

**Testimony of
Joy Simha
Member of the Board of Directors
National Breast Cancer Coalition
and
Co-Founder, Young Survival Coalition**

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Introduction

Thank you, Mr. Chairman and members of the Appropriations Subcommittee on Defense, for the opportunity to submit testimony today about a program that has made a significant difference in the lives of women and their families.

I am Joy Simha, a 16-year breast cancer survivor, communications consultant, a wife and mother, co-founder of The Young Survival Coalition, and a member of the board of directors of the National Breast Cancer Coalition (NBCC). I am also a member of the Integration Panel of the Department of Defense Breast Cancer Research Program. My testimony represents the hundreds of member organizations and thousands of individual members of the Coalition. NBCC is a grassroots organization dedicated to ending breast cancer through action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates wherever breast cancer decisions are made.

Chairman Inouye and Ranking Member Cochran, we appreciate your longstanding support for the Department of Defense Peer Reviewed Breast Cancer Research Program. As you know, this program was born from a powerful grassroots effort led by the National Breast Cancer Coalition, and has become a unique partnership among consumers, scientists, Members of Congress and the military. You and your Committee have shown great determination and leadership in funding the Department of Defense (DOD) peer-reviewed Breast Cancer Research Program (BCRP) at a level that has brought us closer to eradicating this disease. I am hopeful that you and your Committee will continue that determination and leadership.

I know you recognize the importance of this program to women and their families across the country, to the scientific and health care communities and to the Department of Defense. Much of the progress in the fight against breast cancer has been made possible by the Appropriations Committee's investment in breast cancer research through the DOD BCRP. To support this unprecedented progress moving forward, we ask that you support a separate \$150 million appropriation, level funding, for Fiscal Year (FY) 2011. In order to continue the success of the Program, you must ensure that it maintain its integrity and separate identity, in addition to level funding. This is important not just for

breast cancer, but for all biomedical research that has benefited from this incredible government program.

Vision and Mission

The vision of the Department of Defense Breast Cancer Research Program is to “eradicate breast cancer by funding innovative, high-impact research through a partnership of scientists and consumers.” The meaningful and unprecedented partnership of scientists and consumers has been the foundation of this model program from the very beginning. It is important to understand this collaboration: consumers and scientists working side by side, asking the difficult questions, bringing the vision of the program to life, challenging researchers and the public to do what is needed and then overseeing the process every step of the way to make certain it works. This unique collaboration is successful: every year researchers submit proposals that reach the highest level asked of them by the program and every year we make progress for women and men everywhere.

And it owes its success to the dedication of the U.S. Army and their belief and support of this mission. And of course, to you. It is these integrated efforts that make this program unique.

The Department of the Army must be applauded for overseeing the DOD BCRP which has established itself as a model medical research program, respected throughout the cancer and broader medical community for its innovative, transparent and accountable approach. This program is incredibly streamlined. The flexibility of the program has allowed the Army to administer it with unparalleled efficiency and effectiveness. Because there is little bureaucracy, the program is able to respond quickly to what is currently happening in the research community. Because of its specific focus on breast cancer, it is able to rapidly support innovative proposals that reflect the most recent discoveries in the field. It is responsive, not just to the scientific community, but also to the public. The pioneering research performed through the program and the unique vision it maintains has the potential to benefit not just breast cancer, but all cancers as well as other diseases. Biomedical research is literally being transformed by the DOD BCRP’s success.

Consumer Participation

Advocates bring a necessary perspective to the table, ensuring that the science funded by this program is not only meritorious, but that it is also meaningful and will make a difference in people’s lives. The consumer advocates bring accountability and transparency to the process. They are trained in science and advocacy and work with scientists willing to challenge the status quo to ensure that science funded by the program fill important gaps not already being addressed by other funding agencies. Since 1992, more than 600 breast cancer survivors have served on the BCRP review panels.

Last year, Carolina Hinestrosa, a breast cancer survivor and trained consumer advocate, chaired the Integration Panel and led the charge in challenging BCRP investigators to think outside the box for revelations about how to eradicate breast cancer. Despite the fact that her own disease was progressing, she remained steadfast in working alongside scientists and consumers to move breast cancer research in new directions. Unwilling to give up, she fought tirelessly until the end of her life for a future free of breast cancer.

Carolina died last year from soft tissue sarcoma, a late side effect of the radiation that was used to treat her breast cancer. She once eloquently described the unique structure of the DOD BCRP:

The Breast Cancer Research Program channels powerful synergy from the collaboration of the best and brightest in the scientific world with the primary stakeholder, the consumer, toward bold research efforts aimed at ending breast cancer.

No one was bolder than Carolina, who was fierce and determined in her work on the DOD BCRP and in all aspects of life she led as a dedicated breast cancer advocate, mother to a beautiful daughter, and dear friend to so many. Carolina's legacy reminds us that breast cancer is not just a struggle for scientists; it is a disease of the people. The consumers who sit alongside the scientists at the vision setting, peer review and programmatic review stages of the BCRP are there to ensure that no one forgets the women who have died from this disease, and the daughters they leave behind, and to keep the program focused on its vision.

For many consumers, participation in the program is "life changing" because of their ability to be involved in the process of finding answers to this disease. In the words of one advocate:

Participating in the peer review and programmatic review has been an incredible experience. Working side by side with the scientists, challenging the status quo and sharing excitement about new research ideas...it is a breast cancer survivor's opportunity to make a meaningful difference. I will be forever grateful to the advocates who imagined this novel paradigm for research and continue to develop new approaches to eradicate breast cancer in my granddaughters' lifetime.--Marlene McCarthy, two-time breast cancer "thrifter", Rhode Island Breast Cancer Coalition

Scientists who participate in the Program agree that working with the advocates has changed the way they do science. Let me quote Greg Hannon, the FY10 DOD BCRP Integration Panel Chair:

The most important aspect of being a part of the BCRP, for me, has been the interaction with consumer advocates. They have currently affected the way that I think about breast cancer, but they have also impacted the way that I do science more generally. They are a constant reminder that our goal should be to impact people's lives.--Greg Hannon, PhD, Cold Spring Harbor Laboratory

Unique Structure

The DOD BCRP uses a two-tiered review process for proposal evaluation, with both steps including scientists as well as consumers. The first tier is scientific peer review in which proposals are weighed against established criteria for determining scientific merit. The second tier is programmatic review conducted by the Integration Panel (composed of scientists and consumers) that compares submissions across areas and recommends proposals for funding based on scientific merit, portfolio balance and relevance to program goals.

Scientific reviewers and other professionals participating in both the peer review and the programmatic review process are selected for their subject matter expertise. Consumer participants are recommended by an organization and chosen on the basis of their experience, training and recommendations.

The BCRP has the strictest conflict of interest policy of any research funding program or institute. This policy has served it well through the years. Its method for choosing peer and programmatic review panels has produced a model that has been replicated by funding entities around the world.

It is important to note that the Integration Panel that designs this Program has a strategic plan for how best to spend the funds appropriated. This plan is based on the state of the science – both what scientists and consumers know now and the gaps in our knowledge – as well as the needs of the public. While this plan is mission driven, and helps ensure that the science keeps to that mission of eradicating breast cancer in mind, it does not restrict scientific freedom, creativity or innovation. The Integration Panel carefully allocates these resources, but it does not predetermine the specific research areas to be addressed.

Distinctive Funding Opportunities

The DOD BCRP research portfolio includes many different types of projects, including support for innovative individuals and ideas, impact on translating research from the bench to the bedside, and training of breast cancer researchers.

Innovation

The Innovative Developmental and Exploratory Awards (IDEA) grants of the DOD program have been critical in the effort to respond to new discoveries and to encourage and support innovative, risk-taking research. Concept Awards support funding even earlier in the process of discovery. These grants have been instrumental in the development of promising breast cancer research by allowing scientists to explore beyond the realm of traditional research and unleash incredible new ideas. IDEA and Concept grants are uniquely designed to dramatically advance our knowledge in areas that offer the greatest potential. They are precisely the type of grants that rarely receive funding through more traditional programs such as the National Institutes of Health and private research programs. They therefore complement, and do not duplicate, other federal funding programs. This is true of other DOD award mechanisms also.

Innovator awards invest in world renowned, outstanding individuals rather than projects, by providing funding and freedom to pursue highly creative, potentially groundbreaking research that could ultimately accelerate the eradication of breast cancer. For example, in FY08, Dr. Mauro Ferrari of the University of Texas Health Science Center at Houston was granted an Innovator Award to develop novel vectors for the optimal delivery of individualized breast cancer treatments. This is promising based on the astounding variability in breast cancer tumors and the challenges presented in determining which treatments will be most effective and how to deliver those treatments to each individual patient. In FY06, Dr. Gertraud Maskarinec of the University of Hawaii received a synergistic IDEA Award to study effectiveness of the Dual Energy X-Ray Absorptiometry (DXA) as a method to evaluate breast cancer risks in women and young girls.

The Era of Hope Scholar Award supports the formation of the next generation of leaders in breast cancer research, by identifying the best and brightest scientists early in their careers and giving them the necessary resources to pursue a highly innovative vision of ending breast cancer. Dr. Shiladitya Sengupta from Brigham and Women's Hospital, Harvard Medical School, received a FY06 Era of Hope Scholar Award to explore new strategies in the treatment of breast cancer that target both the tumor and the supporting network surrounding it. In FY07, Dr. Gene Bidwell of the University of Mississippi Medical Center received an Era of Hope Postdoctoral Award to study thermally targeted delivery of inhibitor peptides, which is an underdeveloped strategy for cancer therapy.

One of the most promising outcomes of research funded by the DOD BCRP was the development of the first monoclonal antibody targeted therapy that prolongs the lives of women with a particularly aggressive type of advanced breast cancer. Researchers found that over-expression of HER-2/neu in breast cancer cells results in very aggressive biologic behavior. The same researchers demonstrated that an antibody directed against HER-2/neu could slow the growth of the cancer cells that over-expressed the gene. This research, which led to the development of the targeted therapy, was made possible in part by a DOD BCRP-funded infrastructure grant. Other researchers funded by the DOD BCRP are identifying similar targets that are involved in the initiation and progression of cancer.

These are just a few examples of innovative funding opportunities at the DOD BCRP that are filling gaps in breast cancer research.

Translational Research

The DOD BCRP also focuses on moving research from the bench to the bedside. DOD BCRP awards are designed to fill niches that are not addressed by other federal agencies. The BCRP considers translational research to be the process by which the application of well-founded laboratory or other pre-clinical insight result in a clinical trial. To enhance this critical area of research, several research opportunities have been offered. Clinical Translational Research Awards have been awarded for investigator-initiated projects that involve a clinical trial within the lifetime of the award. The BCRP has expanded its emphasis on translational research by also offering five different types of awards that support work at the critical juncture between laboratory research and bedside applications.

The Multi Team Award mechanism brings together the world's most highly qualified individuals and institutions to address a major overarching question in breast cancer research that could make a significant contribution towards the eradication of breast cancer. Many of these Teams are working on questions that will translate into direct clinical applications. These Teams include the expertise of basic, epidemiology and clinical researchers, as well as consumer advocates.

Training

The DOD BCRP is also cognizant of the need to invest in tomorrow's breast cancer researchers. Dr. J. Chuck Harrell, Ph.D. at the University of Colorado, Denver and the University of North Carolina at Chapel Hill, for example, received a Predoctoral Traineeship Award to investigate hormonal regulation of lymph node metastasis, the majority of which retain estrogen receptors (ER) and/or progesterone receptors. Through his research, Dr. Harrell determined that lymph node microenvironment alters ER expression and function in the lymph nodes, effecting tumor growth. These findings led Dr. Harrell to

conduct further research in the field of breast metastasis during his postdoctoral work. Jim Hongjun of the Battelle Memorial Institute received a postdoctoral award for the early detection of breast cancer using post-translationally modified biomarkers.

Dr. John Niederhuber, now the Director of the National Cancer Institute (NCI), said the following about the Program when he was Director of the University of Wisconsin Comprehensive Cancer Center in April, 1999:

Research projects at our institution funded by the Department of Defense are searching for new knowledge in many different fields including: identification of risk factors, investigating new therapies and their mechanism of action, developing new imaging techniques and the development of new models to study [breast cancer] ...Continued availability of this money is critical for continued progress in the nation's battle against this deadly disease.

Scientists and consumers agree that it is vital that these grants continue to support breast cancer research. To sustain the Program's momentum, \$150 million for peer-reviewed research is needed in FY11.

Outcomes and Reviews of the DOD BCRP

The outcomes of the BCRP-funded research can be gauged, in part, by the number of publications, abstracts/presentations, and patents/licensures reported by awardees. To date, there have been more than 12,241 publications in scientific journals, more than 12,000 abstracts and nearly 550 patents/licensure applications. The American public can truly be proud of its investment in the DOD BCRP. Scientific achievements that are the direct result of the DOD BCRP grants are undoubtedly moving us closer to eradicating breast cancer.

The success of the DOD peer-reviewed Breast Cancer Research Program has been illustrated by several unique assessments of the Program. The IOM, which originally recommended the structure for the Program, independently re-examined the Program in a report published in 1997. They published another report on the Program in 2004. Their findings overwhelmingly encouraged the continuation of the Program and offered guidance for program implementation improvements.

The 1997 IOM review of the DOD peer-reviewed Breast Cancer Research Program commended the Program, stating, "the Program fills a unique niche among public and private funding sources for cancer research. It is not duplicative of other programs and is a promising vehicle for forging new ideas and scientific breakthroughs in the nation's fight against breast cancer." The 2004 report spoke to the importance of the program and the need for its continuation.

The DOD peer-reviewed Breast Cancer Research Program not only provides a funding mechanism for high-risk, high-return research, but also reports the results of this research to the American people every two to three years at a public meeting called the Era of Hope. The 1997 meeting was the first time a federally-funded program reported back to the public in detail not only on the funds used, but also on the research undertaken, the knowledge gained from that research and future directions to be pursued.

Sixteen hundred consumers and researchers met for the fifth Era of Hope meeting in June, 2008. As MSNBC.com's Bob Bazell wrote, this meeting "brought together many of the most committed breast cancer activists with some of the nation's top cancer scientists. The conference's directive is to push researchers to think 'out of the box' for potential treatments, methods of detection and prevention..." He went on to say "the program...has racked up some impressive accomplishments in high-risk research projects..."

One of the topics reported on at the meeting was the development of more effective breast imaging methods. An example of the important work that is coming out of the DOD BCRP includes a new screening method, molecular breast imaging, which helps detect breast cancer in women with dense breasts – which can be difficult using a mammogram alone. I invite you to log on to NBCC's website <http://influence.stopbreastcancer.org/> to learn more about the exciting research reported at the 2008 Era of Hope. The next Era of Hope meeting is being planned for 2011.

The DOD peer-reviewed Breast Cancer Research Program has attracted scientists across a broad spectrum of disciplines, launched new mechanisms for research and facilitated new thinking in breast cancer research and research in general. A report on all research that has been funded through the DOD BCRP is available to the public. Individuals can go to the Department of Defense website and look at the abstracts for each proposal at <http://cdmrp.army.mil/bcrp/>.

Commitment of the National Breast Cancer Coalition

The National Breast Cancer Coalition is strongly committed to the DOD BCRP in every aspect, as we truly believe it is one of our best chances for finding causes of, cures for, and ways to prevent breast cancer. The Coalition and its members are dedicated to working with you to ensure the continuation of funding for this Program at a level that allows this research to forge ahead. From 1992, with the launch of our "300 Million More Campaign" that formed the basis of this Program, until now, NBCC advocates have appreciated your support.

Over the years, our members have shown their continuing support for this Program through petition campaigns, collecting more than 2.6 million signatures, and through their advocacy on an almost daily basis around the country asking for support of the DOD BCRP.

Consumer advocates have worked hard over the years to keep this program free of political influence. Often, specific institutions or disgruntled scientists try to change the program through legislation, pushing for funding for their specific research or institution, or try to change the program in other ways, because they did not receive funding through the process, one that is fair, transparent and successful. The DOD BCRP has been successful for so many years because of the experience and expertise of consumer involvement, and because of the unique peer review and programmatic structure of the program. We urge this Committee to protect the integrity of the important model this program has become.

There are three million women living with breast cancer in this country today. This year, more than 40,000 will die of the disease and more than 240,000 will be diagnosed. We still do not know how to

prevent breast cancer, how to diagnose it in a way to make a real difference or how to cure it. It is an incredibly complex disease. We simply cannot afford to walk away from this program.

Since the very beginning of this Program in 1992, Congress has stood with us in support of this important approach in the fight against breast cancer. In the years since, Chairman Inouye and Ranking Member Cochran, you and this entire Committee have been leaders in the effort to continue this innovative investment in breast cancer research.

NBCC asks you, the Defense Appropriations Subcommittee, to recognize the importance of what has been initiated by the Appropriations Committee. You have set in motion an innovative and highly efficient approach to fighting the breast cancer epidemic. We ask you now to continue your leadership and fund the Program at \$150 million and maintain its integrity. This is research that will help us win this very real and devastating war against a cruel enemy.

Thank you again for the opportunity to submit testimony and for giving hope to all women and their families, and especially to the 3 million women in the United States living with breast cancer and all those who share in the mission to end breast cancer.