NATIONAL BREAST CANCER COALITION

Public Policy

2021 Legislative and Public Policy Priorities

Legislative Priorities

PRIORITY#1:

$150 Million for the Department of Defense (DOD) Breast Cancer Research Program (BCRP) for FY2022: As a result of NBCC's grassroots advocacy, the DOD BCRP was created in 1992 to eradicate breast cancer 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 which 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: A bill to waive the 24-month waiting period for Medicare and the five-month waiting period for Social Security Disability Insurance benefits for eligible individuals with Metastatic Breast Cancer. This legislation would waive all waiting periods for Medicare and Social Security Disability Insurance (SSDI) benefits based on disability for 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 also offering a private insurance option, automatically enroll individuals who do not have access to other coverage, and provide 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:

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 represent a constituency have a meaningful seat at the table in all levels of health care decision making, which affects their lives.

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 disease; and
- Be knowledgeable, trained, prepared and confident in their ability to participate in the decision-making process of science and medicine.

Priority #1: $150 million for the Department of Defense (DOD) Peer-Reviewed Breast Cancer Research Program (BCRP) for FY 2022

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 "accelerate high-impact research with clinical relevance, encourage innovation and stimulate creativity, and facilitate productive collaborations." It has grown from a small research program to a far-reaching, influential model that others throughout the cancer and broader medical research community have sought to replicate. Some of the keys to the DOD BCRP's success are:

- 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 areas of research. 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 both the 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 developing the innovative drug Herceptin.

The DOD BCRP also owes its success to the integrated efforts of its partners – from the ongoing dedication of the U.S. 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.

Metastatic Breast Cancer Access to Care: Passage of 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

Individuals diagnosed with metastatic breast cancer automatically qualify for disability benefits from the Social Security Administration (SSA) as long as they apply and meet the SSA’s technical qualification rules. An individual must have been employed within the last ten years and currently be unable to work due to her or his disability in order to earn Social Security disability insurance benefits (SSDI). Once an individual is approved for SSDI, there is a five-month waiting period to begin receiving benefits. Following approval of SSDI, individuals with metastatic breast cancer are eligible for Medicare coverage based on their disability. There is also a waiting period for Medicare coverage, once someone is deemed eligible

Eligibility for Medicare includes individuals over the age of 65, those with disabilities, and those with two specific diseases, End-Stage Renal Disease or Amyotrophic Lateral Sclerosis (ALS). Individuals under age 65 with disabilities other than ESRD or ALS must have received Social Security Disability Insurance (SSDI) benefits for 24 months before gaining Medicare eligibility. These eligibility rules include individuals diagnosed with metastatic breast cancer.

Metastatic breast cancer is cancer that has spread from the breast to the bones, lungs or other distant parts of the body. 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. There is no cure.

Federal Precedent for Extended Coverage

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 five-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.

Legislative Priority #3: 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. 106-354) 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 U.S. territories, and 12 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 women 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, the 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, GAO published a report looking at the status of the Breast and Cervical Cancer Treatment Act entitled, "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 though the Affordable Care Act, 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. There were additional barriers listed in the 2020 report like the 2009 report including 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 Affordable Care Act 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 women will 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.**

Guaranteed Access to Quality Care for All

Background

Ensuring access to quality health care is an urgent and longstanding priority for the National Breast Cancer Coalition (NBCC) and an essential component of our mission to end breast cancer. NBCC's grassroots Board of Directors approved a *Framework for a Health Care System Guaranteeing Access to Quality Health Care for All* and works to identify, advocate for, and support implementing laws such as the "Affordable Care Act," marked critical steps toward access to quality health care. Also, NBCC remains committed to protecting vital existing programs such as the Breast and Cervical Cancer Treatment Program (BCCTP).

History of NBCC's Efforts to Expand Access to Quality Care

NBCC has succeeded in making targeted changes to expand access to health care. After years of NBCC grassroots lobbying and influence, Congress enacted the "Breast and Cervical Cancer Treatment Act" (P.L. 106-354) in 2000. The Act authorized enhanced matching funds to states to provide Medicaid coverage to uninsured or underinsured women and men diagnosed with breast or cervical cancer through a federal screening program. Before this Act, women, and men could be denied treatment due to inability to pay, preexisting conditions, or because they exceeded their lifetime health insurance caps. The passage of this law expanded access to health care for thousands of underserved women and men. The Act is an opt-in program for all 50 states, the District of Columbia, five U.S. territories, and 12 American Indian/Alaska Native tribal organizations.

In 2010, NBCC endorsed and advocated for the passage of the "Affordable Care Act" (ACA). This landmark legislation marked critical steps forward in providing access to quality health care for individuals with and at risk of breast cancer. NBCC continues to support the implementation and expansion of the Act. The ACA provides breast cancer survivors and other vital protections from many of the health care system's past practices, including eliminating lifetime insurance caps and restrictions for women and men with preexisting conditions. As a result of NBCC's advocacy, the ACA requires consumer representation on any committees, boards, panels, or commissions formed under the law. Also, insurance companies must cover the routine patient care costs for clinical trial participation and cannot discriminate against an individual based on their involvement in a clinical trial. The law brings the country closer to comprehensive health care reform that will help the millions of individuals with and at risk of breast cancer.

In addition to safeguarding the Affordable Care Act, NBCC looks forward to working with Congress and the Administration to enact a law(s) that would expand access to Medicare while also offering a private insurance option, automatically enrolling individuals who are not enrolled in other coverage and providing guaranteed benefits including:

- Primary and preventative care
- Hospital services, including emergency services
- Prescription drugs and medical devices
- Maternity, newborn, and reproductive care
- Mental health and substance abuse disorder services
- Habilitative and rehabilitative services
- Dental, vision, and hearing

Any initiative that NBCC supports would also establish a financing mechanism including shared financial responsibility, and where no one can be denied coverage due to an inability to pay.

Public Policy Priority #3: 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.

The cost of breast cancer care continues to rise. Overall, the national cost of cancer care overall 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 U.S. population.[1] This increase does not include 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. Despite the increasing cost of prescription drugs, most approved breast cancer drugs have not been shown to extend life.

Federal agencies spent $243 billion 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. U.S. tax dollars, allocated through NIH grants, were used to discover every pharmaceutical product approved by the FDA from 2000 to 2016. 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.

As patients, we contribute to research by participating in clinical trials, lobbying for research funding, and paying taxes to support it. Our goal is to bring about drugs that will save lives. The research results are often patented, then sold to industry for millions of dollars—the individual doctor and the institution benefit and the companies that manufacture the drugs. But in breast cancer, these drugs rarely extend life and cost so much that they often bankrupt patients and the healthcare system.

Countries like 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. U.S. taxpayers contribute through public university research, grants, subsidies, and other incentives. This means people are often paying twice for their medicines: through their tax dollars and at the pharmacy. It should be

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[1] Mariotto et al. Projections of the Cost of Cancer Care in the United States

unacceptable for taxpayers to find a new medication that the public can't even afford to buy once it hits the market.

Recent reports show that conflicts abound in the research system that currently exists. Moreover, due to the focus on financial gain, patients and the public have lost trust in this system. Passage of legislation to 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 is an essential step towards making healthcare more accessible and saving lives.

Public Policy Priority #3: 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 which affects their lives. Patient participation has been a tenet of the National Breast Cancer Coalition (NBCC) since its inception. NBCC continues to work 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 which 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 healthcare 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.