NATIONAL BREAST CANCER COALITION

Public Policy

2023 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 FY2024: 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 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 (H.R. 549) This legislation would 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.

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 healthcare 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:
Federal Drug Administration 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, which affects their lives.

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NATIONAL BREAST CANCER COALITION

Public Policy

$150 million for the Department of Defense (DOD) Peer-Reviewed Breast Cancer Research Program (BCRP) for FY 2024

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 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 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 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.

House FY24 DOD Breast Cancer Research Program (BCRP) Dear Colleague Letter

Support FY2024 DOD Peer Reviewed Breast Cancer Research Program (BCRP) Appropriations

Dear Colleague:

In 2024, an estimated 297,790 new cases of invasive breast cancer will be diagnosed in women, 2,800 cases diagnosed in men, and an additional 55,720 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. It is estimated that this year, 43,250 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 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 some progress has been made to end this disease, much work remains. As a nation, we must continue to commit to changing these statistics. The Department of Defense Peer Reviewed Breast Cancer Research Program (DOD BCRP) is a critical tool in this effort.

Since its inception, the DOD BCRP has established itself as an innovative, competitive, and accountable medical research program. The groundbreaking science performed through the program is changing the face of biomedical research. The BCRP is streamlined and efficient.

A recent GAO report on the program found that Program "obligated nearly 100 percent of its CDMRP appropriations, prioritizes and assesses biomedical research investments through effective program and project management, and coordinates with NIH and VA for research program planning and project selection and leverages shared data to identify potential overlap." (https://cdmrp.army.mil/pubs/press/2022/CDMRP_gao.aspx)

The program can quickly respond to current scientific advances and fill gaps by focusing on traditionally underfunded research. It involves consumer advocates in all aspects of the process - both the peer review and programmatic review levels - which allows for funding decisions based on the concerns and needs of patients and the medical community.

Last year, nearly 200 U.S. Representatives supported our bipartisan effort to continue funding this worthy program. This year, we again ask that you sign the letter to the Defense Appropriations Subcommittee supporting robust funding for FY2024.

Please contact Niko Keddy (Niko.Keddy@mail.house.gov) in Congressman Garbarino's office or Julie Jochem (Julie.Jochem@mail.house.gov) in Congresswoman Sherrill's office with any questions.

Sincerely,

Andrew R. Garbarino
Member of Congress

Mikie Sherrill
Member of Congress

Vern Buchanan
Member of Congress

James P. McGovern
Member of Congress

United States Senate

WASHINGTON, DC 20510-3205

[[DATE]]

The Honorable Jon Tester
Chairman
Subcommittee on Defense
Senate Appropriations Committee
122 Dirksen Office Building
Washington, DC 20510

The Honorable Susan Collins
Ranking Member
Subcommittee on Defense
Senate Appropriations Committee
122 Dirksen Office Building
Washington, DC 20510

Dear Chairman Tester and Ranking Member Collins:

In 2023, there will be an estimated 297,970 new cases of invasive breast cancer diagnosed in women, 2,800 cases diagnosed in men, and an additional 55,720 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, 43,250 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 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 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 level funding for the program in FY2024.**

As you are aware, the DOD Peer Reviewed BCRP plays a leading role in the fight against breast cancer through its innovative approaches and its focus on research that will bring an end to 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 the 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 that 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, which 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 disease. 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 your support for and investment in the DOD Peer Reviewed BCRP and include level funding in the Department of Defense Appropriations bill for FY2024. This is research that will help us win this very real and devastating war against a cruel disease

[[CLOSING]]

[[SIGNATURES]]

NATIONAL BREAST CANCER COALITION

Public Policy

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 ten years and currently unable to work due to her or his disability 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 and a twenty-four-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 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.

Action Requested

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

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.**

NATIONAL BREAST CANCER COALITION

Public Policy

Food and Drug Administration (FDA) Reform

FDA Reform

NBCC's first priority has been guaranteed access to quality healthcare for all. To achieve its mission to end breast cancer, everyone must have equitable access to interventions that work and are safe and affordable. The Food and Drug Administration (FDA) plays a vital role in achieving that goal. We need an FDA that approves drugs with clinically meaningful benefits for patients. Among a number of critical reforms, NBCC seeks to address systemic deficiencies in FDA regulation of the drug and biologic approval process, including accelerated approval.

Background

A key responsibility of the FDA is to protect the public by ensuring the safety and efficacy of new drugs and other medical interventions that enter the market. Patients assume they are receiving that when they are offered an FDA-approved drug/biologic. Unfortunately, this expectation is not met in many cases.

In 1992, the FDA instituted its Accelerated Approval Program to allow for earlier approval based on surrogate endpoints of drugs/biologics that treat serious conditions and fill an unmet medical need. A surrogate endpoint is an intermediate endpoint (e.g., tumor shrinkage) "reasonably likely to predict clinical benefit" that is a substitute for a direct measure of clinical benefit, such as how a patient feels, functions, or survives. When properly validated, surrogate endpoints are reasonable to use as endpoints in clinical trials, but many surrogates currently in use today have failed to correlate with clinical benefit.

Current Federal law grants FDA the authority to require drug sponsors to conduct confirmatory trials after accelerated approval to verify that the drug or biologic provides the predicted clinical benefit. At the time of accelerated approval, FDA and sponsors agree on the timeline for completing the confirmatory study and other milestones. Upon completion, if the confirmatory trials demonstrate true clinical benefit, the accelerated approval is converted to regular approval. The FDA also can withdraw an accelerated approval if the drug manufacturer fails to conduct the post-approval studies with due diligence, if the studies fail to verify the predicted effect or demonstrate that the product is not safe or effective under the conditions of use, or if the manufacturer disseminates false or misleading promotional material. However, rescinding or withdrawing a drug or biologic that has received accelerated approval is cumbersome and can take many months to years. This creates a drug approval system that allows drugs to come to market and stay on the market without evidence of clinical benefit. These drugs all carry toxicities, and many also have an extraordinary financial cost.

Accelerated Approval: What Can We Do?
Clinical benefit has not been confirmed in a significant majority of the drugs granted accelerated approval. The FDA often permits drug sponsors ridiculously long timelines to complete post-approval trials. While these trials are meant to show whether clinical benefit exists, the trials frequently use the same or other surrogate endpoints rather than clinically meaningful ones. This makes no sense if the goals are to show clinically relevant outcomes and to save lives. In some cases, toxic drugs without any evidence of clinical benefit remain on the market for years.

Congress must consider reforms to the accelerated approval pathway to ensure that the drugs given to patients are safe and have actual clinical benefits (improved survival and/or quality of life). The FDA should impose strict timelines for the initiation of confirmatory trials and require the use of clinically meaningful endpoints. Additionally, the FDA should have the authority to quickly withdraw an accelerated approval if a confirmatory trial has not been initiated or timely completed and/or the drug fails to confirm clinical benefit.

Surrogate Endpoints
While surrogate endpoints may allow for shorter trials and easier measurement, they usually do not yield useful information about how well an intervention improves or prolongs lives. Yet all drugs carry toxicities. That means most of the time, patients are being harmed with no clinical benefit. Individuals should be able to make healthcare decisions based on the highest possible quality of evidence. For that to happen, we need well-designed clinical trials that use valid and meaningful outcome measures. We recognize that the selection of the ideal experimental endpoint is not always possible or practical. On the other hand, designing a trial with practical but inadequate outcome measures will only result in harm to patients, wasted resources, and delays in identifying the most effective healthcare.
The goal should not be to push more drugs to market quickly. Rather, it should be to adhere to a system that approves drugs that clinically benefit patients in an expeditious and scientifically rigorous manner.

Conclusion
NBCC believes that the drug/biologic approval process must bring drugs to market that have been proven to confer significant clinical benefits with minimum harm. In the breast cancer context, the clinical benefit should be a significant increase in overall survival or quality of life**.**

NATIONAL BREAST CANCER COALITION

Public Policy

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.

NATIONAL BREAST CANCER COALITION

Public Policy

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, 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.

NBCC
NATIONAL BREAST CANCER COALITION

Public Policy

Prescription Drug Pricing Should be Based on Value

Background

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

[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.

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.

NATIONAL BREAST CANCER COALITION

2023 BREAST CANCER

FACTS & FIGURES

The National Breast Cancer Coalition (NBCC) is a grassroots organization dedicated to ending breast cancer through action and advocacy.

INCIDENCE

Breast cancer is the most diagnosed cancer among women in the U.S.* In 2023, there will be an estimated **297,790** new cases of invasive breast cancer in women, **2,800** new cases in men, and an additional **55,720** cases of ductal carcinoma in situ (DCIS)** in women.***[1]

Lifetime Risk

For women in the U.S., the lifetime risk of being diagnosed with invasive breast cancer has increased since 1975.[2,3]

2017-2019 | **1 in 8** | **12.9%**

1975-1977 | **1 in 11** | **9.1%**

Incidence By Age

Older women are more likely to get invasive breast cancer than younger women. From 2015-2019, the median age of a breast cancer diagnosis was 62 years.[2]

*Excluding basal cell and squamous cell skin cancers, which are not required to be reported to cancer registries, and carcinomas in situ.

**Annual incidence counts of lobular carcinoma in situ are no longer measured following its removal from the 2017 edition of the AJCC breast cancer staging program.

***These statistics do not account for the effect of the COVID-19 pandemic.

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www.stopbreastcancer.org

2023 BREAST CANCER **FACTS** & **FIGURES**

MORTALITY

In 2020,
685,000
women died from breast cancer globally.[4]

Breast cancer is
the 2nd leading cause of cancer deaths for women
in the United States, after lung cancer.

In 2023, it is estimated that **43,170 women** and **530 men** will die of breast cancer.*[1]

*These statistics are based on 2020 mortality data and account for the first year only of the COVID-19 pandemic.

Progress in reducing breast cancer mortality has slowed in recent years, from 2% to 3% annually during the 1990s and 2000s to 1% annually from 2011 to 2020.[2]

While the breast cancer mortality rate has declined, the number of women and men who die each year is rising and will continue to rise as the aging population grows.

Mortality By Age

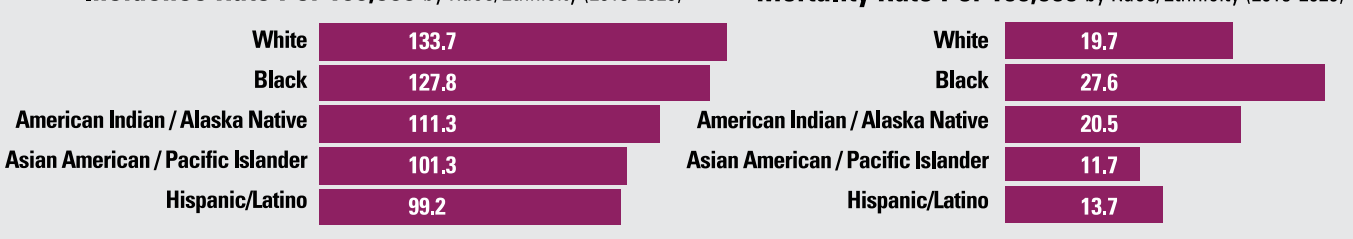
From 2016-2020, the median age at death from breast cancer was **70 years** of age.[5]

Every 13 minutes, a woman dies from breast cancer.

RACIAL DISPARITIES

Despite a similar incidence, mortality from breast cancer among Black women is **40% higher** compared with White women.[1,2]

INCIDENCE & MORTALITY RATES



2023 BREAST CANCER **FACTS** & **FIGURES**

RECURRENCE

The risk of local and distant (metastatic) recurrence varies greatly based on many factors. Estimates of long-term cumulative risk range from about 5% to 60%, with most falling between **10%-30%**.[6–9] Furthermore, recurrence risk remains elevated more than 3 decades from the primary diagnosis.[9]

PREVALENCE

As of January 2022, there were an estimated **>4 million** women living with a history of invasive breast cancer in the U.S.[10]

It is estimated that in 2018, **140,230** women in the U.S. were living with metastatic breast cancer. By 2025, this number is expected to increase to **169,347**.[11]

RISK FACTORS

Only 5-10% of breast cancers are hereditary. The strongest risks for breast cancer are age and being assigned female at birth.

Other non-modifiable risk factors include:[12–14]

- Genetic mutations, such as in *BRCA1* and *BRCA2*
- Starting menstrual periods before age 12 and menopause after age 55
- Having dense breasts
- Personal history of breast cancer or benign breast diseases
- Family history of breast cancer
- Previous radiation therapy in chest or breasts
- Exposure to the drug diethylstilbestrol (DES)
- Naturally high levels of estrogen or testosterone

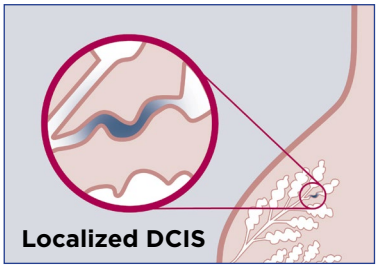
Risk factors that are potentially modifiable include:

- Lack of physical activity
- Being overweight or having obesity (post-menopause)
- Taking hormonal medications, such as menopausal hormone therapy or hormonal contraceptives
- Reproductive history, including being over 30 years of age at first full-term pregnancy, not breastfeeding, and never having a full-term pregnancy
- Alcohol consumption

DCIS & SCREENING

The diagnosis of ductal carcinoma in situ (DCIS) was rare before 1980, but the widespread adoption of screening mammography led to a massive increase in DCIS diagnosis. From 1980-2000, women aged 20-49 experienced a **400% increase** in DCIS diagnoses, and women over the age of 50 experienced over a **900% increase** in DCIS diagnoses.[2] However, screening has not decreased the rate of lethal disease (i.e., distant stage) at diagnosis.[15]

Overdiagnosis of breast cancer (i.e., cancer that would never have become a problem) by screening mammography is difficult to determine, with the most credible estimates ranging from **11%-22%**.[16,17] False positive and false negative mammography results are also possible. Over a 10-year period, **more than half** of women getting an annual mammogram will receive a false-positive result.[18,19]



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2023 BREAST CANCER **FACTS** & **FIGURES**

TREATMENT

The current methods of treatment in use in the U.S.

Surgery (Mastectomy) & Lumpectomy)

Chemotherapy

Radiation

Hormonal

Targeted Therapy

Immunotherapy

LANGUAGE

NBCC acknowledges that breast cancer impacts people of all gender identities.

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