



Breast Cancer and the Environment

Prioritizing Prevention

**Summary of the Interagency Breast Cancer &
Environmental Research Coordinating Committee
&
Breast Cancer Fund's Recommendations for a
National Prevention Research and Policy Agenda**

October 16, 2013

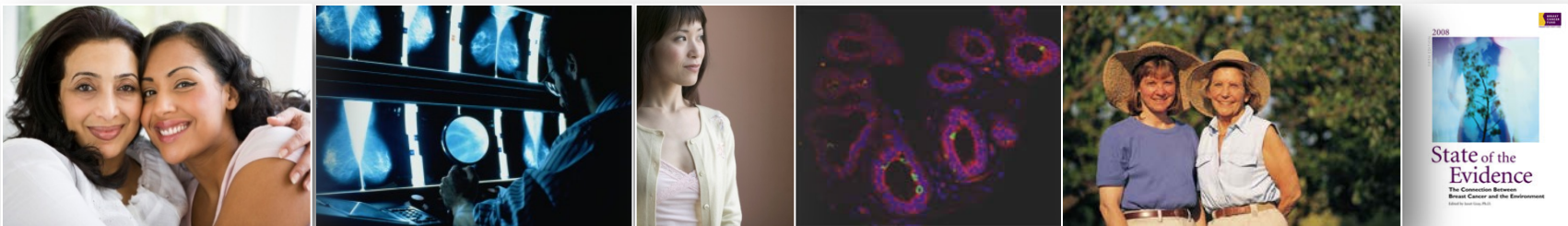
Breast Cancer Fund

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Breast Cancer and Environmental Research Act of 2008

- Signed into law by the President on October 8, 2008.
- Amends the *Public Health Service Act* to establish a committee composed of federal officials, scientists, health professionals, and people who represent individuals with breast cancer.
- DHHS Secretary Sebelius delegated this activity to NIH, specifically to NIEHS and NCI.



Charge to the Committee

- ✓ **Share & coordinate information on existing research activities**
- ✓ **Develop a comprehensive strategy and advise the NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research**
- ✓ **Develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer**
- ✓ **Make recommendations to the Secretary of the DHHS regarding:**
 - **Any appropriate changes to research activities**
 - **Reducing unnecessary duplication of effort**
 - **Increasing the involvement of patient advocacy and community organizations**
 - **Expanding partnerships between public & private entities**

How did they develop the report?

- Chartered federal advisory committee under committee rules reporting to Director NIEHS
- From May 2010 through January 2013
- Three working sub-committees:
 - State of the Science & Advances in Breast Cancer: M Forman
 - Research Process, Coordination and Funding: M Gould
 - Research Translation, Dissemination and Policy Implications: J Rizzo
- Webinars by invited speakers
- Four all committee in-person meetings that were open to the public
 - Developed a working definition of environment early in the process, to set the stage
 - Time allotted for comments from the public
 - Agendas and minutes available at NIEHS
- Countless Conference Calls, also announced in Federal Register and open to the public
- Iterative feedback from committees, government agencies, and outside review to finalize the report before submission to Secretary Sibelius

Breast Cancer Burden

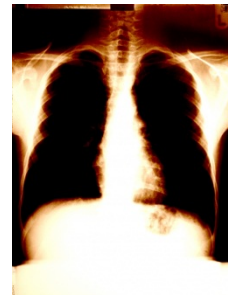
- **In 2013...**
 - **232,340 women and 2,240 men will be diagnosed with breast cancer**
 - **39,620 women and 400 men will die from breast cancer – 14% of all cancer deaths**
 - **National cost projected will be 17.35 billion dollars**
 - **3 million women in the US are breast cancer survivors**
- **Women with breast cancer have 67% increased risk of a new breast cancer diagnosis during the first 10 years after initial diagnosis.**
- **Leading cause of cancer deaths in women worldwide.**

Why Environmental Factors???

- **Genetic and environmental factors individually contribute and interact with each other to increase breast cancer risk.**
- **Breast cancer rates can vary with changing environmental circumstances.**
- **The large majority of cases occur in women with no family history of breast cancer.**
- **Environmental factors are more readily identified and modified than genetic factors and therefore present a tremendous opportunity to prevent breast cancer.**

Defining the Environment

- **Lifestyle and behavioral factors**, such as alcohol intake and physical activity
- **Chemical agents** that people are exposed to through pesticides, industrial pollutants, consumer products, and medications
- **Physical agents**, such as radiation from medical and other environmental sources
- **Social and cultural influences**, such as family, community, psychosocial/social, and societal factors that may influence breast cancer risk



Prevention is the key to reducing the burden of breast cancer

Why don't we know more?

- We have not been looking at environmental exposures at the correct life stage.
- We have not examined the correct environmental agents.
- We have not asked the right questions about complex mixtures, genetic susceptibility, and breast cancer subtypes.

Key themes for the State of the Science

- **Windows of susceptibility and timing of exposure**
- **Animal-to-human research paradigm**

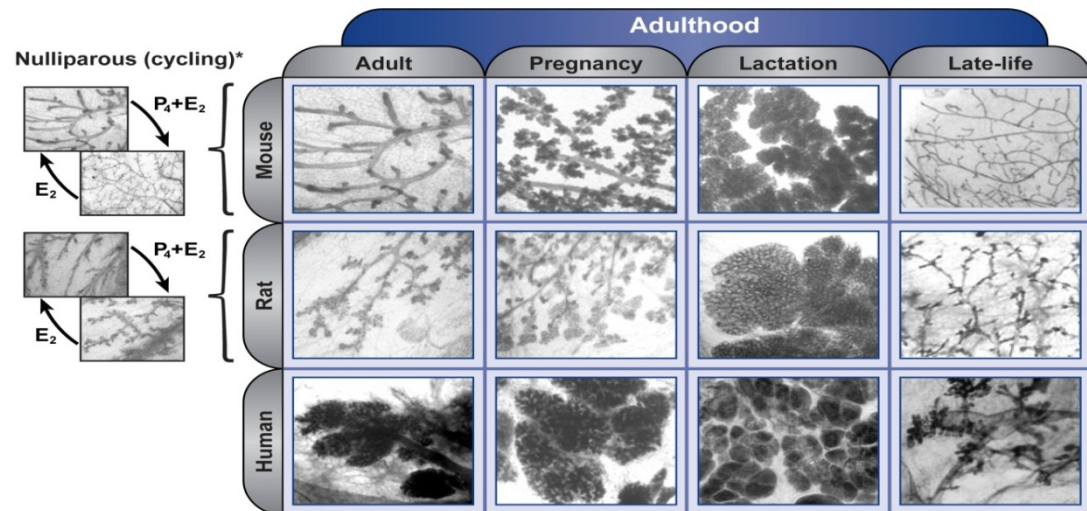
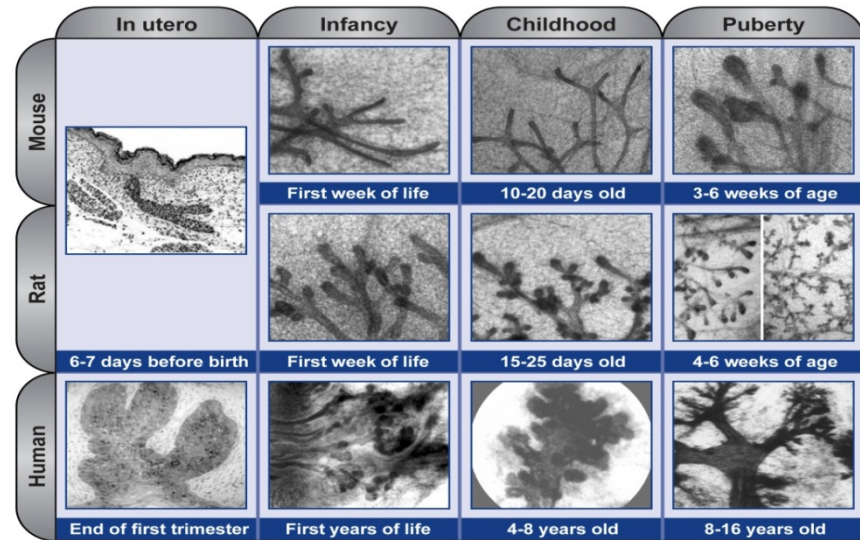


Areas Where Additional Research is Needed

- **Etiology/causes of breast cancer overall and by subtype**
- **Etiology/causes of breast cancer by race and ethnicity**
- **Testing of environmental exposures**
- **Monitoring of environmental exposures**
- **Methodological issues relevant to the study of breast cancer and the environment**
- **Risk assessment**

Breast Cancer and the Environment: Prioritizing Prevention

Gap: Research on environmental exposures on breast development & regulation.



Breast Cancer and the Environment: Prioritizing Prevention

Gap: Timing matters
Understanding the
effect of exposures
on breast cancer
risk & recurrence.

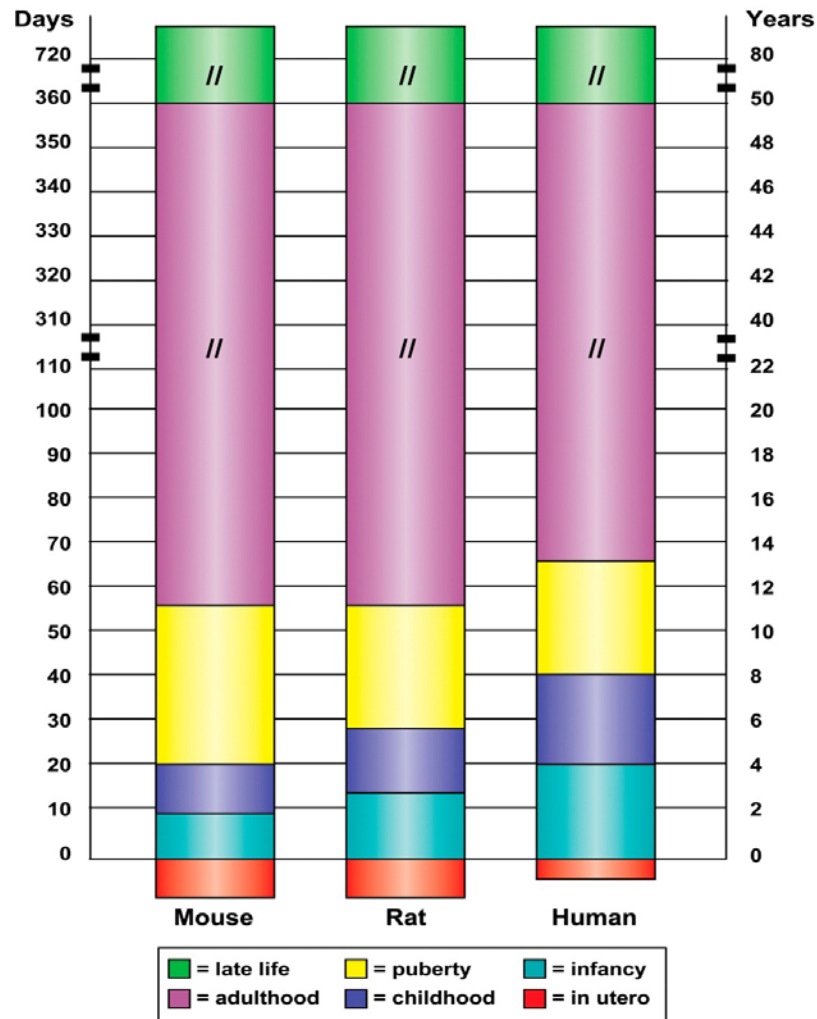


Figure 5.2. Comparison of the Relative Time Spent in the Different Stages of Mammary Gland Development for Mice, Rats, and Humans. Mammary development begins 6-7 days before birth in the rodent or about 6 months before birth in the human, and follows the same course, with a similar relative time spent in each life stage. Rodent strain and ethnicity-dependent variability have been reported during the pubertal stage and in later life, during the transition from adulthood to senescence. Breaks in time are denoted by hashmarks.

Transdisciplinary research is critical to the understanding of mechanisms

- The role of epigenetics in breast cancer etiology as well as the effect of environmental exposures on epigenetic alterations.
- The association between obesity and environmental exposures on risk.
- Among the five or more breast cancer subtypes, there has been very limited research examining the role of environmental exposures on risk by subtype.



Disparities – untangling subtypes and exposures

- **Low income communities often face greater exposure to urban air pollution, chemicals and pesticides that have been implicated in breast cancer**
- **We need to know why:**
 - **Some aggressive forms of breast cancer are more common in Black women than white or Hispanic women**
 - **Breast feeding reduces the risk of triple negative breast cancer in Hispanic women**
 - **Black women are more likely to be diagnosed before age 40**
 - **Ethnic group specific risk differs by subtype and how environmental exposures may be implicated in risk by breast cancer subtype**

Monitoring and testing

- **Techniques to measure levels and response to mixtures of exposures**
- **Regularly monitor levels of environmental and biospecimens from diverse populations**
- **Conduct, coordinate and integrate studies across federal agencies**
- **Rapidly communicate results of the research to inform policy**

Analysis of Federal Research Investments in Breast Cancer & the Environment Research

- ✓ **Etiology Code 2.1:** *Exogenous Factors in the Origin and Cause of Cancer*
- ✓ **Etiology Code 2.3:** *Interactions of Genes and/or Genetic Polymorphisms with Exogenous and/or Endogenous Factors*
- ✓ **Prevention Code 3.1:** *Interventions to Prevent Cancer: Personal Behaviors That Affect Cancer Risk*

Note that some projects fell in more than one code, which inflates the proportion of funding devoted to Environmental Health Research



Common Scientific Outline

<https://www.icrpartnership.org/CSO.cfm>

Breast Cancer Research Funding

DoD Breast Cancer Funding (2006-2010): \$610 million total

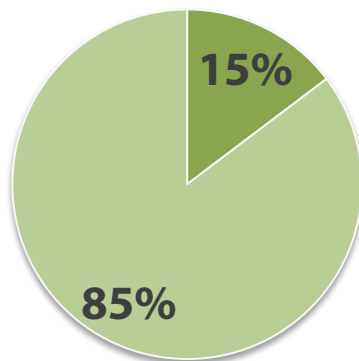
- 8.6% of the total investment in BC focused on breast cancer and environment.

NIH Breast Cancer Funding (2008-2010): \$2.3 billion total

- 15.5% of the total investment in BC focused on breast cancer and environment.

Percent of annual federal funding devoted to BC&E

■ environment ■ everything else



Non-governmental organizations (2005-2009): \$1.50 billion

- 7% of the total investment in BC focused on breast cancer and the environment.

Research Translation, Dissemination, Communication and Policy Implications

- **Knowledge-to-action gap**
- **Prevention requires we close the knowledge-to-action gap and translate science into preventive public health actions that can impact breast cancer incidence in the future**

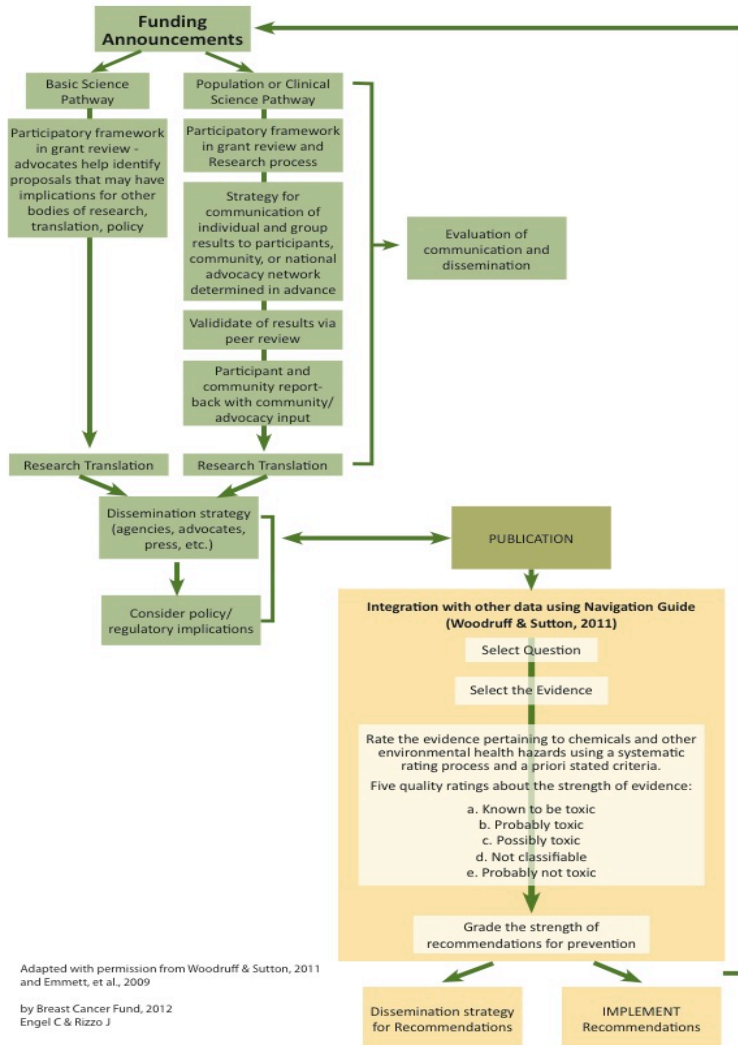


Research Translation, Dissemination & Communication

- **Research Translation:** The transfer of scientific discoveries from laboratory, clinical, or population studies into effective interventions at the individual and population level.
- **Research Dissemination:** Targeted distribution of evidence-based research findings intended to influence health care consumers in ways that ultimately prevent and reduce breast cancer burden in society.
- **Research Communication:** Bidirectional approaches that provide the public with understandable scientific knowledge and scientists with allies who can communicate with others.

Breast Cancer and the Environment: Prioritizing Prevention

Research Translation, Dissemination and Communication



Engaging advocates early on and sustaining that involvement supports development of strong plans to translate, disseminate and communicate findings about breast cancer and the environment.

Adapted with permission from Woodruff & Sutton, 2011 and Emmett, et al., 2009

by Breast Cancer Fund, 2012
Engel C & Rizzo J

Programs that effectively integrated research translation, dissemination and communication efforts, included some or all of the following strategies:

- 1. They had formal structures for translation, dissemination and communication built-in from the inception of the research**
- 2. They included participatory approaches for involving stakeholders**
- 3. They funded advocates and community involvement**
- 4. They considered environmental justice**
- 5. They evaluated partnerships, dissemination and communication, and research impact**

Policy Matters because it:

1. **Affects how research is conducted, reported and interpreted.**
2. **Affects how research is translated into more effective prevention strategies**
3. **Can guide the development and safety assessment of alternative chemical, manufacturing and waste disposal practices**
4. **Can ensure the public's right to know**
5. **Can establish environmental justice**
6. **Can improve the built environment (parks, access to fresh foods)**
7. **Can shape the implementation of research into public health programs**
8. **Can facilitate primary prevention by reducing certain exposures**



Policy Implications of the Report

- 1. Prioritize human studies that evaluate pubertal timing, growth indices, and environmental exposure information across the life course.**
- 2. Require the collection and evaluation of mammary gland samples in testing for industry and government health evaluations.**
- 3. Expand biomonitoring programs and devote adequate resources to communicating biomonitoring results to research participants, the public, and policymakers.**
- 4. Prioritize the testing of chemicals that are produced in high volumes for which there is biologically plausible evidence of their role in the development of breast cancer.**
- 5. Address gaps in risk assessment.**
- 6. Create a mechanism to facilitate joint strategic planning and coordination among funders.**
- 7. Continue and expand the use of advocates and stakeholders in the breast cancer and the environment research enterprise.**

The Path Forward

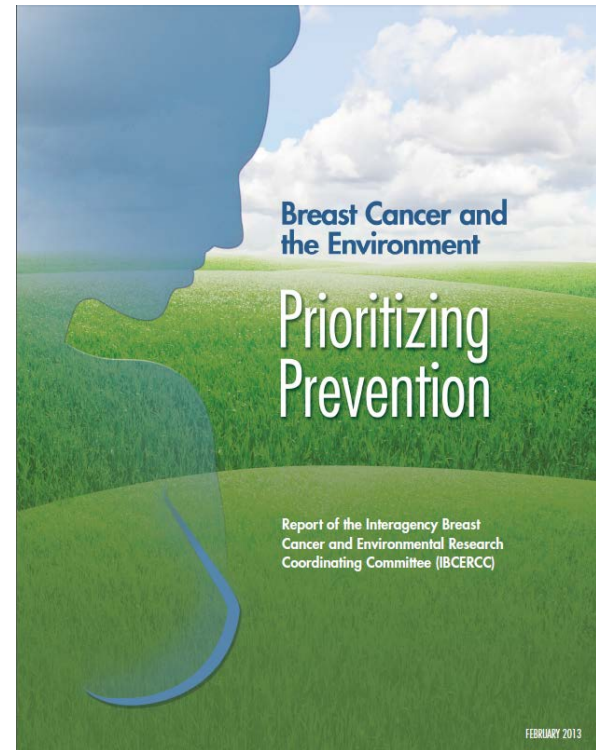


- 1. Prioritize prevention**
- 2. Transform how research is conducted**
- 3. Intensify the study of chemical and physical factors**
- 4. Plan strategically across Federal agencies**
- 5. Engage public stakeholders**
- 6. Train transdisciplinary researchers**
- 7. Translate and communicate science to society**

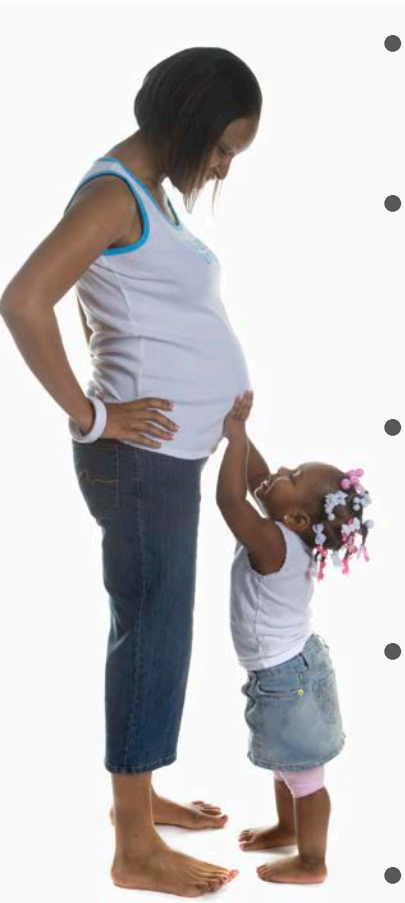
Policy Agenda for Breast Cancer Prevention Research

Our goal is to increase the volume, quality and effectiveness of the scientific research focused on breast cancer *prevention*.

As the *Prioritizing Prevention* report clearly states, preventing breast cancer is the best chance we have to reduce the burden of this disease.



Research Policy Priorities:



- **Double the research funding allocated to primary prevention research: from 15% to 30%, by 2015.**
- **Develop and implement a mechanism to coordinate research efforts across federal agencies and across scientific disciplines.**
- **Intensify the study of chemical and physical factors – including ionizing radiation, chemical mixtures and interactions across these categories.**
- **Incentivize a life-course approach to research to examine the relationship between timing of exposure to environmental chemicals and the increased risk of breast cancer.**
- **Include mammary gland endpoints in safety testing protocols used in chemical management policies.**



Research Policy Priorities, continued:

- Research increased risk of breast cancer and exposure to environmental chemicals in vulnerable populations including people of color, women in the workplace and those with genetic susceptibilities.
- Investigate environmental factors that influence the link between a family history and breast cancer risk.
- Improve monitoring of exposures by enhancing biomonitoring programs.
- Require research projects on breast cancer and the environment to integrate research translation, dissemination, and communication plans throughout the research process in ways that facilitate partnerships with stakeholders from scientific, cancer advocacy, environmental justice and provider communities.

The Time to Act is NOW



Prioritizing Prevention provides a great overview of current research. It offers a vision for future research to support a better understanding of the impact of chemicals and radiation on the risk of breast cancer.

But while we still need to learn more, we must act now on what we do know.

Failure of Federal Regulation

Chemicals are regulated by multiple federal agencies depending on the product or use:

- **Cosmetics and Personal Care Products - FDA**
- **Cleaning Products – CPSC/OSHA/FDA/EPA**
- **Food Packaging - FDA**
- **Toys and Consumer Products - CPSA**
- **Overall Regulation of Industrial Chemicals, Air, Water - EPA**





Policy Recommendations

- **Improve Oversight of Cosmetics/Personal Care Products**
- **Improve Oversight of Household Cleaning Products, particularly consumer right-to-know**
- **Improve Oversight of Food Packaging Safety**
- **Develop policies that limit risk related to exposure to medical radiation**
- **Incentivize Green Chemistry and Require Alternatives Assessments**
- **Strengthen Management of Industrial Chemicals**

Policy Recommendations, continued

- **Develop policies to increase the public right to know**
- **Develop policies to reduce/prevent/eliminate disparities in exposure to toxic chemicals and promote environmental justice**
- **Promote cross collaboration among federal agencies to:**
 - **Share use and exposure data**
 - **Share risk assessment data**
 - **Share chemicals management best practices**
 - **Share and harmonize data related to cumulative exposures**



Reform of the Toxic Substances Control Act is Part of the Solution

TSCA Reform is a public health issue.



Failures of TSCA

- **84,000 chemicals registered for commerce**
- **62,000 grandfathered in with no safety review in 1976**
- **200 of those grandfathered chemicals tested**
- **37 years without updating**
- **5 chemicals regulated**



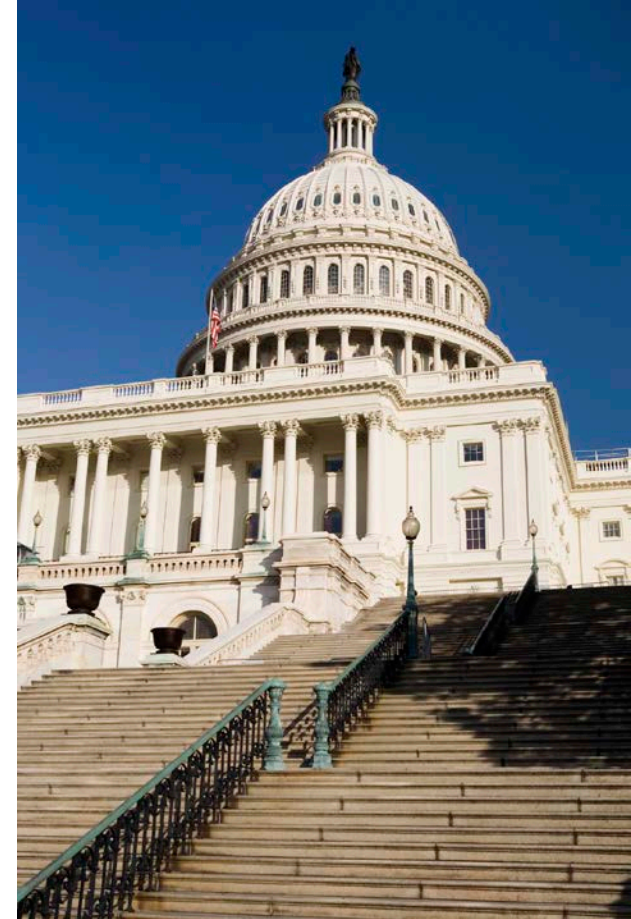
Chemical Safety Improvement Act - Doesn't Improve Chemical Safety

- **No protection vulnerable populations**
- **Same failed safety standard as TSCA**
- **Endless red tape and no timetables or deadlines**
- **Undermines quality of science**
- **Doesn't ensure public's right-to-know**
- **Pre-empts state action**



How to Improve the CSIA

- **Safety standard that protects public health**
- **Protect vulnerable populations, including disproportionately exposed communities**
- **Sufficient data to evaluate chemicals**
- **Public access to safety data**
- **Expedite action on the worst chemicals**
- **Protect the right of states to act**



WINDOW OF OPPORTUNITY

**Push for Creating a CSIA that will
Protect Public Health**