing down or halting altogether needed restrictions rather than expediting action on the worst chemicals. Where we have the evidence that a chemical is toxic, the EPA should not have to embark on a lengthy evaluation process or meet an impossible burden of proof before taking action to protect public health. Toxic chemicals that

are persistent in the environment and bioaccumulate in our bodies (PBTs) are the types of chemicals that the EPA should be able to act on immediately. For example, polychlorinated biphenyls (PCBs), were banned when TSCA was first passed in 1976 and yet they are still in our environment and in our bodies almost four decades later, and we will continue to deal with that legacy well into the future.

Adequate Data for Chemical Prioritization: The CSIA sets up a two-tiered system for EPA review of the safety of industrial chemicals. Chemicals designated as high priority must be scheduled for a safety assessment and safety determination. Low priority chemicals are those that the EPA determines are “likely to meet the safety standard,” and once so designated, are set aside with no further action unless the EPA is explicitly requested to reevaluate the low priority designation of a specific chemical. One problem with the two-tiered system is it does not create a categorization for chemicals that do not have existing safety data of any kind even though we know a lack of data should not be equated with safety. However, there is no upfront requirement for manufacturers to develop or submit safety data showing a chemical is likely to meet the safety standard. In fact, the burden falls to the EPA to find information that is “reasonably available to the Administrator,” including requiring the EPA to actively search for publicly available data. The EPA can request or require more data, by consent agreement or order, but this adds an additional level of administrative burden, a burden that should be industry’s from the beginning. The bill should make clear that no chemical should be designated as low priority without sufficient data to affirmatively show it is safe.

Deadlines and Timetables: CSIA provides virtually no deadlines or timelines for completing critical tasks such as safety assessments and safety determinations. While there are a few deadlines for creating procedural guidelines, language like “promptly,” “every effort to complete...in a timely manner,” “from time to time,” “expeditiously completing,” “reasonable extensions,” “reasonable period,” and “as soon as possible” take the place of specified timetables and deadlines. ***Enforceable deadlines are essential, particularly given the history of the chemical industry’s effective manipulation of the current TSCA process to delay evaluation and regulation of chemicals for years and sometimes decades.*** In our criminal justice system there is an expression that “justice delayed is justice denied.” In this case, chemical regulation delayed allows for dangerous exposures that threaten public health.

Public Right to Know: The CSIA does not ensure the public has adequate access to information on the safety of industrial chemicals that end up in their workplaces, communities and consumer products. Currently, companies frequently designate the very identity of the chemicals they use as confidential business information (CBI), which means that information cannot be released to the public. CBI claims are not adequately justified, even when safety data shows that the substances present a health hazard. The EPA has little authority and even fewer resources to challenge these designations, so the vast majority of CBI claims are simply accepted without serious review of their legitimacy. Chemical identity, particularly of a hazardous substance, is critically important for scientists to conduct effective research, for workers to protect themselves and their families from unsafe exposures, for retailers wanting to craft policies to protect their customers, and ultimately for consumers wanting to make informed purchases to protect their families. Given the historic and ongoing abuse of CBI, it is particularly troubling that the CSIA leaves all current CBI claims in place, grandfathering them in with no requirement or incentive for the EPA to review or substantiate the need for that information to be held as confidential.

Quality of Science: The effectiveness of any chemical management system relies on the ability of regulating agencies to consider all of the scientific information about the risks or safety of a chemical.

For years, the chemical industry has been waging a well-funded campaign against government and academic science that shows adverse health effects and increased health risks associated with specific chemicals. The language in the CSIA reflects those chemical industry efforts to undermine and devalue government and independent science while protecting industry-funded science. To ensure the highest quality and best available science, the CSIA should require scientific procedures and guidelines developed in the bill follow the recommendations of the National Academy of Sciences for 21st century toxicology and risk assessment.

A problematic example of the CSIA's attacks on strong science is its statement that the Administrator "shall encourage the use of good laboratory practices," or GLP, for the test data. "Good laboratory practices" is a technical term referring to a set of record keeping and procedural requirements for chemical testing that was set up in the late 1970s. GLP was developed in response to a scandal involving a number of labs, including Industrial BioTest Labs, which made up or falsified test data. The FDA and the EPA established GLP by rule in 1979 and 1983 respectively. GLP procedures include requirements that are very difficult for academic labs to meet, such as burdensome record keeping procedures and using large numbers of laboratory animals (which is in contradiction to Sec. 4 (i) of CSIA). Requiring GLP does not guarantee a "better" or more scientifically robust study, only that these administrative requirements are met. While the protections implicit in GLP standards are important, the EPA should not value studies using GLP over or to the exclusion of academic or government science, but rather should evaluate studies based on the best scientific methods and designs. A good example of the failings of GLP is the FDA's most recent safety assessment of bisphenol A (BPA). The agency based its assessment on two GLP industry-sponsored studies, while ignoring or undervaluing hundreds of academic studies showing harm from even very low doses of BPA.

Another troubling provision in the bill is the explicit inclusion of "mechanistic information" or "mode of action" in the consideration of "weight of the evidence" in the "Evaluative Framework for Decision-Making" in Section 4. These terms refer to a detailed understanding of the step-by-step process of how a chemical creates a particular outcome. While useful, this information should not be required to determine that a chemical does not meet the safety standard. Evidence that an effect is real should not be ignored just because scientists don't fully understand how that effect happens.

State Preemption: Particularly given the other serious shortcomings of the legislation, the CSIA does not adequately protect the right of states to safeguard their citizens from harmful exposures when the federal government can't or won't take action. The CSIA could roll back the few current state protections in place and would stifle future state protections. With the EPA's hands have been tied by the complete failure of TSCA, states from around the country have stepped up over the past 10 years to protect their citizens from harmful chemical exposures by passing legislation on a variety of chemicals and uses. These laws not only protect citizens within the state borders, but have also had a positive impact on manufacturing practices throughout the country.

Current State Laws: If the CSIA in its current form were enacted, state laws that are in place would be preempted once the EPA has completed a safety determination of the particular chemical in question. However, completion of the safety determination is not the same as having federal safety protections in place. The process and timeframe between issuing a safety determination and issuing of a final rule to implement needed restrictions can be a very long one, including the protracted process of rulemaking and the possibility of lawsuits that could delay implementation indefinitely.

Future State Legislation: Under the CSIA, states would be barred from passing future laws once a chemical is designated as low priority or designated as high priority and scheduled for a safety assessment and determination. Given the lack of deadlines in the bill, once scheduled, a chemical could sit for any number of years before action is taken, during which time the states' hands are tied and the public is unprotected. Once a chemical is designated as low priority, which is designed to be basically an educated guess by the EPA as to whether or not a chemical will meet the safety standard, the states are also prohibited from taking any action on that chemical.

State Waivers: The CSIA includes a state waiver process that allows a state to take action if the EPA determines that the state cannot wait until the end of the scheduled safety determination or the federal safety assessment has been unreasonably delayed. However, it is extremely cumbersome and requires a very high bar of justification – such as showing a “compelling state interest.” In addition, this waiver is not available for regulating a low priority chemical, even when new scientific data emerges showing possible harm.

Unintended Impacts: CSIA could also impact state laws far beyond the intended scope of the legislation. According to a June 25, 2013 letter from the California EPA to Sens. Dianne Feinstein (D-Calif.), Barbara Boxer (D-Calif.) and Kristen Gillibrand (D-N.Y.), “...we have identified dozens of California laws and regulations that may be at risk of preemption under the current provisions of S. 1009 (CSIA).”

The letter goes on to list examples of the laws that would be at risk impacted, including provisions related to global warming, reducing ozone pollution, drinking water safety and consumer product safety.

California is not the only state that will be impacted by the preemption provision. Numerous states around the country have passed protective laws that could be impacted. While the CSIA authors may not have intended to negatively impact state chemicals management laws, the chemical industry lawyers will, without a doubt, argue for an interpretation that most favors their clients, in this case for the broadest possible preemption. The language of the bill must be crystal clear as to the extent of allowable preemption.

Responses to The Honorable Bill Cassidy

During the question and answer period, Rep. Cassidy raised a number of questions about the science regarding the connection between breast cancer risk, obesity and chemicals, including carcinogens and endocrine disrupting chemicals. Answers to those questions are provided here:

What is the situation at U.S Marine Corps Camp Lejeune and its relationship to male breast cancer?

In 1982, the U.S. Marine Corps discovered that two of the water systems at Camp Lejeune were contaminated with volatile organic compounds (VOCs). These VOCs, several of which were used as solvents, included trichloroethylene, tetrachloroethylene, *trans* 1,2-dichloroethylene, vinyl chloride, and benzene. With the exception of *trans* 1,2-dichloroethylene, these chemicals have been designated as known or probable carcinogens. In addition to cancer, these chemicals have been associated with aplastic anemia, infertility, kidney diseases, liver disease, lupus, miscarriage, Parkinson's disease,

scleroderma, and skin disorders. At their peak, the levels of exposures to these toxic chemicals were in some cases orders of magnitude higher than the safe levels set by the EPA.

The situation at Camp Lejeune has garnered a great deal of attention and concern with the public and Congress alike. Several bills have been introduced in both the House and the Senate over the last two Congresses. The House Science and Technology's Investigations and Oversight Subcommittee held a hearing in September of 2010, entitled *Camp Lejeune: Contamination and Compensation, Looking Back, Moving Forward*, where 2 male breast cancer survivors who lived at Camp Lejeune testified. The House bill, the Janey Ensminger Act, was named after a 9 year old girl who died of leukemia, and had 38 bipartisan cosponsors. The Senate legislation, Caring for Camp Lejeune Veterans Act, was sponsored by Republican Senator Richard Burr along with a bipartisan list of 10 cosponsors. Both bills provided health care for veterans and their families who lived at Camp Lejeune during the time the water was contaminate and have been impacted by serious health issues, including 15 different cancers and other illnesses. In August of 2012, the House passed the Janey Ensminger Act by voice vote as part of a larger veteran's bill and President Obama signed it into law.

In addition to Congressional action, the CDC's Agency for Toxic Substances and Disease Registry (ATSDR) is currently conducting a number of health studies looking at the association between exposure to these VOCs in the drinking water and numerous health impacts. These studies include the Birth Defects and Childhood Cancer Study, the Health Survey of Marine Corps Personnel and Civilians, the Male Breast Cancer Study and the Mortality Study.

One of the factors focusing public attention on the contaminated water at Camp Lejeune is the high incidence of the rare disease of male breast cancer (you noted in your comments that the highest risk factor for breast cancer is being a woman). The ATSDR has identified 61 cases of male breast cancer related to Camp Lejeune from 1995 – 2010, the only years of data available from the Veterans Affairs cancer registry. Outreach efforts by individuals like Mike Partain, a breast cancer survivor whose Marine Corps officer father was stationed at Camp Lejeune at the time of Mike's birth, have identified over 20 additional cases. The formal study of the connection between the water contamination and incidence of male breast cancer is underway and results will not be available for some time yet. Lack of accurate information from the military about the levels of contamination in the water, and therefore levels of exposure, and the need to use old paper files (some on microfiche), has delayed the completion of this investigation. While studies are still ongoing, the existence of so many cases of male breast cancer, all connected to the same military base with known chemical exposures, has raised serious concerns and has focused the public's attention on the devastating health impacts of certain chemical exposures. The very rarity of male breast cancer has made the potential chemical impacts all the more evident.

The birth defects and childhood cancer study is currently under peer review and should be published later this year. The mortality study is also nearing completion and should be reviewed for publication later this year. Both will add to the scientific literature about the effects of drinking contaminated water over an extended period of time.

What is the Endocrine Disruptor Screening Program?

An endocrine disrupting compound (EDC) is defined by the Environmental Protection Agency (EPA) as "an exogenous agent that interferes with synthesis, secretion, transport, metabolism, binding action, or

elimination of natural blood-borne hormones that are present in the body and are responsible for homeostasis, reproduction, and developmental process.” Peer-reviewed science has linked EDCs to a vast array of negative health impacts, from breast and prostate cancer to reproductive health problems such as reduced fertility to obesity and metabolism disruption. The Endocrine Society, an extremely well respected professional association with more than 16,000 international members committed to advancing the science of endocrinology, published a position paper in 2009 discussing the issues and science to date on EDCs and raising concern about the impact of EDCs on numerous health endpoints. This report, entitled [Endocrine-Disrupting Chemicals](#), provides an excellent overview of the issues.

Recognizing the potential health impacts of EDCs, Congress created the Endocrine Disruptor Screening Program (EDSP) in the 1996 Food Quality Protection Act (FQPA). FQPA directed the EPA to “develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” While the EDSP has fallen far behind the schedule set by Congress to have the system up and running, the EPA is making progress and we are hopeful that a strong and validated system will be in place soon to identify these very troubling and problematic chemicals. A 2012 article by The Endocrine Society published in the journal *Endocrinology*, entitled [Endocrine-disrupting chemicals and public health protection: a statement of principles from The Endocrine Society](#), highlights two key limitations of the EDSP that need to be addressed to increase the program’s effectiveness. The EDSP screening tests need to: 1) assess hazard using the most sensitive endocrine endpoints; and 2) integrate more thorough testing of low dose exposures, which are most pertinent to endocrine disruption.

How can chemicals contribute to the growing epidemic of obesity in this country?

During the hearing, you noted that greater physical activity leads to reduced obesity, and that obesity is linked to earlier menarche, which increases estrogen exposure and breast cancer risk. A comprehensive review of the literature in this area shows a much more complex situation, as described in the recent report *Breast Cancer and the Environment: Prioritizing Prevention* (see sections 6.1.9 through 6.2.1)

Adult BMI and postmenopausal weight gain are linked to increased risk of postmenopausal breast cancer. On the other hand, adult weight gain inversely correlates with risk of premenopausal breast cancer and little evidence supports a direct relationship between childhood weight and breast cancer risk. Prepubertal overweight and obesity are expected to contribute to early puberty, as are dietary estrogens and chemicals. As noted below, some chemicals likely contribute to childhood obesity, adding a layer of complexity to efforts to determine which factors most directly contribute to breast cancer risk. Furthermore, while physical activity does confer a reduction in risk for breast cancer (Section 6.1.6), the energy expended during physical activity appears to vary by race and ethnicity, providing further complexity to an already unclear body of science.

I mentioned the growing evidence and concern that some chemicals, referred to as obesogens, are exacerbating the public health crisis of obesity in this country. Two recently published articles provide insight into this evolving area in the scientific literature. An article that appeared in *Environmental Health Perspectives*, entitled [Obesogens: An Environmental Link to Obesity](#), provides an overview of the science on this issue. And the day before the hearing another article, entitled [Urine Bisphenol A Level in Relation to Obesity and Overweight in School Age Children](#), was published which found a strong association between levels of the estrogen-mimicking bisphenol A, or BPA, and increased risk of obesity

in girls ages 9 – 12 in China. While we do not yet fully understand the mechanism in play, there is an increasing volume of scientific evidence pointing to a higher risk of serious health problems, including both breast cancer and obesity, related to exposure to these endocrine disrupting compounds.

