

Testimony of Fran Visco, J.D.
President of the National Breast Cancer Coalition
before the Health Subcommittee of the
House Energy and Commerce Committee
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Thank you Chairman Pallone, Ranking Member Deal and Members of the Subcommittee for holding this hearing on such crucial legislation, the Breast Cancer and Environmental Research Act, H.R. 1157. I want to also thank Representative Nita Lowey, the sponsor of this legislation, for her leadership throughout the years on this critical bill, as well as our other lead sponsors, Representatives Sue Myrick and Lois Capps. I am Fran Visco, a 20-year breast cancer survivor, wife and mother, a lawyer, and President of the National Breast Cancer Coalition (NBCC).

NBCC is a grassroots organization dedicated to eradicating breast cancer. The Coalition includes hundreds of organizations and tens of thousands of individual members, many of whom you have heard from often over the past years to express their strong support for H.R.1157. In fact, as you know, we now have 70 Senate and 268 House cosponsors of this legislation.

NBCC's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community; to increase access to high quality treatment and care for everyone as well as access to quality clinical trials; and to increase the influence of women living with breast cancer in all areas of decision-making that impacts breast cancer.

Purpose and Summary of the Legislation

Background

As you know, the causes of breast cancer have not yet been determined. We simply do not know what to tell women to do to prevent breast cancer. We have identified some factors associated with increased risk of breast cancer. Yet, about 70% of breast cancers are not associated with known risk factors. Less than 10% of breast cancers can be attributed to an inherited genetic predisposition. We know it is not solely a genetic question, nor is it solely a question of environment. Rather, it is a complex interaction between genes and environment that is at the core of this problem. Yet, the environmental influences remain largely unexplored and unexplained.

It is especially disturbing that we do not know the causes of this disease since the chances of a woman developing the disease have increased over time. Today, a woman in the United States has a one in eight chance of developing invasive breast cancer in her lifetime. In 1975, that chance was one in eleven. Recent reports of a decline and stabilization in incidence among some groups of women have been linked to the findings of the Women's Health Initiative and a decrease in use of hormone replacement therapy. It remains to be seen if this association between HRT and breast cancer is one of cause and effect or delayed diagnosis. In any event, it accounts for a small percentage of new cases.

The three million women living with breast cancer and all women at risk, which is all women, want to know what causes breast cancer. They want to know how to prevent this disease, so that they, their daughters, other family members and friends will not suffer from it.

There is no doubt this is a complex problem. Ten years ago NBCC held the first of two environmental summits, bringing together scientists, trained consumers, policymakers and other stakeholders to help us determine how best to address the issue of environmental links to breast cancer. The consensus was then, and is now, that little is known and little is done in this area of research. The participants had different perspectives on the problem, including what is encompassed in “environment” in this context. Some working on this issue believe that “the environment” should encompass external exposures (e.g., pesticides) only, and not “internal” (e.g., age of menarche, circulating hormone levels, etc.). Some want to exclude voluntary exposures (e.g., diet). NBCC defines environment broadly, for all its work in this arena and for this proposed legislation. All agreed that these issues are exceedingly complex and must be addressed on many different levels from many disciplines and perspectives, with a strategic approach that respects scientific freedom and public input. It was clear that this is not a question that can be addressed solely by government, or by advocates, or by scientists. This diverse input from all stakeholders was one element that led to the proposed legislation. There are many ways to look at this problem and no one institute, institution or individual has the answers. Of course, if they did we would not be here today.

After an initial significant increase 15 years ago, we have seen annual funding for breast cancer research in both the private and public sectors remain the same or perhaps increase slightly. We know that certainly in the private, and to a lesser extent in the public sectors, much of that research is invested in a search for the next new drug, or the next combination of existing drugs. Technology has increased, looking for biomarkers of disease, primarily so that a therapy can then

be found to attack that biomarker. Yet drugs and other technology have made a modest overall impact in breast cancer. The majority of drugs that result from research result in incremental improvement over existing therapies, often adding toxicity and great financial cost. While it is extremely important to find out how best to treat and hopefully to cure this disease, we must invest significant resources into figuring out how to prevent it. That would be the ultimate and optimum result of our research investments. And government funding is the primary source of support for this approach since there is little commercial incentive.

Why this bill?

NBCC developed this approach as it has many others. As described above, we brought together all stakeholders involved in this issue on several occasions to look at and discuss the issues surrounding the environmental links to breast cancer. NBCC has watched as Congress has funded studies looking at possible breast cancer “hot spots”. States have legislated pesticide and other registries. Given what we learned from our summits, from working with and looking at the Department of Defense peer-reviewed Breast Cancer Research Program, from our work with scientists around the world, we concluded that continuing to ask specific questions and funding isolated approaches is not enough. A piecemeal approach to this very complex area is not a good use of resources, nor is it in the best interest of the public. The decisions about which questions to research should not be made in a vacuum, rather they should be made as part of a national strategy that takes into account past research, research underway and prioritizes the gaps that still exist.

We see excellent research being done, such as the Sisters Study and other studies at the National Institute for Environmental Health Sciences, and the technological advances brought about in part through the Human Genome Project that underlie the Genes, Environment and Health Initiative at the National Institutes of Health (NIH). We are not suggesting nor would we want, that this bill take the place of these or any other studies. This bill will enhance and complement those efforts. The approach contemplated by this legislation would allow the scientific community across the country to identify gaps in our knowledge, design ways to address those gaps and collaborate on the best research needed to respond. It will allow the research community throughout the country to set the agenda, to come together in multi-disciplinary, multi-institutional collaborations including the public, to decide questions to be asked, and to work together to launch a strategic, national approach incorporating all aspects of this problem.

What would the bill do?

With this country's investment in biomedical research, we have learned a great deal about how science works best in addressing complex questions that require the attention of the full range of scientific expertise.

It is most important to recognize that this bill will allow the scientific community to decide how the funds should be spent and will require that they be spent through a peer review process and a programmatic review that is based on proven, successful research programs.

The legislation would authorize \$40 million a year for five years for the National Institutes of Health to develop a collaborative, peer-reviewed grant program to study environmental factors

that may contribute to breast cancer. This number was based on analyses of existing research mechanisms and the input of many researchers across the country who are experts in this area.

The grant-making model in this bill is based on the successful and internationally acclaimed structure of the Department of Defense (DOD) peer-reviewed Breast Cancer Research Program, which has been replicated in other areas of research. The model was originally recommended by the Institute of Medicine at the National Academy of Sciences (IOM/NAS). The IOM has twice reviewed the DOD Breast Cancer Research Program and lauded its innovative and effective structure. There are several features of the DOD peer-reviewed Breast Cancer Research Program that are included in the legislation we are discussing today

- The Breast Cancer and Environmental Research Act would establish a Breast Cancer and Environmental Research Panel made up of experts in the field and trained consumers. (The Senate version includes an NIH representative also). The Panel would develop mechanisms based on the intent of the legislation, and a Request for Proposals will be published to the scientific community. The bill contemplates a strategic, broad approach to the issue that would be shaped by the scientific collaborations' response to the Request for Proposals. Scientists, working with community groups, are free to decide the critical questions to ask and the scientific approaches to be taken. The request will be for proposals looking at broad approaches to a broad definition of environmental links to breast cancer.
- After scientific and technical peer review is conducted, the Panel would review the proposals to make certain they, as a whole, address in a non-duplicative, strategic way,

the fundamental questions necessary to look at the issue. The Panel would then make recommendations for allocations of funds to the grantees. This critical step will prevent unnecessary duplication of research and ensure consistency with an overarching strategy as contemplated by the bill.

- Trained consumer advocates are included on the Panel. We believe the perspective of informed, educated breast cancer advocates must be present everywhere that breast cancer research decisions are made. A true partnership between advocates and scientists is the most efficient and effective way to reach the mutual goal of eradicating breast cancer, because both parties bring distinct and valuable knowledge to the process. Trained advocates have been included on the Integration Panel and at all other levels of the DOD Breast Cancer Research Program since 1993. This unique feature has been hailed as a success by the scientists, the advocates and the Institute of Medicine.

This bill includes a broad definition of the environment – from contaminants to lifestyle factors such as diet and exercise, stress levels, socio-economic status and other endogenous factors.

Multi-disciplinary and multi-institutional groups of researchers receiving the grants would look at the factors that may contribute to breast cancer development from different angles. A main feature of the research model proposed in this bill is flexibility. It is the grantees themselves, the researchers, who would identify the area to be studied – the science would not be dictated to them.

Collaboration is a key component of this legislation. The bill envisions that the best and brightest scientists and trained advocates from different institutions and different disciplines

would come together to apply for a grant, studying a complex question of the relationship between breast cancer and the environment, and breaking down the traditional silos of research. In turn, all the grantees would then collaborate with each other as well as with community groups representing a breast cancer constituency. This would prevent duplication of research, encourage new ideas and dynamic thinking, and with the involvement of community groups and trained consumers, ensure that the research is innovative and meaningful.

History of the Legislation

This bill was first introduced in 1999 by Representative Nita Lowey. I remember discussing the contents of the proposed legislation with then acting director of NIH, Dr. Ruth Kirschstein. As a result of those discussions, the content of the bill changed before it was actually introduced, as we wanted to address some of NIH's questions. We came to an agreement with NIH on the content and approach of the bill at that time. In 2000, Senators Lincoln Chafee and Harry Reid introduced the bill in the Senate. Since then the bill has had incredible bipartisan support and political momentum. Over two-thirds of the Energy and Commerce Committee Members are cosponsors.

The Senate Environment and Public Works Committee held a field hearing on this bill in the 107th Congress. In 2002, the Senate Labor-HHS Appropriations Subcommittee agreed that a strategic approach like the one taken in this legislation was necessary. They included language in their Committee Report urging the National Institute of Environmental Health Sciences (NIEHS) "to establish centers to conduct multi-disciplinary and multi-institutional research on

environmental factors that may be related to breast cancer.” The following year, the Labor HHS Conference Report included similar language.

In response, NIEHS established four research centers to focus on the environmental determinants of puberty and mammary gland development that may increase a woman’s risk of breast cancer. These centers do not address an overall national strategy for researching the possible links between the environment and breast cancer, and they focus on a narrow question. They are important, but are not what is envisioned by this legislation.

The Senate HELP Committee approved S. 579 in February of this year. Prior to that mark up, changes in the bill were negotiated to respond to concerns expressed by NIH. As a result of those changes, NIH no longer opposes the Senate version of the bill. We hope that this Committee will approve the Senate version of the bill.

The Senate Version

The bill was clarified by removing references to centers. The intent of the legislation was never to establish brick and mortar centers, but rather, as I have said, the grantees would be a collaboration of scientists and consumers from various disciplines and institutions. The reference to centers in the language was confusing and distracted from the true intent of the legislation.

A peer review protection clause was added. The bill was never intended to override or otherwise interfere with the peer review process at NIH. The Panel takes the peer-reviewed research and

makes recommendations for funding based on the strategy that has been developed, to make sure that not only the most scientifically important research is funded, but also the research that will have the most impact.

Changes were made to the Panel at the request of NIH. First, an NIH representative was added to the panel, and language was added so that the selection of the Chairperson of the Panel is subject to the approval of the NIH Director. Finally, language regarding how the HHS Secretary adopts the recommendations of the Panel was changed at NIH's request.

The bill has evolved over the years, taking into account concerns raised by not only Members of Congress but also by the National Institutes of Health. I am hopeful that this Committee will mark up this bill promptly following this hearing, and include the changes made to the Senate version.

Public Support

The National Breast Cancer Coalition has educated its grassroots membership across the country on the purpose and content of this bill. They in turn have worked very hard to get support from their Senators and Representatives for this bill. We are very proud of the fact that we now have 70 Senators and 268 Members of the House as cosponsors for this bill. We have had several negotiations with Committees and with the National Institutes of Health, to revise the bill and address concerns, while retaining the integrity and vision of the bill. The NIH has withdrawn its opposition to the Bill.

Now, the public is looking to you: we have done all that you ask, with this level of bipartisan support for the bill, with no administrative opposition. Women's lives depend on your actions. It has been eight years since this legislation was first introduced. Women can't wait any longer.

In summary, this bill offers a strategic approach to researching the potential links between the environment and breast cancer. It would establish a proven model for conducting this critical research. It would enhance and complement work that is ongoing at NIH. It leaves the scientific community and the public impacted by the disease free to decide, within the strategic approach of the legislation, what and how to research. Innovative thinking and meaningful research that gets us closer to finding the answers about the causes of breast cancer is critical to the eradication of this disease. The current research is not enough. We need to not only do more research, but we need to spend our precious federal dollars more efficiently and effectively. The approach this bill envisions does just that.