NATIONAL BREAST CANCER COALITION

2024 Legislative and Public Policy Priorities

Legislative Priorities

PRIORITY #1

$150 Million/Level Funding for the Department of Defense (DOD) Breast Cancer Research Program (BCRP) for FY2025: As a result of NBCC's grassroots advocacy, the DOD BCRP was created in 1992 to end breast cancer for service members, veterans, and the general public by funding innovative, high-impact research through a partnership of scientists and consumers. The DOD BCRP is widely viewed as an innovative, unique, and efficient medical research model that has proven to be accountable to the public and has produced extraordinary results. NBCC seeks continued level funding.

PRIORITY #2

Metastatic Breast Cancer Access to Care Act (H.R. 549/S.663): This legislation would waive the 24-month waiting period for Medicare and the 5-month waiting period for Social Security Disability Insurance benefits for eligible individuals with Metastatic Breast Cancer.

PRIORITY #3

Preservation of the Medicaid Breast and Cervical Cancer Treatment Program: Congress enacted the Breast and Cervical Cancer Treatment Act in 2000 after years of NBCC grassroots lobbying and influence. NBCC remains committed to ensuring all women and men screened and diagnosed with breast cancer have access to the treatment they need.

Public Policy Priorities

PRIORITY #1

Guaranteed Access to Quality Care for All: Ensuring access to quality evidence-based health care has been a top priority of NBCC for many years. NBCC supports health care access initiatives that expand access to Medicare while offering a private insurance option, automatically enrolling individuals who do not have access to other coverage and providing guaranteed benefits, including primary and preventive care, hospital services, and prescription drug coverage. NBCC believes that there must be shared financial responsibility and that no individual should be denied coverage due to an inability to pay.

PRIORITY #2

Access to Affordable and Effective Therapies: NBCC supports policies that address systemic deficiencies in the law, regulation, and science policy that result in the approval of drugs that do not significantly extend or save lives and whose prices are not based on value or effectiveness.

PRIORITY #3

Food & Drug Administration (FDA) Reform: NBCC supports a drug approval system that prioritizes approving drugs with clinically meaningful benefits for patients. NBCC seeks to address systemic deficiencies in FDA regulation and the drug development process, including reforms to the accelerated approval pathway and the use of unvalidated surrogate endpoints.

PRIORITY #4

Ensure the Participation of Educated Patient Advocates in Science Research and All Levels of Health Care Decision-Making: NBCC continues to work to ensure that educated patient advocates who are trained and represent a constituency have a meaningful seat at the table in all levels of health care decision-making that affects their lives.

NATIONAL BREAST CANCER COALITION

$150 Million for the Department of Defense (DOD) Peer-Reviewed Breast Cancer Research Program (BCRP) for FY2025

Background

The DOD BCRP was created in 1992 as a result of the National Breast Cancer Coalition's "$300 Million More" campaign to increase federal funding for breast cancer research. Due to NBCC's efforts and the congressional leadership of Senators Tom Harkin (D-IA) and Alfonse D'Amato (R-NY) in FY1993, Congress appropriated $210 million in the DOD research and development budget for a breast cancer peer-reviewed research program administered by the Department of the Army. As a result of NBCC's grassroots advocacy and the DOD BCRP's demonstrated success, Congress has appropriated funding for it each year since.

A Model Medical Research Program

Since its inception, the DOD BCRP has sought to "eradicate breast cancer by funding innovative, high-impact research through a partnership of scientists and consumers." It has grown from a small research program to a far-reaching, influential model that others have sought to replicate throughout the cancer and broader medical research community.

Some keys to the DOD BCRP's success:

- **It is innovative and unique.** The DOD BCRP has a unique grant structure that allows it to be more flexible than other traditional competitive, peer-reviewed medical research programs. This structure can fund innovative, high-risk, high-return research and quickly respond to current scientific advances. The DOD BCRP can also fill gaps by focusing on promising but otherwise underfunded research areas. In its reviews of the DOD BCRP, the Institute of Medicine has stated "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 good vehicle for forging new ideas and scientific breakthroughs in the nation's fight against breast cancer."
- **It is efficient.** Due to the program's flexibility, the Army can administer it with unparalleled efficiency and little bureaucracy. The program allows approximately 90% of the appropriated funding to go directly to competitive, peer-reviewed research grants awarded to the best science.
- **It is accountable to the public and transparent.** Information on all funded grants is posted on the program website, accessible to the public. In addition, educated, trained consumer advocates participate in a two-tiered process where research proposals are reviewed for scientific quality and programmatic relevance. This consumer involvement allows grant funding decisions to be informed by trained breast cancer survivors and based on patient and medical communities' concerns and needs. It provides for those who have no agenda other than to end breast cancer for everyone. This transparency allows scientists, consumers, and the public to view the progress made in breast cancer research through the DOD BCRP.
- **It has produced extraordinary results.** From new methods of extracting breast cancer cells at their earliest stages to unprecedented research into gene/environment interaction to quality-of-life issues, the DOD BCRP leads the way in generating new approaches to breast cancer prevention and treatment. It has produced fascinating insights into the biology of breast cancer. It has directly impacted lives through the research it has funded, such as the revolutionary work that led to the development of the innovative drug Herceptin.

The DOD BCRP owes its success to the integrated efforts of its partners—from the ongoing dedication of the US Army and their belief and support of this mission, to the members of Congress who support the program through continued funding, to the scientists and consumers who participate, and to the researchers who every year submit proposals that reach the highest level asked of them by the program.

NATIONAL BREAST CANCER COALITION

Metastatic Breast Cancer Access to Care Act, 118th Congress (H.R. 549, S. 663)

Legislation to waive the 24-month waiting period for Medicare and the 5-month waiting period for Social Security Disability Insurance benefits for eligible individuals with metastatic breast cancer.

Background

Metastatic breast cancer is cancer that has spread from the breast to the bones, lungs, or other distant parts of the body. Unfortunately, 90% of breast cancer deaths are a result of metastatic disease. There are treatments, some of which have extended survival for women and men with metastatic breast cancer, but today, there is no cure.

Individuals diagnosed with metastatic breast cancer automatically qualify for disability benefits from the Social Security Administration (SSA) and for Medicare coverage regardless of age, as long as they apply and meet the SSA's technical qualification rules. An individual must have been employed within the last 10 years and currently unable to work due to their disability to earn Social Security disability insurance benefits (SSDI). Once an individual is approved for SSDI, there is a 5-month waiting period to begin receiving benefits and a 24-month waiting period for Medicare coverage.

Federal Precedent for Extended Coverage

Applying waiting periods to individuals with a lethal disease like metastatic breast cancer is arbitrary and cruel. The National Breast Cancer Coalition urges Congress to enact legislation to amend the Social Security Act to eliminate waiting periods for disability insurance benefits and Medicare coverage for eligible individuals with metastatic breast cancer.

In 2001, Congress passed a bill to add Amyotrophic Lateral Sclerosis (ALS) as a qualifying condition for automatic Medicare coverage and, in 2020, waived the 5-month waiting period for SSDI for individuals with ALS, thus creating a federal precedent. Based on the limited life expectancy of individuals with metastatic disease—an average of 3 years—NBCC believes that both automatic SSDI and Medicare coverage should also apply to metastatic breast cancer patients who qualify.

Action Requested

NBCC urges Congress to enact legislation to amend the Social Security Act to waive all waiting periods for Medicare and SSDI for eligible individuals with metastatic breast cancer.

Congress of the United States

Washington, DC 20515

April 8, 2024

The Honorable Ken Calvert
Chair
Subcommittee on Defense
House Appropriations Committee
H-405, the Capitol
Washington, D.C. 20515

The Honorable Betty McCollum
Ranking Member
Subcommittee on Defense
House Appropriations Committee
1036 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Calvert and Ranking Member McCollum:

In 2024, an estimated 310,720 new cases of invasive breast cancer will be diagnosed in women, 2,790 cases diagnosed in men, and an additional 56, 500 cases of ductal carcinoma in situ (DCIS) will be diagnosed in women. Breast cancer is the second leading cause of cancer death for women in the United States after lung cancer. This year, an estimated 42,450 women and 530 men will die of breast cancer. Female active-duty Service members have a 20-40% higher incidence rate of breast cancer than the general public. The incident rate of breast cancer for active-duty women is seven times higher than the average incident rate of fifteen other cancer types across all Service Members. While there has been incremental progress towards ending this disease, much work remains. As a nation, we must continue to commit to changing these statistics.

Fortunately, thanks to your leadership and support, as well as that of the DOD Subcommittee and the entire Appropriations Committee, the Department of Defense (DOD) Peer Reviewed Breast Cancer Research Program has led the way in the fight against breast cancer since 1992. **We ask that you support robust funding for the program in FY2025 to continue this progress.**

As you know, the DOD Peer Reviewed BCRP plays a leading role in the fight against breast cancer through its innovative approaches and focus on research that will end the disease. The mission of the DOD BCRP is a world without breast cancer. The program's vision is to end breast cancer for Service Members, Veterans, and all individuals 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. The BCRP challenges scientists to pursue high-risk, high-reward research, explore new paradigms that could lead to critical discoveries, and make an unprecedented impact on breast cancer. The BCRP also promotes synergistic collaborations across disciplines. This unique collaboration is successful: researchers submit proposals that reach the highest level asked for by the program every year.

The DOD BCRP is a model medical research program respected throughout cancer and the broader medical community for its innovative, transparent, and accountable approach. It is incredibly streamlined and efficient, a flexibility that allows the Army to administer it with unparalleled effectiveness. The program's specific focus on breast cancer will enable it 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 revolutionary research performed through the program and the unique vision it maintains can benefit not just breast cancer but all cancers and other diseases. The DOD BCRP has and continues to transform biomedical research.

We ask that you recognize the importance of what has been initiated by the Appropriations Committee. You have set in motion an innovative and highly efficient approach to the fight against breast cancer. Please continue supporting and investing in the DOD Peer Reviewed BCRP and include robust funding in the

Department of Defense Appropriations bill for FY2025. This research will help us win this very real and devastating war against a cruel disease.

Sincerely,

[[SIGNATURES]]

United States Senate

WASHINGTON, DC 20510

[[DATE]]

The Honorable Jon Tester
Chair
Appropriations Subcommittee on Defense
United States Senate
Washington, DC 20510

The Honorable Susan Collins
Ranking Member
Appropriations Subcommittee on Defense
United States Senate
Washington, DC 20510

Dear Chair Tester and Ranking Member Collins:

In 2024, there will be an estimated 310,720 new cases of invasive breast cancer diagnosed in women, 2,790 cases diagnosed in men, and an additional 56,500 cases of ductal carcinoma in situ (DCIS) diagnosed in women.

Breast cancer is the second leading cause of cancer death for women in the United States after lung cancer. It is estimated that this year, 42,250 women and 530 men will die of breast cancer. Female active-duty Service members have a 20-40% higher incidence rate of breast cancer than the public. The incident rate of breast cancer for active-duty women is seven times higher than the average incident rate of fifteen other cancer types across all Service Members.

While some progress has been made to end this disease, much work remains to be done. As a nation, we must continue to show a commitment to changing these statistics. Fortunately, thanks to your leadership and support, as well as that of the DOD Subcommittee and the entire Appropriations Committee, the Department of Defense (DOD) Peer Reviewed Breast Cancer Research Program has led the way in the fight against breast cancer since 1992.

To continue this progress moving forward, we ask that you support robust funding for the program in FY2025. As you are aware, the DOD Peer Reviewed BCRP plays a leading role in the fight against breast cancer through its innovative approaches and focus on research that will end the disease. The mission of the DOD BCRP is a world without breast cancer. The program's vision is to end breast cancer for Service Members, Veterans, and all individuals by funding innovative, high-impact research through a partnership of scientists and consumers.

The BCRP challenges scientists to pursue high-risk, high-reward research, explore new paradigms that could lead to critical discoveries, and make an unprecedented impact on breast cancer. The BCRP also promotes synergistic collaborations across disciplines. The meaningful and unprecedented partnership of scientists and consumers has been the foundation of this model program from the very beginning.

This unique collaboration is successful: every year, researchers submit proposals that reach the highest level asked for them by the program. The DOD BCRP is a model medial research program, respected throughout the cancer and broader medical community for its innovative, transparent, and accountable approach. It is incredibly streamlined and efficient, with a flexibility that allows the Army to administer it with unparalleled effectiveness.

The program's specific focus on breast cancer allows it 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 revolutionary research performed through the program and the unique vision it maintains can benefit not just breast cancer but all cancers and other diseases.

The DOD BCRP has and continues to transform biomedical research. We ask that you recognize the importance of what has been initiated by the Appropriations Committee. You have set in motion an innovative and highly efficient approach to the fight against breast cancer. Please continue supporting and investing in the DOD Peer Reviewed BCRP and include robust funding in the Department of Defense Appropriations bill for FY2025. This is research that will help us win this very real and devastating war against a cruel disease. Thank you for your consideration of this request.

[[CLOSING]]

[[SIGNATURES]]

NATIONAL BREAST CANCER COALITION

Ensuring the Participation of Educated Patient Advocates in Science Research and All Levels of Health Care Decision-Making

Background

The voice of educated patient advocates must be part of all levels of health care decision-making that affects their lives. Patient participation has been a tenet of the National Breast Cancer Coalition (NBCC) since its inception. NBCC continues to ensure that educated patient advocates who represent a constituency have a meaningful seat at the table in all levels of health care decision-making that affects their lives.

Why Patient Advocates are Necessary

Educated patient advocates provide a unique perspective that others cannot offer. They are the ones who ultimately receive health care services and, along with their families, are required to navigate the complexities of the health insurance and health care delivery systems. They have no agenda in the scientific community other than looking for the best science and saving lives; they have no conflict of interest. Their perspective cannot be duplicated by the doctors who care for them or the scientists searching for answers, even if these doctors and scientists are patients.

A lay advocate perspective is key to moving forward to the end of breast cancer.

Criteria for Patient Advocates

Patient advocates must:

- Have a patient-led, patient-centered organization with a patient constituency to which they are responsible and accountable;
- Have been personally affected by the disease; and
- Be knowledgeable, trained, prepared, and confident in their ability to participate in the decision-making process of science and medicine.

NATIONAL BREAST CANCER COALITION

Prescription Drug Pricing Should Be Based on Value

Background

The National Breast Cancer Coalition's mission is to end breast cancer. We cannot achieve that mission until all individuals with and at risk of breast cancer have access to the quality health care they need. Access requires a system that facilitates affordable and effective treatments. One step to achieve that goal is to make certain that breast cancer drug pricing is based on value.

The cost of breast cancer care continues to rise. **Overall, the national cost of cancer care in 2015 was $183 billion, with a minimum projected increase of 34 percent to $246 billion by 2030** based solely on the aging and growth of the US population.[1]

On top of that are anticipated increases in **national costs for medical services and prescription drugs, which are predicted to increase during this period by 34 percent and 40 percent**, respectively.

Patients make critical contributions to the discovery of new drugs through their participation in clinical trials and lobbying for research funding, in addition to paying taxes to support federally funded research. Federal agencies spent $243 billion in taxpayer dollars in 2018 on medical and health research and development, much of it on competitive grants given for early-stage research. Findings from federally funded research are the basis for the product development work done by private pharmaceutical companies. US tax dollars, allocated through National Institutes of Health (NIH) grants, were used to discover every pharmaceutical product approved by the Food & Drug Association from 2000 to 2016.[2]

In addition to funding scientific findings via grants, the federal government encourages drug development by providing tax incentives. Drugmakers may write off some of the amount they spend each year on research and development using one or a combination of tax incentives.

Patients are then rewarded with drugs that create both financial and health toxicities. And despite the increasing cost of prescription drugs, most approved breast cancer drugs have not been shown to extend life.

The national goal should be to bring about drugs that save lives. Yet the priorities in the existing system are to protect proprietary interests and maximize profits. For example, patent laws were created to incent discovery and reward inventors, but today's patent system benefits institutions and industry at the expense of patients and the health care system.

Countries such as Britain and Germany have taken extensive steps to introduce cost-effectiveness assessments into their healthcare systems, refusing to pay higher prices for new drugs that do not improve treatment effectiveness over existing options.

NBCC urges Congress and the administration to support initiatives that address systemic deficiencies in law, regulation, and science policy that result in the approval of drugs that do not significantly extend or save lives and whose prices are not based on value or effectiveness.

[1] Mariotto et al. Projections of the Cost of Cancer Care in the United States
[2] Ledley, Cleary, Jackson: "US Tax Dollars Funded Every New Pharmaceutical in the Last Decade," Institute for New Economic Thinking, September 2020

NATIONAL BREAST CANCER COALITION

Preservation of the Medicaid Breast and Cervical Cancer Treatment Program

Background

After years of NBCC grassroots lobbying and influence, Congress enacted the Breast and Cervical Cancer Treatment Act (P.L. 706-354) in 2000. This law expanded access to health care for thousands of underserved women. The Act authorized enhanced matching funds to states to provide Medicaid coverage to uninsured or underinsured women diagnosed with breast or cervical cancer through a federal screening program. All 50 states, the District of Columbia, 5 US territories, and 72 American Indian/Alaska Native tribal organizations opted into the Breast and Cervical Cancer Treatment Program (BCCTP). **NBCC remains vigilant in ensuring that the program endures and that eligible individuals continue to receive the lifesaving screening and treatment they deserve.**

Importance of Maintaining the BCCTP

Before the BCCTP, women diagnosed through the federal Centers for Disease Control and Prevention (CDC) screening program—ineligible for Medicaid coverage yet unable to afford insurance on their own—were falling through the cracks. Following diagnosis, the legacy system left them to rely on an unreliable system of dwindling charity care. NBCC recognized this system's injustice and continues to believe that a federally funded program to screen and diagnose women with breast cancer must include a treatment component.

Since 1991, National Breast and Cervical Cancer Early Detection Program (NBCCEDP) funded programs served more than 5.8 million women. The program provided more than 15.1 million breast and cervical cancer screening examinations and diagnosed 71,107 invasive breast cancers and 4,863 cervical cancers.

In May 2009, the Government Accountability Office (GAO) published a report looking at the status of the Breast and Cervical Cancer Treatment Act, "Source of Screening Affects Women's Eligibility for Coverage of Breast and Cervical Cancer Treatment in Some States." The report identified the screening source requirements as a barrier to women's eligibility for treatment in some states. A follow-up report was published in October 2020, "Federal Programs Provide Screening and Treatment for Breast and Cervical Cancer." GAO analysis of CDC data showed that as a result of Medicaid expansions enacted through the Affordable Care Act (ACA), some low-income women had additional resources for screening and treatment beyond the NBCCEDP, accounting for the reduction in the number of women screened through the program from 2011 through 2017. Additional barriers listed in the 2020 report, like the 2009 report, included certain requirements to qualify for the program.

Under the BCCTP, states must extend Medicaid eligibility to women or men whose screening or diagnostic services were paid specifically with CDC funds. States can be more generous in expanding Medicaid coverage under the BCCTP but cannot fall below this minimum standard. While implementing health care reform through the ACA increased access to breast and cervical cancer screening for low-income, underserved women, efforts to cut expanded insurance coverage and eliminate cost-sharing threaten their access to screening and treatment.

Even with adequate health insurance, many people still face significant obstacles to obtaining breast and cervical cancer screening and treatment due to geographic isolation, limited health literacy or self-efficacy, inconvenient times to access services, and language barriers.

We must not move backward in our progress, even in the face of budget challenges. We must critically examine the impact of any changes to Medicaid, Medicare, or other existing laws based on the effect these changes will have on overall access to quality care.

NBCC remains committed to ensuring all women and men diagnosed with breast cancer have access to the treatment they need.

2001 L Street, NW | Suite 500 PMB #50111 | Washington, DC 20036 | P 202.296.7477 | F 202.314.3458 | www.stopbreastcancer.org