



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

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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.<sup>i</sup> <sup>ii</sup> 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.<sup>iii</sup>

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<sup>iv</sup> 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

<sup>i</sup> 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.

<sup>ii</sup> 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/](http://seer.cancer.gov/csr/1975_2006/), based on November 2008 SEER data submission, posted to the SEER web site, 2009.

<sup>iii</sup> 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](http://www.niehs.nih.gov/about/assets/docs/ibcercc_full_508.pdf) (6/11/13).

<sup>iv</sup> 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>.