

# PROGRESS REPORT

2020

2019

2018

2017

2016

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2014

**2013**

2012

2011

## **Breast Cancer Deadline 2020<sup>®</sup>** 3<sup>rd</sup> Annual Progress Report

National Breast Cancer Coalition

The  
**Breast  
Cancer  
Deadline**

**2020**

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Founded in 1991, the National Breast Cancer Coalition's (NBCC) mission is to end breast cancer through the power of action and advocacy. On September 20, 2010, NBCC set a deadline and launched a plan of action to reach its mission: **Breast Cancer Deadline 2020**<sup>®</sup>—we will know how to end breast cancer by January 1, 2020.

NBCC increases federal funding for breast cancer research; monitors how research funds are spent; expands access to quality health care for all; and ensures that trained advocates influence all decision making that affects breast cancer.

NBCC links hundreds of organizations and tens of thousands of individuals from across the country into a dynamic, diverse coalition that gives breast cancer a meaningful voice in Washington, DC and state capitals, in laboratories and health care institutions, and in local communities everywhere.

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**Breast Cancer  
Deadline 2020<sup>®</sup>**  
3<sup>rd</sup> Annual  
Progress Report

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National Breast Cancer Coalition

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# EXECUTIVE SUMMARY

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# EXECUTIVE SUMMARY

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## INTRODUCTION

In 2010, the National Breast Cancer Coalition set a deadline to know how to end breast cancer and launched a plan to achieve it. [Breast Cancer Deadline 2020](#)<sup>®</sup> is a call to action for all stakeholders to focus efforts on knowing how to end the disease by the end of the decade. As part of **Breast Cancer Deadline 2020**<sup>®</sup>, NBCC issues Annual Progress Reports. The reports, summarizing the state of breast cancer as well as the status of NBCC's work to end breast cancer, hold NBCC and the entire breast cancer community accountable to **Breast Cancer Deadline 2020**<sup>®</sup>. The [2011 Progress Report](#) served as a baseline and provided a snapshot of the current state of breast cancer. With a review of breast cancer trends, research, advocacy and public policy, the report portrayed the reality of breast cancer and the lack of adequate progress despite the significant public and private resources directed at the disease.

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*This **Third Annual Breast Cancer Deadline 2020**<sup>®</sup> Progress Report provides an update with the latest data on breast cancer incidence and mortality as well as news about treatment options; information on public policy, advocacy, and the media's coverage of breast cancer; a look at the current research priorities as demonstrated by research funding; and finally, an update on Breast Cancer Deadline 2020<sup>®</sup> activities.*

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This *Third Annual Breast Cancer Deadline 2020*<sup>®</sup> Progress Report provides an update with the latest data on breast cancer incidence and mortality as well as news about treatment options; information on public policy, advocacy, and the media's coverage of breast cancer; a look at the current research priorities as demonstrated by research funding; and finally, an update on **Breast Cancer Deadline 2020**<sup>®</sup> activities.

**This report must be read in conjunction with the [Baseline Report issued in 2011](#).** In the 2013 report, NBCC provides updates only where information has changed. It is important to note that there were no "breakthroughs" in treatment or diagnosis in the past year, and the information in the Baseline Report remains the most pertinent.

There are many myths and misunderstandings that surround breast cancer. To make real progress toward saving lives and ending breast cancer, we need to better understand its reality at all levels. The reality is troubling.

Breast cancer continues to take a toll in the US and globally despite significant attention and resources directed at the disease. Billions of dollars have been invested in breast cancer research, and many organizations and public health officials continue to focus attention on early detection and awareness campaigns as the primary approach to addressing breast cancer.

Given the attention and resources directed to breast cancer, the public understandably believes that we have made significant progress. As shown in the Baseline Report and in this year's Progress Report, that is not the case. We know little about how to prevent breast cancer or how to prevent deaths from the disease.



While we have discovered new ways to treat breast cancer, they have not had a great effect on the important outcomes: preventing breast cancer and making certain no one dies of it.

## BREAST CANCER STATISTICS: THE NUMBERS TELL A COMPELLING STORY

The trends for breast cancer incidence and mortality have not changed since NBCC issued its Baseline Report in 2011. The overall number of women being diagnosed continues to increase as the population ages, though the rate remains constant, and mortality continues to decline slightly.

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Worldwide, breast cancer accounts for nearly a quarter of all cancers in women.

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Worldwide, breast cancer accounts for nearly a quarter of all cancers in women. In 2008, there were 1.4 million women diagnosed with breast cancer<sup>1</sup> and in 2010 there were 438,000 deaths from the disease globally.<sup>2</sup> In the United States in 2013, it is estimated that

more than 296,000 women and 2,240 men will be diagnosed with breast cancer, and 39,620 women and 410 men will die of the disease.<sup>3</sup> That is one death every 14 minutes.

By any standard, we have not made adequate progress. Despite years of campaigns to raise awareness, ever expanding screening programs, increased fundraising efforts and more research, there has been little impact on the important outcomes in breast cancer. Breast cancer incidence and mortality have not changed significantly. In 2030, with no major changes in prevention or treatment, it is estimated that 747,802 women will die from breast cancer worldwide.<sup>4</sup>

In the United States, the chance of a woman developing breast cancer during her lifetime has increased from about 1 in 11 in 1975 to 1 in 8 today.<sup>5</sup> US breast cancer mortality has been declining but only slightly.

In 1991, in the United States, 119 women died of breast cancer every day.<sup>4</sup> This year, that number is estimated to be 108.<sup>5</sup> If we continue making progress at the current rate, it could take a few centuries to end breast cancer. These are not merely statistics, they represent millions of lives. These losses are unacceptable.

### Incidence

Overall incidence of breast cancer has fluctuated over the years. Recently, researchers at the National Cancer Institute (NCI) projected that the overall breast cancer incidence rate will stay the same through 2016. The median age at diagnosis remains at 61 years.<sup>5</sup> Because of increased screening beginning in 1980, there has been a dramatic increase in the incidence of ductal carcinoma in situ (DCIS), abnormal cells contained within the milk ducts that have not spread to other parts of the body. Most of DCIS will never become cancer. However, we are not able to distinguish between the harmful kind of DCIS (that will develop into cancer) and the harmless kind; as a result, many women are treated with interventions that will not help them and could hurt them.<sup>5</sup>

### Mortality & Survival

Despite fluctuations in breast cancer incidence, and dramatic increases in the use of mammography, there has only been a slow, gradual decrease in the rate of breast cancer deaths, or breast cancer mortality, over time. Women do not die of primary breast cancer. More than 90% of breast cancer deaths are due to the spread of the disease to other parts of the body. While we want to believe we have made significant progress in saving lives, that is not the case. The incidence of women diagnosed with advanced breast cancer has not changed.

Rates of diagnosis of truly lethal disease have remained stable since 1975.<sup>5</sup> Mortality rates have not changed significantly. Between 1975 and 1990, the mortality rate increased slightly then began decreasing slightly in

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In contrast to mortality statistics, survival statistics do not reflect the real experience of people with breast cancer.

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the late 1990s for all women, with the highest rate of decrease in white women.<sup>5</sup> The rate of decrease in mortality appears to be slowing. This year, 39,620 women and 410 men will die of breast cancer. While a slight decrease in mortality is an accomplishment, it is far from success.

In contrast to mortality statistics, survival statistics do not reflect the real experience of people with breast cancer. NCI reports that five-year breast cancer survival is 98% for localized disease. Survival rates are skewed by screening: the more you screen, the more you find and thus more women will be alive at five years. But they were not going to die of breast cancer

in that time frame even if they had not been screened.<sup>6</sup> And these numbers do not take recurrence into account. While many mistakenly point to five-year survival statistics as proof of progress, an estimated 20% to 30% of women diagnosed with invasive breast cancer will have a recurrence of their disease and may go on to die of the disease, yet they are included as survivors in the five-year survival statistics.<sup>7</sup> We still do not know how to prevent recurrence and metastasis or how many of the women reported to have survived five years will go on to have their breast cancer recur.

### The Uncomfortable Reality Behind Early Detection

A great deal of attention and resources have focused on the area of early detection. A mantra that has been drummed into our consciousness during the past 40 years is that early detection saves lives. The reality is otherwise. About 70% of women in this country over age 40 have had a mammogram in the last two years.<sup>8</sup> Unfortunately, randomized controlled trials for mammography have shown, at best, a marginal benefit.<sup>9,10</sup> Breast self-exam (BSE) also has long been a key women's health mantra. But research has demonstrated that routine BSE does not lead to a decrease in mortality from breast cancer nor does it find breast cancer at an earlier stage.<sup>11,12</sup>

In the past year, several studies have been published that describe the impact of screening. While the incidence of early-stage breast cancer increased significantly in the period between 1976 and 2008, the incidence of late-stage disease decreased only slightly and the incidence of metastatic breast cancer did not change at all.<sup>13</sup> More data continues to be collected regarding the magnitude of overdiagnosis due to mammography screening and the resulting harms. One study estimates the rate of overdiagnosis from screening to be between 15% and 25%.<sup>14</sup> The harms from overdiagnosis are not insignificant. The *British Medical Journal* published estimates from Dr. Michael Baum this year that for every breast cancer death avoided from screening, an additional one to three deaths can be expected as a result of radiotherapy for those overdiagnosed, because of their increased risk of dying of heart disease and lung cancer.<sup>15</sup>

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Yet many resources are devoted to giving the message of early detection and promoting breast self-exam and mammography screening for younger and younger populations. Attempts to apply evidence to the message of early detection are often met with anger and derision, as evidenced by the response to the revised screening guidelines issued by the United States Preventive Services Task Force in 2009. But these are matters of science. As our knowledge progresses, our beliefs must change to accommodate new information, no matter how much this challenges long-held beliefs and no matter how much we do not like the answer.

## WE HAVE MADE SOME PROGRESS IN THE TREATMENT OF BREAST CANCER

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We have made some progress in breast cancer treatments. We have learned that not all breast cancers are the same. We now divide breast cancer into subtypes, based on the biology of the tumor. We have made some progress toward developing treatments targeted to different subtypes. But the majority of women with breast cancer still receive the same treatment as though all breast cancers were the same. In reality, to date, our knowledge of the biology of breast cancer has not been translated into many new therapies to treat it.

There have been no major advances in treatment for breast cancer in the last year. For decades, breast cancer treatment has included surgery, radiation therapy, chemotherapy, and/or hormonal therapy, and within the past 15 years, targeted therapy. Ironically, much of the recent progress in treatment has been in doing less. In the 1970s, the primary treatment for breast cancer was a radical mastectomy, but once researchers found no difference with respect to outcomes in patients with lumpectomy versus patients with total mastectomy, the standard of care shifted to a less invasive surgery. Studies have shown that removing a few lymph nodes has the same survival advantage as removing most if not all.<sup>16</sup> These two developments have a major impact on quality of life. While important, they do not change the mortality statistics.

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Meanwhile, the cost of treating breast cancer continues to rise without accompanying significant decreases in breast cancer mortality. The national cost of cancer care in 2010 was estimated to be \$124.6 billion, with female breast cancer care leading all cancer sites at an estimated \$16.5 billion.<sup>17</sup> Despite that investment, a person with a new diagnosis of cancer has approximately a one in five chance of failing to receive elements of cancer care that are evidence-based and consistent with practice standards.<sup>18</sup> And millions of Americans have no insurance, which not surprisingly has an impact on the quality of their health care.

Like all medical treatments, breast cancer treatments can be harmful as well as helpful. Common morbidities include cardiac complications and lymphedema, among others. And the treatments can themselves be life-threatening. We need treatments that prolong life or significantly increase quality of life, with minimal risk. Too often, progress is defined by new treatments that do neither. In the past year alone, the FDA approved three drugs for the treatment of metastatic breast cancer, with only one of the drugs showing an improvement in overall survival.

## PUBLIC POLICY PLAYS A SIGNIFICANT ROLE IN ALL ASPECTS OF BREAST CANCER

Breast cancer is a political issue. The level of government funding for research, the expansion and regulation of access to health care, the regulatory process for drug approval, and health insurance are just some of the issues that are determined through the political process.

From 1991 to 2012, over 870 resolutions and bills with the words “breast cancer” were introduced in the United States Congress. Many more have been introduced in state legislatures. On the federal level, of the hundreds introduced since 1991, 11 resolutions were agreed to and 45 bills became law.<sup>19</sup>

The 112<sup>th</sup> Congress introduced more than 10,000 pieces of legislation, including the [Accelerating the End of Breast Cancer Act](#) (S. 3237/H.R. 3067), a bill created by NBCC to support the goals and efforts of **Breast Cancer Deadline 2020**<sup>®</sup>. Yet only 283 of the 10,000 pieces of legislation (less than 3%) became law.<sup>20</sup> This is the lowest ratio of any Congress since 1948 when scholars began tracking congressional productivity.

## **BREAST CANCER RESEARCH MAY BE WELL FUNDED, BUT ARE THE FUNDS WELL SPENT?**

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As outlined in the [2011 Baseline Report](#), billions in public funding, private investment and charitable contributions have been directed toward decreasing the burden of breast cancer throughout the last several decades, but the investment has not paid off in dramatic improvements in incidence or mortality from the disease.

The Federal Government remains the largest funder of breast cancer research in the US; although the National Cancer

Institute (NCI) invests the most resources, a variety of other agencies also are involved. In 2012, NCI directed \$602,728,719 to breast cancer research. This is a decline of almost \$30 million from the level in 2010.<sup>21</sup> The Federal government also funds research through the Department of Defense (DOD) Breast Cancer Research Program (BCRP). In 2012, the DOD BCRP funded research grants totaled \$98,606,123, a decrease of more than 22% from 2010 funding levels.<sup>22</sup>

While federal funding of breast cancer research has decreased in the last two years, the proportion of research funds coded in the area of breast cancer progression and metastasis has increased during that same period.<sup>21,22</sup>

Private philanthropy underwrites a significant amount of research in breast cancer. The largest private funder of breast cancer research is Susan G. Komen, which awarded \$42 million in grants in 2013, a significant decrease from the \$57 million granted in 2011.<sup>23</sup> Additional funders exist across the country, from gifts in the hundreds of millions of dollars to local walks that raise a few thousand. With a diversity of supporters and vast number of donations and events, it is not possible to determine the amount of funding in this category.

ClinicalTrials.gov collects information about federally and privately supported research once it reaches the clinical stage. On August 7, 2013, there were 150,162 clinical trials listed; 5,439 were listed as breast cancer trials and 31% (1,706) of these were listed as trials for metastatic breast cancer.<sup>24</sup>

## **BREAST CANCER ADVOCACY HAS MADE A DIFFERENCE**

There are probably thousands, if not tens of thousands, of breast cancer groups in this country alone and a growing global movement.

Breast cancer advocates can help shape the breast cancer research agenda, the federal drug approval process, the health care system, and federal and state legislation. They can serve as liaisons between patients and

physicians, as well as patients and the scientific community. Some groups provide direct services such as hotlines, support groups, counseling, educational materials, financial aid and community presentations.

During the past year, breast cancer organizations advocated within the research community for clinical trials with less toxic treatment options and at the Supreme Court against the patenting of genes. Breast Cancer advocates also played a role in the area of access to quality care, weighing in on the *Affordable Care Act*, joining with other leading disease and disabilities advocacy groups on an amicus brief supporting the constitutionality of key provisions of the legislation being challenged in courts across the nation (and in the Supreme Court), and ensuring patient participation on key committees of the Patient-Centered Outcomes Research Institute (PCORI). Yet, advocacy can unfortunately be manipulated, and uneducated advocacy can be harmful. This was evident in the past year when it was learned that British and US pharmaceutical trade associations were attempting to recruit patient groups to promote their own interests in preventing data sharing, and again when Angelina Jolie's public revelation about her personal health decision was followed by much misinformation and unwarranted fear.

## THE BREAST CANCER DEADLINE 2020® STRATEGY

It is clear that “more of the same” will not be effective; additional funding and time can only be used fruitfully if efforts are part of a larger strategic plan focused exclusively on the one goal of knowing how to end breast cancer.

This effort requires a critical look at research and health care priorities, financial incentives, funding mechanisms and advocacy efforts. It requires a concentrated strategy to expand quality, evidence-based care. It must embrace unprecedented coordination, information sharing and accountability.

It requires individuals and institutions to cooperate in new ways and to an extent never before considered. Vision, urgency, unwavering focus, and creative collaboration under true leadership are the key ingredients for success. A collaborative deadline-driven mission approach to breast cancer has never been attempted before now. But examples of success in other fields suggest that often it is the lack of vision, willpower, accountability and leadership—not level of knowledge or the science itself—that stymies progress.

NBCC's *Blueprint for Breast Cancer Deadline 2020®* describes how the organization is harnessing the energy, resources and leadership around the world to achieve **Breast Cancer Deadline 2020®**. The blueprint is designed around three goals:

1. research needed to know how to end breast cancer;
2. global access to the necessary information and lifesaving interventions; and
3. the influence of leaders everywhere in the strategies to end breast cancer.

During the past year, NBCC continued to make progress in each of these areas.

### Research

NBCC is leading an effort among all stakeholders involved in research, particularly the scientific community, to create synergy and develop partnerships to advance the pace of research. The goal is to take what is known and build upon it for the sole purpose of ending the disease.

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To assess the extent of the problems, identify meaningful questions and determine the individuals and tools needed to answer them, NBCC hosted two strategic summits in 2011 bringing together stakeholders and other visionaries: one on primary prevention, the other on preventing metastasis. NBCC has refined and prioritized the recommendations from those summits, and is launching additional catalytic projects to address those priorities that will achieve the deadline. These projects are collectively called the Artemis Project®—an innovative, advocate-led, mission-driven model, which ensures appropriate focus on the end result. The participants in these project collaborations design and implement research plans, and NBCC awards seed grants to begin the necessary work.

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[The first Artemis Project®](#) to arise from this work brings together a collaborative group of advocates, scientists and other stakeholders to take a strategic, systematic, yet broad approach to the design of a five-year development plan for a breast cancer preventive vaccine. In addition to annual meetings, NBCC has awarded \$400,000 of seed grants for research through generous support of the National Philanthropic Trust, held smaller meetings on specific sub-topics and convened webinars for the research teams to share data.

An Artemis Project® on the causes and prevention of metastasis was launched in June 2013, with a kickoff meeting that brought together 17 scientists and advocates to discuss launching a project around tumor dormancy as a fundamental approach for preventing metastasis. Plans are being made to hold a follow-up meeting to explore tumor dormancy in the context of immunology and cell aging.

In the public policy arena, NBCC has developed the first piece of legislation to support and complement the research work of **Breast Cancer Deadline 2020®**. The [Accelerating the End of Breast Cancer Act](#) was introduced in the 112<sup>th</sup> Congress and gained bipartisan support from 27 Senators and 236 Members in the House, but did not pass. The legislation was reintroduced in May 2013. Comparable policies will be designed as the need is identified.

## Access

NBCC is bringing together stakeholders from around the world at all levels, from policy makers to grassroots advocates, and engaging them throughout the process to make certain that location, economic status, and societal factors are not barriers to access. NBCC has trained women and men from other continents through its various scientific and policy training programs and is working with advocates and scientists in Europe, Africa, Asia and South America to create **Breast Cancer Deadline 2020®** continent-wide networks.

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NBCC has increased the representation of stakeholders from other countries in all **Breast Cancer Deadline 2020**<sup>®</sup> activities. The 2013 meeting for the Artemis Project<sup>®</sup> on the causes and prevention of metastasis included a non-US scientist among the 17 who participated. More than ten countries are represented among the organizations endorsing **Breast Cancer Deadline 2020**<sup>®</sup>. Nearly 10% of the advocates in attendance at the Inaugural Advocate Leadership Summit in 2013 were from countries outside of the United States. These leaders are building advocacy campaigns within their countries to gain more support, endorsement and participation from leaders in government and science worldwide.

## Influence

Media, advocates, researchers, policy makers and others must be educated to change the conversation and shift the essential public dialogue about breast cancer from awareness and screening to prevention and saving lives.

NBCC leadership has been proactive in delivering the message of **Breast Cancer Deadline 2020**<sup>®</sup> through various media channels. **Breast Cancer Deadline 2020**<sup>®</sup> work in public policy during the past year included educating Congress and the Administration on strategies to know how to end breast cancer by 2020. NBCC also is reaching out to leaders in the scientific community by speaking and exhibiting at breast cancer scientific conferences and meeting with various scientific associations.

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NBCC continues to educate and mobilize the breast cancer advocacy community and the general public behind the goals of Breast Cancer Deadline 2020<sup>®</sup>.

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At the same time, NBCC continues to educate and mobilize the breast cancer advocacy community and the general public behind the goals of **Breast Cancer Deadline 2020**<sup>®</sup>. The [Center for NBCC Advocacy Training](#) programs include NBCC's science training [Project LEAD](#)<sup>®</sup>, [Advocate Summits](#), and [online trainings](#), all of which involve international advocates. NBCC informs and activates the public through online messaging, print publications, and presentations at events related to

breast cancer. Local and international **Breast Cancer Deadline 2020**<sup>®</sup> Action Networks are being created with leadership identified in nearly every state and almost a dozen countries. The [list of organizations endorsing the deadline](#) has now grown to nearly 300.

## CONCLUSION

Throughout the last several decades, the investment in breast cancer has not led to significant progress in ending the disease or in preventing deaths from the disease. This did not change in the past year. This is true for research and health care and also advocacy.

Since 1971 when the war on cancer was launched, our understanding of the biology, etiology and genetics of breast cancer has increased. New disciplines have shed light on the process of innovation and how organizational systems evolve. And, of course, our capacity to gather, synthesize and analyze information is beyond anything even conceivable 40 years ago. NBCC launched **Breast Cancer Deadline 2020**<sup>®</sup> to leverage these past investments and innovations in order to catalyze real progress in breast cancer.

In the three years since the launch of the **Breast Cancer Deadline 2020**<sup>®</sup> campaign, NBCC has moved quickly to put its plan into action. We have mobilized a collaborative of renowned experts in epidemiology, immunology,

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clinical care, biotechnology, product development and advocacy to begin work on two key areas: preventing the disease from ever developing; and preventing metastasis, the spread of the disease to other organs, which causes 90% of breast cancer deaths. We have introduced bipartisan legislation to support our efforts in the US Congress while also building support among public officials. We have educated and mobilized grassroots advocates and

organizations to spread the word about **Breast Cancer Deadline 2020**<sup>®</sup> and engage women and men in the campaign. And, we have reached out to the media and shared information with the general public to change the conversation in breast cancer to one that is focused on knowing how to end the disease and saving lives.

With less than seven years remaining until January 1, 2020, it is critical that we continue to put forth our most ambitious efforts and pursue them with uncompromised commitment. The goal is achievable with the right amount of passion, leadership and funding. It will require all of us who care to play a role in meeting the goal to find the will, the strength, and the belief to do what it takes to achieve the end of breast cancer. The tools, information, resources and wisdom exist to create a global strategy to end breast cancer.



# 1 | INTRODUCTION

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# 1 | INTRODUCTION

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In 2010, the National Breast Cancer Coalition set a deadline to know how to end breast cancer by January 1, 2020—**Breast Cancer Deadline 2020**<sup>®</sup>. As part of **Breast Cancer Deadline 2020**<sup>®</sup>, NBCC issues Annual Progress Reports.

The reports, summarizing the state of breast cancer as well as the status of NBCC’s work to know how to end breast cancer, hold NBCC and the entire breast cancer community accountable to **Breast Cancer Deadline**

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It is important to note that there were no “breakthroughs” in treatment, or diagnosis, in the past year and the information in the Baseline Report remains the most pertinent.

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**2020**<sup>®</sup>. The 2011 Progress Report served as a baseline, giving an overview of breast cancer trends, including a discussion of the research landscape, advocacy, and public policy. The report portrayed the reality of breast cancer and the lack of adequate progress despite the significant public and private resources directed at the disease.

The report also offered the advocate perspective on barriers that have hindered progress. This report will provide an update with the latest data on breast cancer incidence and mortality, as well as news about treatment options; information on public policy, advocacy and the media’s coverage of breast cancer; a look at the current research priorities as demonstrated by research funding; and finally, an update on **Breast Cancer Deadline 2020**<sup>®</sup> activities.

**This *Third Annual Breast Cancer Deadline 2020*<sup>®</sup> Progress Report must be read in conjunction with the [Baseline Report issued in 2011](#).** In this 2013 report, NBCC provides updates only where information has changed. For example, NBCC does not again review the overall landscape of breast cancer treatment, but reports on a few studies that were released during the past year. It is important to note that there were no “breakthroughs” in treatment, or diagnosis, in the past year and the information in the Baseline Report remains the most pertinent.

# 2 | BREAST CANCER STATISTICS

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## 2 | BREAST CANCER STATISTICS

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The incidence of breast cancer in the United States remains relatively constant, after fluctuating during the 1990s and early 2000s. During the period of 2006–2010, the overall incidence of breast cancer was 123.8 cases per 100,000 women.<sup>1</sup> The National Cancer Institute (NCI) projects overall breast cancer incidence to remain constant through 2016.<sup>2</sup>

Though the incidence, or rate of diagnoses, remains constant, the number of women being diagnosed continues to increase each year as the number of women in age groups at risk of breast cancer increases. The median age of diagnosis remains at 61 years.<sup>1</sup> NCI estimates that in the United States more than 296,000 women and 2,240 men will develop invasive and in situ breast cancer in 2013, and 39,620 women and 410 men will die from the disease.<sup>3</sup>

Because of increased mammography screening beginning in 1980, there has been a dramatic increase in the incidence of what is referred to as in situ breast cancer, abnormal cells found within the milk ducts or lobules that have not spread to the surrounding tissues in the breast or other parts of the body. Almost one quarter of the 296,000 diagnoses in 2013 will be in situ, and of those, 85% will be ductal carcinoma in situ (DCIS), meaning the abnormal cells are contained within the milk ducts, and approximately 15% will be lobular carcinoma in situ. The terms are misleading however, as these lesions are not cancers. Most in situ carcinoma will never become invasive.<sup>4</sup> It is currently not possible to predict which of the in situ carcinoma will develop into invasive cancer and as a result, many women are treated with unnecessary interventions that are associated with potential short-term and long-term morbidities.<sup>5</sup>

Despite fluctuations in breast cancer incidence over the last several decades, and dramatic increases in the use of mammography, there has only been a slow, gradual decrease in the rate of breast cancer deaths, or breast cancer mortality, over time. In the US, between 1975 and

1990, the mortality rate increased by 0.4% annually, but began decreasing in 1990. The rate of decrease in mortality appears to be slowing, with an average decrease of 1.9% annually from 1998 to 2010<sup>1</sup>. Breast cancer mortality in 2010 was 21.9 deaths per 100,000 women.<sup>6</sup>

Worldwide, breast cancer accounts for nearly a quarter of all cancers in women. In 2008, there were 1.4 million women diagnosed with breast cancer<sup>7</sup> and in 2010 there were 438,000 deaths from the disease globally.<sup>8</sup> In 2030, with no major changes in prevention or treatment, it is estimated that 747,802 women will die from breast cancer worldwide.<sup>9</sup>

Some types of breast cancer are known for long asymptomatic periods lasting several years before reappearance of the disease, which has often metastasized, or spread to other organs in the body. Unfortunately, neither NCI nor World Health Organization (WHO) track the incidence of recurrent breast cancer or metastatic breast cancer, though it is metastatic breast cancer that is responsible for the majority (90%) of breast cancer deaths. As a result, there is no accurate information on trends in the incidence for

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recurrent disease, or for overall metastatic disease. However, it is known that the incidence of women diagnosed with metastatic breast cancer at the initial diagnosis has remained constant in the US since 1975.<sup>1</sup>

A study published in the *New England Journal of Medicine* in 2012 looked at the impact of mammography screening on breast-cancer incidence between 1976 and 2008 in US women over 40. The authors examined the change in incidence of early-stage and late-stage breast cancer after the introduction of widespread screening in the mid-1980s. They found that while the incidence of early-stage (defined as DCIS and breast cancer localized to the breast only) increased significantly, the incidence of late-stage (regional and metastatic breast cancer) decreased only slightly (likely due to slight change in regional diagnoses).<sup>10</sup>

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In 2008, there were 1.4 million women diagnosed with breast cancer<sup>7</sup> and in 2010 there were 438,000 deaths from the disease globally.<sup>8</sup> In 2030, with no major changes in prevention or treatment, it is estimated that 747,802 women will die from breast cancer worldwide.<sup>9</sup>

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The incidence of metastatic breast cancer at diagnosis did not change at all over the three decades. In addition, the authors, Dr. H. Gilbert Welch and Dr. Archie Bleyer estimated that more than one million women have been overdiagnosed as a result of mammography screening, and have undergone treatments involving surgery, radiation, hormones, and chemotherapy for abnormalities that otherwise would not have caused illness.

More data continues to be collected regarding the magnitude of overdiagnosis due to mammography screening and the resulting harms. A 2012 study of the screening program in Norway estimated the rate of overdiagnosis attributable to the program to be between 15% and 25%.<sup>11</sup>

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The resulting harms of overdiagnosis are not insignificant. In January, 2013, the *British Medical Journal* published estimates from Dr. Michael Baum: for every 10,000 women screened in the UK screening program, between 120 to 140 will be overdiagnosed, meaning they will be told they have breast cancer though their pathology is not life threatening; and for every breast cancer death avoided from screening, an additional one to three deaths can be expected as a result of radiotherapy for those overdiagnosed, because of their increased risk of dying of ischaemic heart disease and lung cancer.<sup>12</sup>

....more than one million women have been overdiagnosed as a result of mammography screening, and have undergone treatments involving surgery, radiation, hormones, and chemotherapy for abnormalities that otherwise would not have caused illness.

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# 3 | BREAST CANCER TREATMENT

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## 3 | BREAST CANCER TREATMENT

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News regarding treatments and outcomes for breast cancer during the past year showed that while there may be slight improvements in survival for some women, it is at a great cost to many.

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While our understanding of breast cancer biology has increased during the past year there are no significant breakthroughs in treatment and outcomes to report for women with breast cancer.

News regarding treatments and outcomes for breast cancer during the past year showed that while there may be slight improvements in survival for some women, it is at a great cost to many. Most reports involved tweaks in doses or schedules of existing treatments, and too many reports involved the morbidity and mortality

experienced by patients as side effects from treatments. And while new ways of delivering targeted treatments that could lower toxicity were brought to market, they continue to be used and evaluated with existing regimens of chemotherapy, adding toxicity rather than fulfilling the promise of lowering toxicity.

During the past year, the Food and Drug Administration (FDA) approved three drugs for the treatment of metastatic breast cancer, with only one of the drugs showing an improvement in overall survival of about five months. Two new drugs, a PARP inhibitor and a CDK inhibitor, began Phase III clinical trials.

### Understanding Research Language: Clinical Trial Endpoints

To understand the “benefit” of a new drug or other medical intervention, it is important to know the language researchers and regulators use to report the results of studies. Many times something is reported as a “statistically significant” finding. Statistically significant means that the result found is “real,” and unlikely to be due to chance. It does not mean that the result is important or that it is significant to a patient.

Before a clinical trial begins, researchers must determine what outcomes or endpoints they will monitor to be able to reach meaningful conclusions about the effect of the intervention they are studying. Because survival is the most important issue for most breast cancer patients, overall survival is usually the primary endpoint measured in a trial. The median overall survival (OS) is the length of time from either the date of diagnosis or the start of treatment to the point when half of the patients in the group are still alive. It is important to look at overall survival and not just breast cancer survival to capture, for example, deaths caused by the intervention being studied.

To shorten the time needed to reach conclusions about an intervention under study, sometimes cancer clinical trials also measure interim or secondary outcomes such as disease-free survival or progression-free survival. Disease-free survival (DFS) is the time from the beginning of an intervention until a patient experiences a recurrence, a new primary cancer, or death. Progression-free survival (PFS) is the time from the beginning of an intervention until the disease gets worse or progresses, or the patient dies from any cause. It is important to understand, however, that the validity of secondary outcomes relies on the assumption that a favorable interim outcome actually correlates with lower mortality. Unfortunately, sometimes an intervention that has a beneficial effect on the interim outcome might ultimately be proven to have no effect or a negative effect on survival. If the study were ended without collecting the mortality or survival data, the overall effectiveness of the intervention would be misunderstood. And the interim outcome may have no effect on a patient’s quality of life. For example, progression-free survival may measure progression of metastasis by the use of scans. If scans show that with the drug, metastasis or a tumor progresses more slowly than without the drug, that is defined as a benefit. However, that intervention may not extend a patient’s life by an hour, let alone a day or a month, and the fact that progression of disease is slower may have no impact on how a patient feels or other quality of life issues.

Another endpoint that is sometimes used in trials of interventions designed to reverse tumor development is tumor response rate. The FDA recently issued draft guidelines for the use of a measure of tumor response rate as an endpoint in neo-adjuvant (treatment before surgery) clinical trials called pathological complete response (pCR), or the absence of residual disease at the time of surgery.



## 3.1 DRUG APPROVALS

### Afinitor (everolimus)

In July of 2012, the FDA announced approval of Afinitor (everolimus) in combination with Aromasin (exemestane) for the treatment of metastatic, hormone receptor-positive breast cancer in postmenopausal women who already have been treated with Femara (letrozole) or Arimidex (anastrozole).<sup>1</sup> Afinitor is the first mTOR inhibitor approved for breast cancer. mTOR (mammalian target of rapamycin) is a type of enzyme called a kinase, which is involved in energy metabolism. mTOR can be overactive in breast cancer, and it is believed that it may help the cancer to grow.

The approval was based on improvements in progression-free survival (PFS), the length of time patients lived without the cancer progressing, not on overall survival (OS). In a study, BOLERO-2 (Breast Cancer Trials of Oral Everolimus 2) of 724 patients who had experienced menopause, had estrogen receptor-positive, HER2-negative breast cancer that had spread, and had previously received treatment with Femara or Arimidex, patients who were assigned to receive Afinitor plus Aromasin in combination had a 4.1 month improvement in PFS compared to patients receiving the placebo plus Aromasin.<sup>2</sup>

The most common side effects observed in patients receiving Afinitor for breast cancer were mouth ulcers, infections, rash, fatigue, diarrhea and decreased appetite. More serious side effects that can occur include lung infections, trouble breathing and kidney failure. The FDA cautions that patients aged 65 years and older should be monitored closely as these patients experience a higher rate of serious side effects than younger patients receiving the treatment.

### Perjeta (pertuzumab)

In June of 2012, the FDA announced approval of Perjeta (pertuzumab) in combination with Herceptin (trastuzumab) and Taxotere (docetaxel) to treat HER2-positive, metastatic breast cancer that has not been treated with either Herceptin or chemotherapy.<sup>3</sup>

Perjeta is a humanized monoclonal antibody, similar to Herceptin, but thought to work by targeting a different part of the HER2-protein than Herceptin.

The FDA approval was based on PFS results from the CLEOPATRA (CLinical Evaluation Of Pertuzumab And TRAstuzumab) study. In the study of 808 women diagnosed with metastatic, HER2-positive breast cancer, those treated with a combination of Perjeta, Herceptin and Taxotere had a median PFS of 18.5 months compared to 12.4 months for the women who received Herceptin, Taxotere and placebo.<sup>4</sup> There was a small increase in the number of side effects in the group receiving Perjeta. Adding Perjeta to Herceptin in the treatment regimen did not increase the risk of heart problems. The most common serious side effects in both treatment groups were low white blood cell counts (neutropenia), with or without fever, and severe diarrhea.

In September, 2013, the FDA approved Perjeta under accelerated approval, using the new endpoint, pCR, described in section 3.4 of this report, for neoadjuvant treatment in women with HER2-positive early-stage breast cancer.<sup>5</sup>

### Kadcyla (T-DM1)

The FDA also approved Kadcyla for HER2-positive, metastatic breast cancer patients, specifically those who were previously treated with trastuzumab and taxanes.<sup>6</sup> Kadcyla (T-DM1) is a combination of the antibody Herceptin (trastuzumab) and the chemotherapy DM1 (emtansine) attached together using a stable linker. The drug is an antibody drug conjugate (ADC) and is designed to target and inhibit HER2 and then deliver chemotherapy directly inside HER2-positive cancer cells.

The FDA approved Kadcyla based on results of the EMILIA trial. In EMILIA, Kadcyla alone was compared to a combination regimen of Xeloda and Tykerb (XT) in 991 women with HER2-positive metastatic breast cancer that had progressed, despite treatment with Herceptin and taxanes and/or anthracyclines. The women in the study treated with Kadcyla alone survived a median of 5.8 months longer than those who received Tykerb and Xeloda.<sup>7</sup> This difference was statistically significant. There were five adverse events leading to death in the XT arm, compared to one in the Kadcyla arm; cardiotoxicity was minimal, at less than 2% in both arms. The main Kadcyla toxicities were low platelet counts and abnormal liver function, which the investigators reported were reversible, while those on XT experienced more nausea, hand-foot disease, diarrhea and hair loss.

Kadcyla was approved with a boxed warning alerting patients and health care professionals that the drug can cause liver toxicity, heart toxicity and death. The drug also can cause severe life-threatening birth defects, and pregnancy status should be verified prior to starting Kadcyla treatment.

## 3.2 DRUG DEVELOPMENT

### CDK Inhibitor

A new agent, a CDK inhibitor, being developed by Pfizer Inc., showed encouraging results for women with ER-positive metastatic disease, when given in combination with letrozole, as reported at the 2012 San Antonio Breast Cancer Symposium (SABCS). The study was a small, phase II study of the CDK inhibitor, PD 0332991, done in two parts, with just under 200 women who had ER-positive advanced breast cancer. The drug is an inhibitor of cyclin-dependent kinases (CDK), necessary for DNA synthesis.

In the first part of the study, women were randomized to receive PD 0332991 with letrozole, or to receive letrozole alone. In the second part of the study, women were screened for a biomarker, looking for elevated levels of the CDK protein. Women who took the CDK inhibitor, an oral pill, had a median progression-free survival of 26.1 months, compared to 7.5 months for the women who took letrozole alone.<sup>8</sup> Unfortunately, the effort to identify a biomarker of response beyond ER was not successful, meaning elevated levels of CDK protein were not associated with benefit from the drug. More low white and red blood cell counts were reported with the new drug, but were readily managed and produced few complications for the women. A phase III trial of the CDK inhibitor begins in 2013.

### PARP Inhibitors

Interest in drugs that block PARP, an enzyme involved in DNA repair, has resurfaced with the knowledge that the drugs might be useful in targeting cancers driven by a mutation in BRCA. During 2013, NBCC announced it would be partnering with BioMarin Pharmaceutical on a phase III trial for one of these agents: BMN 673. Promising phase I/II results for BMN 673 were presented at the June meeting of the American Society of Clinical Oncologists (ASCO). Of the 18 BRCA breast cancer patients in the study, 12 demonstrated a clinical benefit from the drug (a partial response, a complete response, or stable disease for at least 12 weeks), which was generally well-tolerated.<sup>9</sup> The dose-limiting toxicity was Grade 4 thrombocytopenia. Myelosuppression, most of which was moderate in severity, occurred in 10-20% of patients with chronic dosing. Fatigue, nausea and alopecia were observed in 20-30% of patients.

This year, the results from five phase I and II trials were presented at the annual ASCO meeting. Results presented at ASCO in ovarian cancer for Olaparib showed a PFS of 11.2 months compared with 4.3 with placebo.<sup>10</sup> In September 2013, AstraZeneca began enrolling a phase III trial of Olaparib for both BRCA mutated breast and ovarian cancers and is partnering with Myriad on the BRCA diagnostic for the trial. Two phase I trials for Rucaparib (Clovis Oncology) were presented demonstrating activity in combination with carboplatin in BRCA solid tumors.<sup>11</sup> Rucaparib is currently being evaluated in phase II trials in breast and ovarian cancers. Four phase I trials of Veliparib (Abbot Laboratories) were presented at ASCO in BRCA solid tumors with a preliminary median PFS of 3.9 months in 11 women with advanced breast cancer.<sup>12</sup> Tesaro presented phase I results for

Niraparib in BRCA ovarian and prostate cancers, showing the drug was well-tolerated and demonstrated biological activity.<sup>13</sup> A phase III trial in BRCA ovarian cancer began enrolling in the summer of 2013.

### 3.3 LONG-TERM FOLLOW-UP

#### Tamoxifen

The ATLAS study (Adjuvant Tamoxifen—Longer Against Shorter) was the study most covered by the media during 2012, reporting a slight benefit from ten years of tamoxifen versus five, with an increase in toxicities. In this study, more than 6,800 women who had completed five years of treatment with tamoxifen for early breast cancer were randomized to continue tamoxifen for five more years or to stop treatment. The group who stopped treatment did not receive a placebo, weakening the design of the study. Compliance was approximately 80% and a benefit was found for the longer treatment, but the benefit did not show up until after the treatment was completed, in years 10-15 following diagnosis. Breast cancer mortality was 15% for the women who stopped tamoxifen at five years, compared to 12.2% for those who continued for ten years. Mortality without recurrence from causes other than breast cancer was not significantly different between the two groups. The cumulative risk of recurrence was 21.4% for women who took tamoxifen for ten years, compared to 25.1% for those who stopped. The rate of endometrial cancer was 3.1% in the ten year group, compared with 1.6% in the group that stopped at five. There also was an increased risk of pulmonary embolism in the ten year treatment group, though there were no differences in the risk of stroke.<sup>14</sup>

#### Herceptin® (trastuzumab)

The Cochrane Collaboration published a large review of eight Herceptin studies with almost 12,000 HER2-positive women with early-stage or locally advanced breast cancer. The authors concluded that there was a statistically significant improvement in overall survival, but also a statistically significant increase in the risk of congestive heart failure and left ventricular ejection fraction decline, a measure of heart function. Studies with concurrent administration (chemotherapy with Herceptin) gave similar efficacy and toxicity results to sequential studies, and two small trials that administered Herceptin for less than six months did not differ in efficacy from longer studies, but found fewer cardiac toxicities.<sup>15</sup>

Analyses from larger studies investigating the optimal duration of Herceptin treatment were presented later in the year. The HERA (Herceptin Adjuvant) trial, following more than 5,000 women, found no difference in recurrence or survival between one or two years of treatment after a median eight years of follow-up,<sup>16</sup> and the PHARE (Protocol for Herceptin as Adjuvant Therapy with Reduced Exposure) trial, which was designed to determine if six months did not give a worse outcome and followed more than 3,000 women, had results that were inconclusive.<sup>17</sup> One year of Herceptin treatment remains the standard of care.

#### Radiation Therapy

Ten year follow-up from the START (Standardization of Breast Radiotherapy) trial, looking at the schedule of radiation therapy as adjuvant treatment, was reported in 2012. The results confirmed that three weeks of radiation treatment is at least as safe and effective as the standard five-week schedule of treatments.<sup>18</sup>

#### Avastin (bevacizumab)

Avastin (bevacizumab) was approved for metastatic breast cancer through the accelerated approval process in 2008, but approval was revoked in 2011 when post-marketing trials failed to establish a long-term benefit that outweighed the risk of toxicities. However, although FDA approval for Avastin in the metastatic breast cancer setting was revoked, clinical trials of the drug continue. Results from two studies were presented at the 2012 San Antonio Breast Cancer Symposium—the BEATRICE (Bevacizumab Adjuvant Therapy in Triple-Negative Breast Cancer) trial, looking at Avastin to prevent recurrence in women with triple negative disease, and the LEA (Letrozole/Fulvestrant and Avastin) trial, looking at Avastin in

combination with hormonal treatment for first line treatment of metastatic breast cancer. In BEATRICE, a trial of more than 2,500 patients, the three year recurrence rate was virtually the same for both arms of the study, with greater toxicity in the Avastin arm.<sup>19</sup> In LEA, investigators were hoping to show that Avastin, if given without chemotherapy, would be more beneficial. But results from the trial of 380 women showed no differences in overall survival, and in fact, there was a trend toward lower survival in the Avastin arm, though this was not statistically significant.<sup>20</sup>

In addition, a Cochrane meta-analysis of Avastin studies to treat metastatic breast cancer involving more than 4,000 women was published in July 2012, and confirmed that although Avastin increased progression-free survival slightly, overall survival did not increase at all.<sup>21</sup> Also, women who received Avastin had more serious side effects, including heart problems, low white blood cell count, and blood clots.

### 3.4 TREATMENT POLICY

#### New Trial Endpoint for Drug Evaluation in Breast Cancer Trials

To expedite approvals of treatments of early-stage breast cancer, the FDA issued draft guidelines during 2012 for use of a new surrogate endpoint—pathologic complete response (pCR).<sup>22</sup> The guidelines discuss the use of pCR to support approval of drugs given before surgery (neoadjuvant). The FDA proposed defining pCR as the absence of any residual invasive cancer in breast specimens and lymph nodes at the time of surgery, following completion of neoadjuvant systemic therapy.

However, a meta-analysis looking at the relationship of pCR with long-term outcomes was also released in 2012, and failed to establish the surrogacy of pCR.<sup>23</sup> The Collaborative Trials in Neoadjuvant Breast Cancer (CTNeoBC) meta-analysis showed that individual patients who attain a pCR tended to have a more favorable long-term outcome such as event-free survival (EFS) and overall survival (OS), but the magnitude of pCR improvement between treatment arms that predicts long-term clinical benefit could not be established. Also, the association of pCR with EFS and OS differs among different tumor subtypes, with the association being strongest for aggressive tumor subtypes (HER2-positive and triple-negative tumors) compared to less aggressive tumor subtypes (hormone-receptor positive low-grade tumors).

Since the surrogacy of pCR was not established, the FDA plans to open the regulatory pathway for neoadjuvant trials via the accelerated approval process, which allows the use of a surrogate endpoint reasonably likely to predict clinical benefit as the basis of approval.<sup>24</sup> The accelerated approval process requires post-marketing studies to confirm the long-term clinical benefit.

Though this approach allows for quicker approval, it comes with the risk of approving an agent that ultimately does not demonstrate clinical benefit and in the interim exposes patients to the toxicity of therapy without certainty of benefit.

### 3.5 MOLECULAR PROFILING

#### Genomic Assays

Genomic assays to predict recurrence of breast cancer are being used increasingly in the clinic, and are affecting treatment decisions. A prospective study looking at the clinical use of Oncotype Dx found the test changed treatment decisions in 33% of cases.<sup>25</sup> A review of 29 studies on the use of Oncotype Dx and MammaPrint confirmed their cost-effectiveness compared to traditional approaches in making treatment decisions.<sup>26</sup> In other words, the cost of using the tests was made up for in reduced treatment costs. However, while several studies have confirmed the prognostic capability of the tests, or the capability that it can predict recurrence, the capability of the tests to impact overall survival from the disease has not yet been confirmed.<sup>27</sup>

Oncotype Dx produces a 21-gene recurrence score (RS) and predicts the rate of distant recurrence in patients with early-stage, ER-positive, lymph node–negative breast cancer. More recently, the company has used the test to develop a DCIS score to quantify the risk of local recurrence of ductal carcinoma in situ (DCIS) or development of invasive breast cancer for those diagnosed with DCIS. Research published in May 2013 found the DCIS score was statistically significantly associated with the risk of developing a recurrence or invasive breast cancer.<sup>28</sup> However, in an accompanying editorial, Dr. Christine D. Berg cautions there are limitations, including that it was tested in a selected subset of patients.<sup>29</sup> The clinical application of the test for the majority of women with DCIS remains to be determined.

Mammaprint, like Oncotype Dx, is for early-stage breast cancer to predict metastasis; however the test can be used for both hormone receptor-positive and hormone receptor-negative patients. Clinical use of the 70-gene signature may increase as frozen tissue is no longer required to carry out the test; rather, the test can be carried out from fresh tissue following a biopsy. Mammaprint has been validated as prognostic in trials of women not receiving adjuvant chemotherapy, but results from ongoing clinical trials are needed for prospective validation of predictive benefit from adjuvant chemotherapy. A small study of 67 patients presented in 2012 compared the results between Oncotype Dx and Mammaprint in the same patients and found significant differences.<sup>30</sup> Nearly half of the patients who received high risk scores from the Mammaprint test received a low risk recurrence score from the Oncotype Dx test.

## **3.6 MORBIDITY & MORTALITY CAUSED BY TREATMENT**

### **Leukemia Risk from Treatment for Early-Stage Breast Cancer**

Clinical trial results have indicated that adjuvant treatment for breast cancer increases the risk of developing leukemia. A review of the records from more than 20,000 women treated for early-stage breast cancer presented at the 2012 San Antonio Breast Cancer Symposium explored and quantified this risk; authors of the review found an overall cumulative risk of developing leukemia after ten years of 0.27%, or between two to three women per 1,000 women diagnosed with breast cancer.<sup>31</sup> The women who developed leukemia tended to be older, and the risk increased in those receiving chemotherapy vs. no chemotherapy, and for any radiotherapy vs. no radiotherapy. After ten years, the women who had had both chemotherapy and radiation had a 0.54% risk of developing leukemia. About ten years ago, a report from the National Surgical Adjuvant Breast and Bowel Project (NSABP) showed a 0.27% risk of leukemia after treatment with doxorubicin/cyclophosphamide combination chemotherapy.<sup>32</sup>

### **Heart Problems in Older Women Receiving Herceptin**

A review published during the year looking at Surveillance, Epidemiology and End Results (SEER) data from more than 45,000 women aged 67 to 94 diagnosed with early-stage breast cancer found that older women diagnosed with early-stage, HER2-positive breast cancer treated with Herceptin have a higher risk of heart failure than that reported in clinical trials.<sup>33</sup> The absolute incremental risk of adding Herceptin to anthracycline therapy was 17.9 per 100 patients in the study, compared to 1.6 per 100 patients for heart failure and 7.2 per 100 patients for cardiomyopathy in a meta-analysis of four Herceptin trials with all ages.



# 4 | BREAST CANCER PUBLIC POLICY

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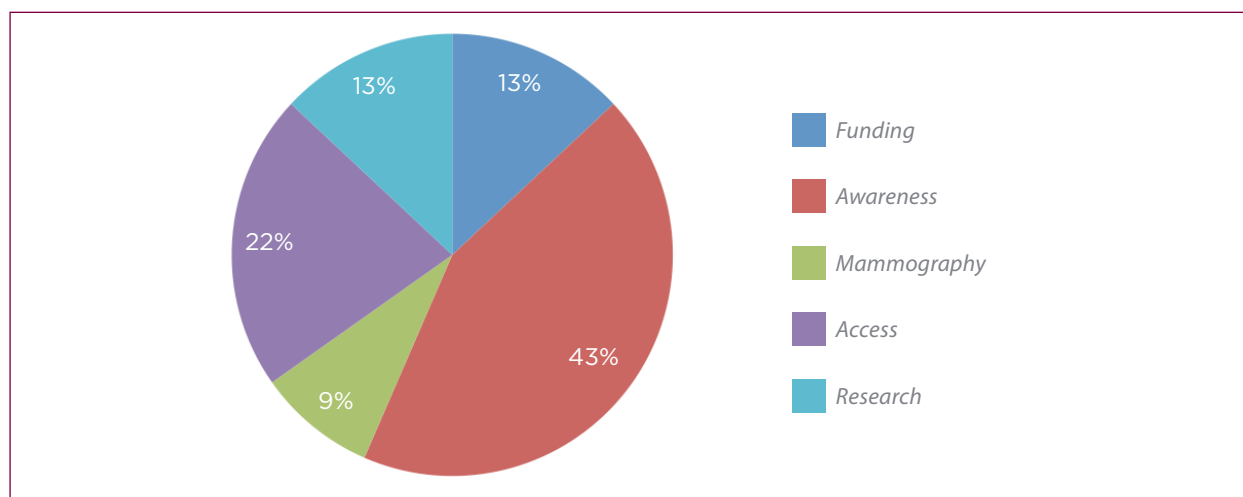
**2013**

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## 4 | BREAST CANCER PUBLIC POLICY

During the 112<sup>th</sup> Congress, which lasted from 2011 through 2012, 10,437 resolutions and bills were introduced in the Senate and House of Representatives.<sup>1</sup> Of these, 23 resolutions and bills contained the words “breast cancer” and had some relevance to the disease.<sup>2</sup> Other policies that would affect breast cancer but did not specifically reference the disease are not included in that number. These include various bills around the *Patient Protection and Affordable Care Act*, appropriations bills for the National Institutes of Health (NIH) and the Department of Defense (DOD) Breast Cancer Research Program (BCRP); as well as broad public health legislation such as the *Food and Drug Administration (FDA) Safety and Innovation Act* (S. 3187), the bill passed in 2012 to reauthorize the prescription drug user fee program, commonly referred to as PDUFA, at the Food and Drug Administration (FDA).



**Figure 1.** Resolutions and Bills introduced in the 112<sup>th</sup> Congress which included the words “breast cancer”

**Data Source:** The Library of Congress THOMAS; 2013. <http://thomas.loc.gov/cgi-bin/thomas>. Accessed July 29, 2013.

Of these 23 resolutions and bills, the references in nine bills and three resolutions (52%) focus on the intertwined areas of breast cancer awareness and mammography.<sup>3</sup> They are:

- *National Defense Authorization Act for Fiscal Year 2012* (H.R. 1540)
- *Mammogram and MRI Availability Act of 2011* (H.R. 1784)
- *To award a Congressional Gold Medal to Dr. Balazs “Ernie” Bodai in recognition of his many outstanding contributions to the Nation, including a tireless commitment to breast cancer research* (H.R. 3003)
- *Breast Density and Mammography Reporting Act of 2011* (H.R. 3102)
- *National Defense Authorization Act for Fiscal Year 2013* (H.R. 4310)

Of these 23 resolutions and bills, the references in nine bills and three resolutions (52%) focus on the intertwined areas of breast cancer awareness and mammography.<sup>3</sup>



- *Armed Forces Breast Cancer Research Act of 2012* (H.R. 4869)
- *Breast Cancer Patient Education Act of 2012* (S. 3628/H.R. 5937)
- *Recognizing the importance of breast cancer early detection efforts* (H. Res. 234)
- *Supporting efforts to raise awareness of, improve education on, and encourage research on inflammatory breast cancer* (H. Res. 796)
- *A resolution supporting early detection for breast cancer* (S. Res. 144)
- *A resolution honoring the life and legacy of Evelyn H. Lauder* (S. Res. 335)

This surpasses the 40% found in the breakdown of the 828 resolutions and bills related to breast cancer, including two executive actions, introduced between 1991 and 2011 as reported in the **Breast Cancer Deadline 2020**<sup>®</sup> 2011 Progress Report, *Ending Breast Cancer: A Baseline Status Report*.

### Access

Five of the 23 (more than 20%) were bills categorized as improving access to health care or medical devices for breast cancer survivors and those at risk of the disease. This category includes the *Breast and Cervical Cancer Prevention and Treatment Improvement Act of 2011* (H.R. 2135), which would eliminate funding limitations for services provided under the *Breast and Cervical Cancer Prevention and Treatment Act of 2000* for the territories of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa. Other bills in this category are:

- *Breast Cancer Patient Protection Act of 2011* (H.R. 111)
- *Breast Cancer Patient Equity Act of 2011* (S. 1217/H.R. 2233)
- *Breast Cancer Recovery Improvement Act* (H.R. 2510)

### Research Funding

Three of the 23 (13%) were bills that appropriate specific funds to support breast cancer research. Two of the three bills in this category (S. 384/H.R. 466), continue the *Breast Cancer Research Semipostal*, a first-class stamp, which can be purchased on a voluntary basis by the public. Net revenues from the sales of the stamp are provided to two designated federal agencies, the DOD BCRP and NIH, to support breast cancer research. The *Taxpayers' Cancer Research Funding Act of 2011* (H.R. 3466), which would allow taxpayers to designate on their tax returns a \$5 contribution to a newly created Breast and Prostate Cancer Research Fund, was the third bill in this category.

### Research Conduct

Three of the 23 (13%) were bills which specify the quantity and conduct of research. The focus of these laws includes areas to be prioritized, exposures examined and population subgroups defined. The [Accelerating the End of Breast Cancer Act](#) (S. 3237/H.R. 3067) falls into this category. It was designed and advocated for by NBCC, is a vital component of **Breast Cancer Deadline 2020**<sup>®</sup>, and defines an important role the federal government must play to know how to end breast cancer. The *Triple-Negative Breast Cancer Research and Education Act of 2011* (H.R. 6417) would require additional research on triple-negative breast cancer at NIH and the dissemination of additional information on triple-negative breast cancer to the general public and health care providers by the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA).

## Legislation Enacted

Of the 23 resolutions and bills with the words “breast cancer” introduced, three bills became law.<sup>4</sup> Two were National Defense Authorization Acts. These bills authorize yearly activities for the Armed Services, including those related to breast cancer, and must be passed annually for these activities to continue and be funded. The only piece of legislation among these that dealt entirely with breast cancer was S. 384, legislation to continue a first-class stamp, the *Breast Cancer Research Semipostal*, for an additional 4 years. The remaining resolutions and bills, including the *Accelerating the End of Breast Cancer Act* (S. 3237/H.R. 3067), in Congressional parlance, “died in Committee” and must be reintroduced in the 113<sup>th</sup> Congress, which began in January 2013.

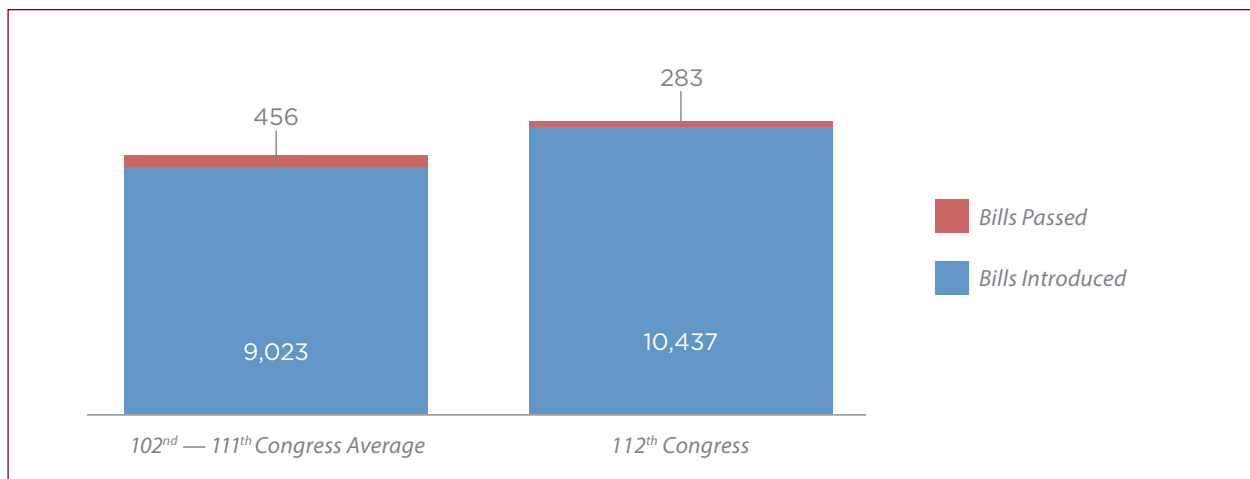
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Of the 23 resolutions and bills with the words “breast cancer” introduced, three bills became law.<sup>4</sup>

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In addition, although not specifically mentioning breast cancer, bills appropriating funding for cancer research, including breast cancer research, through the DOD BCRP and at the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), were enacted into law in both 2011 and 2012. The Department of Defense Appropriations Act for FY2011 provided \$150 million for the DOD BCRP, with \$120 million provided for the program by the FY2012 Act.<sup>5</sup> Of the funding provided to the NIH by the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts, NIH reported that \$625 million was directed to breast cancer research in FY2011 and \$602.7 million in FY2012.<sup>6</sup>

Since 1991, for each Congress, an average 9,023 pieces of legislation have been introduced in the Senate and House of Representatives,<sup>7</sup> with 456 or slightly more than 5% becoming law<sup>8</sup>. During the 112<sup>th</sup> Congress, 10,437 pieces of legislation were introduced; only 283<sup>9</sup> (less than 3%) became law (Figure 2). This is the lowest ratio of any Congress since 1948 when scholars began tracking congressional productivity.



**Figure 2.** Total Pieces of Legislation Introduced Compared with the Total Pieces Which Became Law

**Data Source:** The Library of Congress THOMAS; 2013. <http://thomas.loc.gov/home/LegislativeData.php?&n=PublicLaws&c=102-112>. Accessed August 5, 2013.

# 5 | BREAST CANCER RESEARCH

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## 5 | BREAST CANCER RESEARCH

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The total amount of funding directed to breast cancer research by the US Government, both through the National Cancer Institute (NCI) and the Department of Defense (DOD) Breast Cancer Research Program (BCRP), and by the largest private funder, Susan G. Komen, has decreased during the last two years. In 2012, NCI directed \$602,728,719 to breast cancer research, down by almost \$30 million from 2010.<sup>1</sup> NCI awarded \$631,228,554 to breast cancer research during 2010 and \$625,059,900 during 2011. The DOD BCRP awarded \$98,606,123 during 2012, down by \$40 million from 2010.<sup>2</sup> The DOD BCRP awarded \$138,190,175 in grants during 2010 and \$126,830,151 during 2011. Susan G. Komen awarded just over \$42 million in grants for 2013, down \$15 million from 2011.<sup>3</sup>

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The total amount of funding directed to breast cancer research by the US Government, both through the National Cancer Institute (NCI) and the Department of Defense (DOD) Breast Cancer Research Program (BCRP), and by the largest private funder, Susan G. Komen, has decreased during the last two years.

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Although maintaining adequate funds for research is important, equally important is monitoring how the research funds are being spent. Is there an overall strategy for allocating funds in the areas that will lead to ending the disease? Is the funding focused, efficient, one grant award building upon another, leading in the same direction? Or are the awards focused in many different directions, with no mission-driven approach?

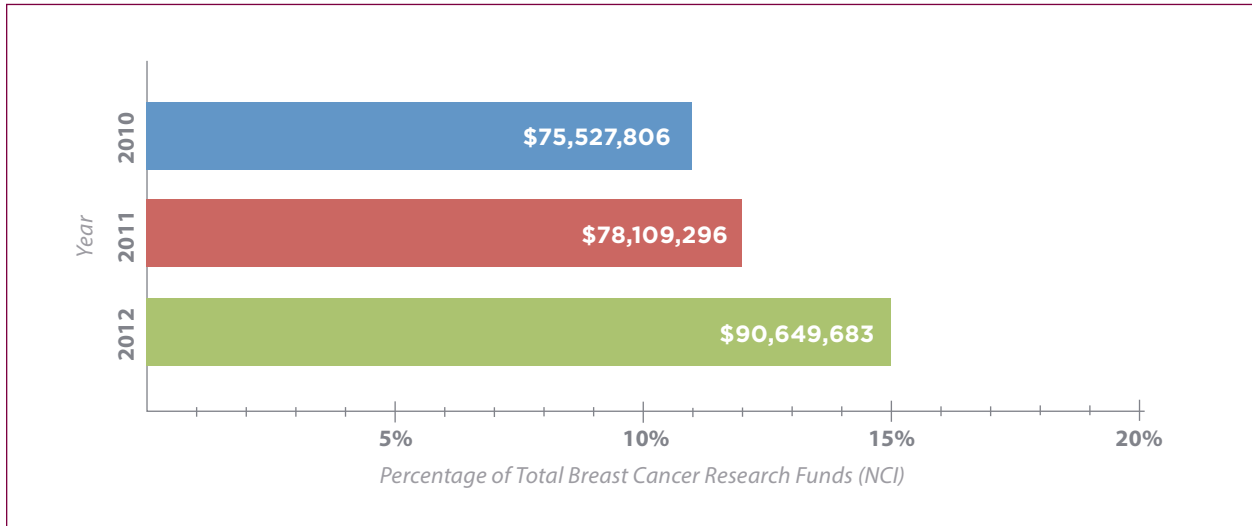
NBCC is currently working with SAGE Bionetworks on an in-depth analysis of breast cancer research funds and outcomes over the last five years, particularly focused in the area of metastasis research. The results of this analysis will be reported later this year. Here we report on some broad generalizations regarding research grants awarded by the US government, based on Common Scientific Outline (CSO) coding of research. Susan G. Komen no longer reports their grants within the seven CSO categories. As outlined in the last Progress Report, the seven broad areas include biology; etiology (causes of cancer); prevention; early detection, diagnosis, and prognosis; treatment; cancer controls, survivorship, and outcomes research; and scientific model systems. Research included in the biology category looks at the biology of how cancer starts and progresses, and metastasizes, as well as normal biology relevant to these processes.<sup>4</sup>

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Looking at research funding through NCI and the DOD BCRP, the proportion of research funds coded within biology, and specifically in the area of breast cancer progression and metastasis, has increased.

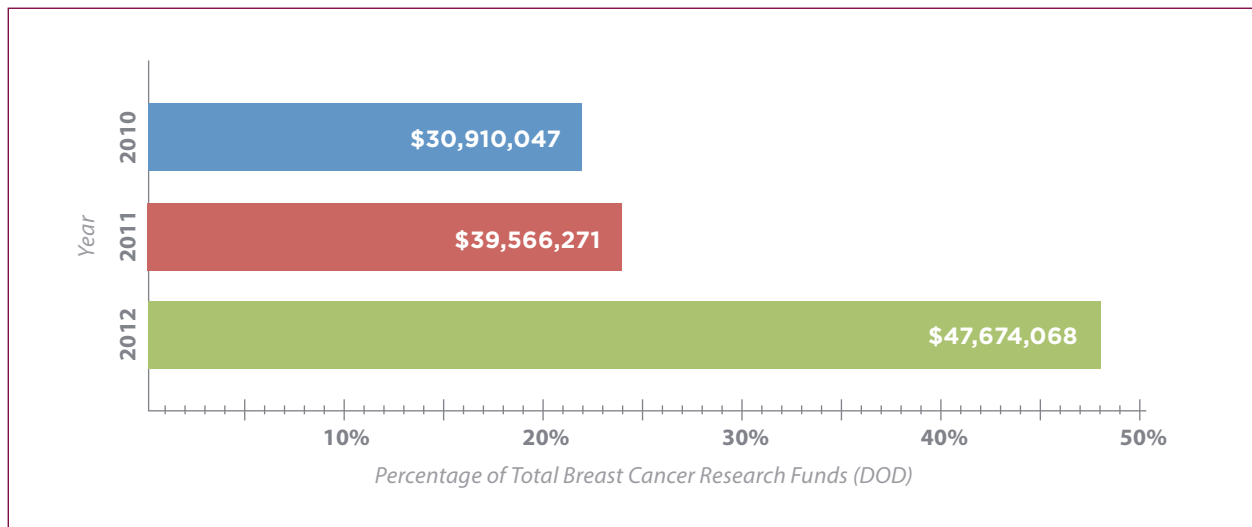
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Looking at research funding through NCI and the DOD BCRP, the proportion of research funds coded within biology, and specifically in the area of breast cancer progression and metastasis, has increased. Approximately 15% of the funds awarded by NCI for breast cancer research in 2012 were coded under progression and metastasis, up from 11% in 2010 (Figure 3).<sup>1</sup> Approximately 48% of the DOD BCRP research funds for 2012 were coded under progression and metastasis, up from 22% in 2010 (Figure 4).<sup>2</sup>



**Figure 3.** Percentage of Breast Cancer Research Dollars Allocated to Research on Breast Cancer Progression & Metastasis (NCI)

**Data source:** National Cancer Institute Funded Research Portfolio at <http://fundedresearch.cancer.gov/nciportfolio/>



**Figure 4.** Percentage of Breast Cancer Research Dollars Allocated to Research on Breast Cancer Progression & Metastasis (DOD)

**Data source:** Department of Defense Breast Cancer Research Program: Funded Research FY 2010 - 2012, obtained through personal communication with program manager

As outlined previously, significant resources are directed at breast cancer drug development through the pharmaceutical industry, but the specifics are not available publicly. ClinicalTrials.gov collects information about federally and privately supported research once it reaches the clinical stage. On August 7, 2013, there were 150,162 clinical trials listed; 5,439 were listed as breast cancer trials and 31% (1,706) of these were listed as trials for metastatic breast cancer.<sup>5</sup>



# 6 | BREAST CANCER ADVOCACY

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## 6 | BREAST CANCER ADVOCACY

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Today, there are thousands, if not tens of thousands, of non-profit groups in this country that focus on breast cancer, with advocates involved in a wide range of activities, ranging from helping to shape the breast cancer research agenda and federal and state legislation, to serving as liaisons between patients and physicians.

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As described in previous Progress Reports, the National Breast Cancer Coalition (NBCC) was founded in 1991 by women who sought to go beyond awareness and mammography to end breast cancer. Today, there are thousands, if not tens of thousands, of non-profit groups in this country that focus on breast cancer, with advocates involved in a wide range of activities, ranging from helping to shape the breast cancer research agenda and federal and state legislation, to serving as liaisons between patients and physicians.

NBCC continues to encourage advocate involvement that will make a difference in bringing an end to the disease by empowering advocates with knowledge and skills, and a focus on evidence-based approaches. It is of utmost importance that advocates speak for the best interests

of women at risk of or with breast cancer, not in the best interest of physician groups, industry or even non-profit groups. Breast cancer is big business, and many interested parties are seeking to leverage the advocate voice to protect or influence their own interests. NBCC continues to train advocates to move beyond simply being a “face” of breast cancer, to look at the evidence, to be discerning, and ultimately to focus on changing the status quo so that women’s needs and the need to end this disease are the driving force.

Advocacy can be manipulated, and uneducated advocacy can be harmful.

A British paper recently published the contents of a memo circulating between European and US pharmaceutical trade associations outlining a strategy for protecting their interests regarding issues of data sharing—by leveraging the influence of patient advocacy groups.<sup>1</sup> Fortunately, there is not much evidence that they have been successful in recruiting patient groups to promote their own interests in preventing data sharing, but the documented strategy to do so is concerning.

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It is of utmost importance that advocates speak for the best interests of women at risk of or with breast cancer, not in the best interest of physician groups, industry or even non-profit groups.

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NBCC has a history of seeking meaningful advocate involvement in all breast cancer related decisions.

During the 1990s, NBCC conceived of the *Breast Cancer and Environmental Research Act* as a result of two Environmental Policy Summits, and pushed for enactment of the bill beginning in 1999. The bill called for the creation of a national research strategy and a program to competitively fund collaborations of researchers and community groups to identify overarching questions and then conduct research to answer them. Unfortunately, with the support of groups outside NBCC, that was not the bill that Congress passed. Instead, a 21-member Interagency Breast Cancer and Environmental Research Coordinating Committee



(IBCERCC) was ultimately formed to survey federal research and to make recommendations. After two years of meeting, the Committee released a report in 2013 which called on the federal government to prioritize prevention research.<sup>2</sup> The committee recommended the research be collaborative, reaching across different scientific disciplines and different federal agencies, and that it involve stakeholders. The report, and its recommendations, now rests on the desk of the Secretary of Health and Human Services.

A different type of advocacy was represented over the past year when the actress Angelina Jolie went public with her decision to undergo genetic testing and a prophylactic mastectomy. Her decision created an unfortunate shift in the conversation about breast cancer. While her choice is a personal one and understandable on that basis, her public revelation has resulted in much misinformation and unnecessary fear, as described in section 7 of this report.

Advocacy also extends to the conduct of research. NBCC led a petition addressed to Genentech expressing the concern of nearly 60 organizations over the design of the adjuvant clinical trials of T-DM1. The petition, and surrounding discussions, was designed to convince the company to include a systemic chemotherapy-free arm in the trial. For an explanation of the issues, see sections 3 and 7 of this report. In sum, because T-DM1 is both a targeted therapy and chemotherapy, trials to test its efficacy and toxicity in early-stage breast cancer provide a chance to move away from the usual systemic chemotherapy and its negative side effects.

Advocacy again had an impact on research with a Supreme Court ruling in 2013 that highlighted the issue of patenting genes associated with breast cancer risk. The Supreme Court ruled that human genes cannot be patented in response to *Association for Molecular Pathology et al v. Myriad Genetics, Inc.*, though in somewhat of a compromise the Court ruled that synthetic versions of genes could be patented. NBCC advocates provided meaningful input into this issue since the technology first emerged. NBCC's position can be found in the 2000 letter to the Commissioner of Patents and Trademarks stating that patenting naturally occurring genes and disease-causing mutations stifles the research process. NBCC strongly believes that "gene patenting should not impede biomedical research progress. To realize the full potential of genetic research, scientists should have free access to the raw fundamental data on the human genome. Such unencumbered access would benefit the public by providing the greatest opportunity for scientific advancements against diseases."<sup>3</sup> NBCC also expressed concern that allowing patents to be held and allowing companies to have sole possession of gene tests, would "raise the cost of these tests to astronomical levels, making the tests too expensive for patients or for wide scale research." Other groups such as Breast Cancer Action, a San Francisco based organization, were co-plaintiffs along with several medical organizations, physicians, academic researchers, cancer survivors, and patient advocates in *Association for Molecular Pathology et al v. Myriad Genetics, Inc.* which was first filed by the American Civil Liberties Union in 2009.

Another Supreme Court case is relevant to advocacy and breast cancer. Following the passage of the *Patient Protection and Affordable Care Act of 2010*, NBCC joined with other leading disease and disabilities advocacy groups on an amicus brief supporting the constitutionality of key provisions of the legislation being challenged in courts across the nation. Through the brief and in the press, NBCC worked to let all know why this legislation was so important for women living with and at risk for breast cancer and why the important protections it offers are vital to reaching the **Breast Cancer Deadline 2020**<sup>®</sup> goal of knowing how to end breast cancer by January 1, 2020. In June 2012, the Supreme Court affirmed the constitutionality of the law.

Strong advocacy had an additional effect on access over the past year. NBCC ensured meaningful patient participation on key committees of the Patient-Centered Outcomes Research Institute (PCORI). The *Patient Protection and Affordable Care Act of 2010* established PCORI as an independent, not-for-profit entity. Its mission is to help people make informed health care decisions and improve health care delivery by producing high-integrity, evidence-based information that derives from research guided by patients, caregivers and the broader health care community.

The persistence of advocates resulted in the statutory language of the Act, which supports a strong patient-centered orientation in terms of patient participation on key committees, in the grants review process and in integrating public comment.

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To implement the advocate participation requirements of its mandate, PCORI has looked to NBCC as a model for effective advocacy training.

To implement the advocate participation requirements of its mandate, PCORI has looked to NBCC as a model for effective advocacy training. This advocacy work has had an impact. PCORI has invested \$88.6 million to fund 51 patient-centered comparative clinical effectiveness research projects all of which were reviewed by panels that included 50% stakeholders and 50% scientists.

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In addition, the PCORI Patient-Stakeholder Mentor Program was inspired by the Project LEAD® mentor program. Project LEAD® graduates have served as grant reviewers in every PCORI funding cycle and some are now serving on PCORI leadership committees. The lead PCORI trainers are Project LEAD® faculty or former staff members. Its key facilitators report that the sizable representation of Project LEAD® graduates as PCORI reviewers has brought measurable strength to PCORI's peer review process.<sup>4</sup>

In the spring of 2013, Project LEAD® graduates helped to design the PCORI Patient and Stakeholder Training and Support Program. In

# 7 | ADVOCATE PERSPECTIVE

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## 7 | ADVOCATE PERSPECTIVE

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As breast cancer advocates, our mission is to end breast cancer. To save lives. We have all lost far too many loved ones, too many friends and family and we want it to stop. That is the lens through which we view what has happened in breast cancer throughout the past year. The results are disappointing. Yet we see some promise that the tide is indeed turning as more of the breast cancer community focuses on the goals of **Breast Cancer Deadline 2020**<sup>®</sup>—preventing people from getting the disease and stopping people from dying of it.

At the same time, powerful voices continue for the status quo and they are joined by others whose stories pull attention to misleading information that slows down the search for meaningful answers to breast cancer. But as is often the case, persistence, with a constant focus on the goal, will force a change in direction. The role of advocates is ever more important as we are the ones who speak only to the needs of women with or at risk of breast cancer.

As happens each year, the issue of mammography was the topic of much of the discussion in breast cancer. NBCC has questioned the role of mammography screening for many years now. We have reviewed and reported on the evidence many times. The point of screening should be to save lives, but the conversation

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The point of screening should be to save lives, but the conversation has made the focus that of finding more cancer.

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has made the focus that of finding more cancer. If those same women die at the same time they would have without screening, finding their cancer early is not success. In fact, it can be a major step back, as we have subjected those women to toxic treatments that may have lifelong effects or even take their lives. New data this year demonstrated even more vividly how misplaced the emphasis on early detection has been. But throughout the past year, it appears that the reaction of some in the news media, the advocacy community and the public has begun to change.

The conversation began to change noticeably when the work by Dr. H. Gilbert Welch, et al, published during the past year and discussed in section 2 of this report, gave rise to media coverage that was more balanced than that of the past.<sup>1,2</sup> Peggy Orenstein's personal narrative explaining her changing views on breast cancer screening published in *The New York Times Magazine* on April 25, received wide coverage.<sup>3</sup> This not only helped change the conversation about screening; it also made the public more aware of the fact that treatments for breast cancer are harmful. And they do not help many women.

What will help? More of a focus on primary prevention. How do we stop women and men from getting breast cancer? As noted in our last Progress Report, the amount of funding for this area of research is quite low. And we need to also figure out why women die of breast cancer. We need to push for treatments that will save lives. The goal is treatment that results in a cure without toxicity. Often it seems to advocates that the goal of the large portion of the breast cancer world is to get as many new drugs as possible into patients, regardless of how effective or toxic they are. We have looked, with alarm, at the FDA's move

to approve drugs on what is known as surrogate endpoints (see section 3 of this report for a detailed explanation)—results that have not been proven to have major and often, any, clinical benefit.

When the bar is set low, that is what many stakeholders aim for. With breast cancer drugs, the bar is often set at slowing tumor progression, which may or may not increase length of life. And may or may not help with quality of life. It is promising that this past year members of the American Society of Clinical Oncology (ASCO) expressed concern about new drugs being brought to market based on incremental benefit found in clinical trials, such as tumor progression, which do not always result in a benefit for patients in the clinic, especially when those drugs are associated with increased toxicity. ASCO formed four working groups to look at the issue and included clinicians, researchers and advocates.

The breast cancer working group decided to focus on trials for previously untreated, metastatic, triple-negative breast cancer, with overall survival as the meaningful trial endpoint. The group recommended that a four to five month improvement in overall survival, with minimal toxicity, would be considered a clinically meaningful benefit.<sup>4</sup> A recent pharmaceutical industry analysis estimates that, based on current trends, median survival for metastatic breast cancer will increase by six months by the year 2021.<sup>5</sup> These incremental advances are considered “innovation” and “meaningful” by many in the world of breast cancer. While welcome, to NBCC advocates they are still too low a bar. We do understand that the incremental benefits accumulated through the years have contributed to the reduced mortality rate. But that reduction is small, has been decreasing and does not take into account the toxicities of the treatments.

As explained elsewhere in this report, most drugs are approved because they show a difference in weeks or months in “progression-free survival.” And that “benefit” does not mean a person lived an hour longer because of the drug or had a better quality of life. We also have to remember that a certain percentage of breast cancers resolve on their own, with no treatment. Investigators in Norway looking at populations of screened and unscreened women estimated that 22% of women diagnosed with breast cancer would have had their tumors regress if left alone.<sup>6</sup> More recently, it was reported that an analysis of Surveillance, Epidemiology and End Results (SEER) data looked at ten different cancers and found that married people were 17% less likely to present with metastasis. For breast cancer, the benefit of marriage was significantly better than the reported benefits of chemotherapy on survival.<sup>7</sup> These findings should be a large part of the conversation in breast cancer. They are not. So the rush to fund research looking for new drugs and the push to get them approved sooner must be viewed in the entire context of breast cancer, including the increasing cost to the health care system and to people’s lives.

NBCC advocates work with researchers and industry to move more rapidly to drugs that will have true benefit for patients, with no or very limited toxicity. That issue—toxicities from treatments—is the central problem of overdiagnosis and overtreatment. NBCC wants to change the way clinical trials are done to take advantage of advances in technology and

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NBCC wants to change the way clinical trials are done to take advantage of advances in technology and knowledge and reduce the toxicities women are subjected to.

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knowledge and reduce the toxicities women are subjected to. NBCC’s advocacy around the development and clinical trials for T-DM1 is a prime case in point. One important way to minimize toxicity is to eliminate systemic chemotherapy that affects all cells, cancer and healthy. For too long clinical trials have been of the “add on” variety, so that new drugs and other interventions are merely added on to the existing systemic, toxic therapy that makes up “standard of care.” Adding on increases toxicity and typically results in minimal, if any, improvement in efficacy.

A promise of targeted therapy is to minimize toxicity through a drug targeted directly and only to cancer cells, sparing normal cells. During the past year, NBCC advocates led efforts to petition Genentech, expressing concerns over the design of the adjuvant clinical trials of Kadcyla (T-DM1), a drug recently approved for use in women with metastatic HER2-positive breast cancer. Trials to test its efficacy and toxicity in early breast cancer provided a real chance to move away from the usual systemic chemotherapy and its negative side effects, because the drug delivered both toxic chemotherapy and targeted therapy, in one package, directly to cancer cells.

[The petition, signed by 60 groups](#), and the surrounding discussions with the FDA and the company, were designed to convince the company to include a systemic chemotherapy-free arm in the trial.

Unfortunately, the response from the drug maker, Genentech, was that while the leadership understood NBCC's position and does hope to get to a point where Kadcyla could be given alone to realize the potential of targeted therapy, they were not willing to take this step at this time. Therefore, standard of care will continue to follow the "add-on" model with the attendant life-threatening toxicities and questionable benefit. It could take years for other trials to answer the question of whether Kadcyla would be best given without systemic chemotherapy for adjuvant use. Another example of powerful forces pushing for the status quo.

The status quo also includes the issue of funding for breast cancer research, one that seems simple on its face. Many voices urge increased funding everywhere for research. But the reality is more complex. NBCC's perspective is that increased funding may not be helpful; rather it is how the funds are being spent and what research is occurring that are

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NBCC's perspective is that increased funding may not be helpful; rather it is how the funds are being spent and what research is occurring that are the important issues.

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the important issues. As our Progress Report makes clear this year, the percentage of funding for research into metastatic breast cancer—which is responsible for more than 90% of breast cancer deaths—has increased significantly. That statistic is based on a coding format employed by government agencies and until recently, some private funders. It does not tell us what issues are being addressed. And the statistics, while encouraging in the area of metastatic research, are troubling when you look at the issue of primary prevention.

In research, however, during the past year we have seen a movement toward more innovative ideas, as can be seen in the proposals funded through the [Department of Defense Breast Cancer Research Program](#) and programs such as the [Provocative Questions Project at the National Cancer Institute \(NCI\)](#).

At the same time, the behavior of a number of stakeholders made clear that achieving the goals of **Breast Cancer Deadline 2020**<sup>®</sup> remains a daunting task. As advocates, we must look at ourselves also. As pointed out above and in section 6 of this report, advocacy can be misplaced and abused. Moreover, there is diversity of opinion among advocacy organizations. And not all advocacy is informed.

The story behind the *Breast Cancer and Environmental Research Act* is instructive. As described in section 6 of this report, while NBCC designed the original legislation and pushed hard for its passage, other breast cancer groups supported congressional efforts to weaken the bill. That resulted in enactment of the weakened bill which resulted in little more than yet another white paper, in this instance, *Breast Cancer and the Environment: Prioritizing Prevention*. NBCC is disappointed that in 2013 there is nothing more

than another report. This report follows the 2011 release of the Institute of Medicine report *Breast Cancer and the Environment: A Life Course Approach*; the 2010 President's Cancer Panel report, *Reducing Environmental Cancer Risk: What We Can Do Now*; and the 2009 report from the National Conversation on Public Health and Chemical Exposures, *Addressing Public Health and Chemical Exposures*; among others.

We all know that breast cancer is a complex disease. Throughout the many decades breast cancer has been in the public awareness, much of the information the public received has been reduced to often misleading sound bites. "Early detection saves lives." "Funding for research will cure breast cancer." Reducing complex information to sound bites often results in misinformation.

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Reducing complex information to sound bites often results in misinformation.

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This past year, driven by a personal decision made by a celebrity and exacerbated by the media, a misleading message drove the national conversation around breast cancer for a while. The actress Angelina Jolie publicly shared her decision to undergo genetic testing and a prophylactic mastectomy.<sup>8</sup> Her choice was a personal one and understandable on that basis, but her public revelation resulted in much misinformation and unnecessary fear.

Few women have the genetic mutation that caused Jolie to act, but many extrapolated Jolie's personal situation to be the solution for all women facing the risk of breast cancer. Some began advocating to make genetic testing available for all women around the world. While this is helpful to Myriad Genetics, the company with a patent on the test, it is a great disservice to women. The vast majority of women do not fall into the group with the genetic mutation. For those who do, we need to change the landscape so that we are not left with a choice between scary uncertainty and disfiguring, life-altering surgery. Or left with the issue of breast cancer at all. And, as we know, the urgent need for women in poor countries is access to effective drugs, radiation therapy and pathology services, and to have the infrastructure necessary to deliver quality health care.

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Advocates must continue to do the hard work of critically analyzing policies and research and challenging the status quo in a meaningful way.

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NBCC has always focused on the scientific evidence women need to make educated decisions about their own health. Through **Breast Cancer Deadline 2020**<sup>®</sup>, we are focusing on changing the conversation in breast cancer to what really matters—for example, true prevention for all, not just lowering risk. We must act so that the projected number of annual worldwide deaths in 2030 is reduced from 747,802 to a figure closer to 0. Genetic testing, for example, will not make a noticeable dent in that statistic.

Outside of NBCC's work in **Breast Cancer Deadline 2020**<sup>®</sup>, much of what we report this year is more of the same. The status quo as described here and in previous Progress Reports has been developed over more than 40 years and has been designed to achieve incremental, if any, progress.

Advocates must continue to do the hard work of critically analyzing policies and research and challenging the status quo in a meaningful way. That critical analysis must apply to all issues in breast cancer, including drug approval, the substance of the research, study design, the priorities set, the allocation of funding, access to care and advocacy itself.





**8 | PROGRESS TOWARD  
BREAST CANCER DEADLINE 2020®**

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# 8 | PROGRESS TOWARD BREAST CANCER DEADLINE 2020®

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To renew the sense of urgency to its mission and to refocus global efforts on ending breast cancer and saving lives, the National Breast Cancer Coalition has set a deadline to know how to end breast cancer by January 1, 2020—**Breast Cancer Deadline 2020®**. NBCC has a strategic plan of action to achieve the deadline. The plan focuses on primary prevention, stopping women from getting breast cancer, and understanding and preventing metastasis (the spread of cancer), which is responsible for 90% of breast cancer deaths.

NBCC's [Blueprint for Breast Cancer Deadline 2020®](#) describes how the organization is harnessing the energy, resources and leadership around the world to achieve **Breast Cancer Deadline 2020®**. The blueprint is designed around three goals:

1. research needed to end breast cancer;
2. global access to the necessary information and lifesaving interventions; and
3. the influence of leaders everywhere in the strategies to end breast cancer.

NBCC is pointing the way, creating and facilitating collaborations, formulating and implementing plans of action, and identifying and pushing for the policies needed. Ultimately, success depends upon those outside NBCC—leaders, researchers, public officials, the philanthropic and funding community, breast cancer advocates, and the general public.

What does the end of breast cancer by 2020 mean? By January 1, 2020, we must understand how to prevent people from getting breast cancer in the first place and how to prevent them from dying from the disease. NBCC has a strategic plan in place to achieve its mission, is implementing much of it, and has obtained support and partnership from leadership among all key stakeholder groups.

During the past year, NBCC continued to implement its strategic plan of action in pursuit of the goals outlined in the Blueprint. Specific achievements are summarized below.

## 8.1 RESEARCH

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NBCC is leading an effort among all stakeholders involved in research, particularly the scientific community, to create synergy and develop partnerships to advance the pace of research. The goal is to take what is known and build upon it for the sole purpose of ending the disease. In pursuit of these goals, NBCC has accomplished the following.

What does the end of breast cancer by 2020 mean? By January 1, 2020, we must understand how to prevent people from getting breast cancer in the first place and how to prevent them from dying from the disease.

### Strategic Summits

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To assess the extent of the problems, identify meaningful questions and determine the individuals and tools needed to answer them, [NBCC hosted two strategic summits](#) in 2011 bringing together stakeholders and other visionaries: one on primary prevention, the other on preventing metastasis. NBCC has refined and prioritized the

recommendations from those summits, and is launching additional catalytic projects to address those priorities that will achieve the deadline. Future summits will be planned as needed.

Priority issues identified through summits and other **Breast Cancer Deadline 2020®** work are the subject of catalytic projects, [collectively called the Artemis Project®](#), an innovative, advocate-led, mission-driven model that ensures appropriate focus on the end result. For each catalytic project, NBCC forms collaborations on specific issues to define solutions and implement research plans to achieve them. The work takes place within an infrastructure maintained by NBCC which includes in-person meetings and use of the web and social media to exchange data and information and facilitate collaboration. Within this infrastructure, project participants develop, implement and oversee research plans.

### **Artemis Project® for a Breast Cancer Preventive Vaccine**

The topic chosen for the first Artemis Project® was a five year development plan for a breast cancer preventive vaccine, because of the potential impact on breast cancer and the progress made in the field of immunology.

In 2011, working teams were formed around four areas critical for vaccine development:

- Identification and prioritization of antigens (vaccine targets for immunization);
- Characterization of the immune system response to breast cancer;
- Development of strategies to evaluate efficacy relevant to breast cancer subtypes; and
- Development of a plan to ensure safety.

At the 2012 annual meeting, and throughout the year, project members focused on the first stages of the vaccine development program—antigen identification and evaluation—and on developing strategies and models for determining what the vaccine needs to accomplish. A plan of action was developed around antigen identification in the areas of pathogens; self-encoded, neo-antigens; native self-antigens; and immune profiling.

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Within each Artemis Project®, NBCC awards seed grants to allow scientists to begin the research required in each of the key areas identified in the collaborative research plans.

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Within each Artemis Project®, NBCC awards seed grants to allow scientists to begin the research required in each of the key areas identified in the collaborative research plans. Seed funding allows researchers to apply for the majority of the grants from existing resources such as government, private foundations and corporations.

To search for neo-antigens, or protein targets that spontaneously develop as cancer begins and progresses, through generous support of the National Philanthropic Trust (NPT), [NBCC awarded a seed grant](#) for nearly \$200,000 to Dr. Paul Spellman and Dr. Joe Gray of Oregon Health and Science University. These investigators have begun work to identify possible vaccine targets using existing and developing human genomic data within different breast cancer subtypes, and will generate a prioritized list of about 50-100 potential breast cancer specific targets to be considered for incorporation into a preventive vaccine. While this work focuses on data from invasive breast cancer samples, other team members are carrying forward efforts to evaluate the genomic data from DCIS samples for comparison.

To carry forward the work of identifying pathogens or viruses, [a second seed grant was awarded](#) to Dr. Paul Ewald, Professor of Biology and Director, Program on Disease Evolution at the University of Louisville, and

Dr. Vladimir Belyi, Assistant Professor at the Cancer Institute of New Jersey, Robert Wood Johnson Medical School to look for associations between breast cancer and an extensive library of pathogens within genomic datasets from breast tumor samples. The outcome of that study will lead to the identification of appropriate target vaccine candidates.

To search for self-antigen targets, or targets that already exist in humans but are over-expressed in cancer cells, advocates have combed the literature for existing information on breast cancer self-antigens, and have developed a list of priority candidates.

A focused meeting was held in October 2012 to delve more deeply into immune profiling for identifying vaccine targets, and to consider how all identified candidates will be evaluated and prioritized. Many questions regarding the immune system response to a vaccine must be addressed before the next steps can take place in formulating a vaccine. To tackle these issues, NBCC organized a one-day meeting of Artemis Project® immunology team

members along with additional immunology and vaccine experts from other fields, such as HIV vaccine development, to share relevant experience and to collaborate on answering key questions in formulating a breast cancer preventive vaccine.

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Grants will be awarded during 2013 to look for vaccine targets in DCIS samples and to carry out immunological studies required before vaccine formulation.

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The 2013 Annual Meeting for the Artemis Project® for a Preventive Breast Cancer Vaccine was held in California in March. At the meeting, updates from the various research projects, including initial data and analyses, were presented. Scientific presentations and updates were followed by intensive, small group sessions

focused on updating plans for the next two years of work. In addition, analyses occurred in real-time at the meeting through a hands-on bioinformatics, computing workshop with graduate students and post-doctoral fellows. Following the meeting, NBCC has identified additional research projects for the next round of seed grants and topics for smaller group meetings on targeted issues. Grants will be awarded during 2013 to look for vaccine targets in DCIS samples and to carry out immunological studies required before vaccine formulation. In addition, NBCC maintains communication among the full team of stakeholders through webinars and an online shared data environment. Advocates continue to be an integral part of all aspects of the project, keeping the focus on the end result of safe, and reliable, breast cancer prevention for all women. Several Project LEAD® trained advocates are helping collect evidence to inform the Artemis Project® team regarding particular issues from other prevention trials, both in cancer and in other diseases. Other Project LEAD® trained advocates are helping to identify biospecimen needs for the project, and to connect investigators with appropriate resources to meet those needs.

This vaccine project serves as the model for other catalytic projects.

### **Artemis Project® on the Causes & Prevention of Metastasis**

All of our work and leadership throughout our history on issues relating to metastatic disease laid the groundwork for our focus on the causes and prevention of metastasis as part of **Breast Cancer Deadline 2020®**. We believe it is necessary to look at the issue of metastatic disease differently to achieve the goal of ending the disease. Much of the current research, funded as a result of our efforts, is focused on looking for biomarkers and targets, and development of drugs to be evaluated in and to treat late stage disease—all vitally important—and we want to complement that work with a different approach, with a focus on the causes and prevention of metastasis in order to accelerate progress against this disease.

Areas of focus include the role of viruses in the spread of breast cancer; the role of inflammation in breast cancer; targeting the immune system to prevent breast cancer metastasis; the role of lifestyle and other external exposures in progression of breast cancer; and identifying the windows when women are most vulnerable to breast cancer metastasis.

To begin this work, NBCC launched an Artemis Project® on the causes and prevention of metastasis. The kickoff meeting was held in Tennessee in June 2013, with a focus on tumor dormancy, and related issues. NBCC brought

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NBCC brought together 17 scientists and advocates to discuss launching a project around tumor dormancy as a fundamental approach for preventing metastasis.

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together 17 scientists and advocates to discuss launching a project around tumor dormancy as a fundamental approach for preventing metastasis. The scientists represented diverse perspectives, including physical sciences, immunology, mathematics and modeling, cancer biology, molecular biology and biotechnology.

On the first day, initial presentations addressed the landscape of breast cancer and the advocate perspective on the issue of tumor dormancy—how it is defined and why it is important. This

was followed by scientific presentations on the biological properties of metastatic tumor cells and immune system regulation of tumor dormancy. This provocative discussion led to further exploration of three key areas in small group discussion: metabolism, modeling and the immune system.

Subgroups were formed to separately address three questions:

1. What role might metabolism play in tumor dormancy and the metastatic process?
2. How does our immune system affect tumor dormancy and the metastatic process?
3. How can we create models that will help us understand the characteristics of residual disease and that will inform our approach to tumor dormancy and preventing metastasis?

There was consensus among the diverse meeting participants that there is little known about breast cancer tumor dormancy, but that addressing this gap in knowledge should be a priority within the field. Participants agreed that increased knowledge could lead to an understanding of how to prevent metastasis for significant numbers of women.

Plans are being made to hold a follow-up meeting in conjunction with the Artemis Project® vaccine meeting to explore tumor dormancy in the context of immunology and cell aging. Experts will be invited to attend from the areas of metabolism and neurodegeneration. A second mission-driven Artemis Project® will be launched in 2014 focused on prevention of metastasis.

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## Public Policy Approach

About one month after NBCC's 2012 Lobby Day, the [Accelerating the End of Breast Cancer Act](#) was introduced by Senator Sheldon Whitehouse (D-RI), along with Senators Grassley (R-IA), Brown (D-OH), Collins (R-ME), Shaheen

(D-NH), Murkowski (R-AK), Warner (D-VA) and Heller (R-NV) as companion legislation to the bill in the House of Representatives, which was introduced the year before by Reps. Karen Bass (D-CA-33) and Rep. Charlie Bass (R-NH-2). The legislation is a vital component of NBCC's strategy to leverage existing resources. The bill focuses on ending breast cancer by identifying strategies for the primary prevention of the disease and identifying methods to prevent breast cancer metastasis, thereby saving lives.

The *Accelerating the End of Breast Cancer Act* creates the Commission to Accelerate the End of Breast Cancer comprised of a few representatives of biomedical research, business, breast cancer advocacy and other related and unrelated disciplines, who have demonstrated an ability to be innovative. This "lean and mean" Commission will be tasked with identifying promising opportunities, tools, technology and ideas not currently being prioritized for breast cancer by the public and private sectors, but which taken together and applied to this issue, hold true promise in ending breast cancer.

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The Commission then will create collaborations to leverage these opportunities and move them forward. It seeks to harness the nation's continued drive for innovation, help ensure our position as the worldwide leader in medical and scientific advancement, and build on the decades of this nation's investment and achievement in these areas. Passage of the *Accelerating the End of Breast Cancer Act* could significantly further our efforts to end breast cancer deaths and learn how to prevent the disease within the next decade.

The 112<sup>th</sup> Congress ended without the bill being passed, but with bipartisan support of 27 Senators and 236 Members in the House. NBCC worked with lead sponsors to reintroduce the *Accelerating the End of Breast Cancer Act* in May 2013. Senators Sheldon Whitehouse (D-RI) and Dean Heller (R-NV) and Representatives Shelley Moore Capito (R-2-WV) and Kathy Castor (D-14-FL) are the lead sponsors of the legislation (S. 865/H.R. 1830). Joining Senators Whitehouse and Heller in introducing the legislation were Senators Charles Grassley (R-IA), Mark Begich (D-AK), Sherrod Brown (D-OH), Bob Casey (D-PA), Al Franken (D-MN), Jack Reed (D-RI), and Mark Warner (D-VA). In the House, Reps. Capito and Castor were joined by Reps. Blackburn (R-7-TN), Bass (D-37-CA), Latham (R-3-IA), Loebsack (D-2-IA), Markey (D-5-MA), Moore (D-4-WI) and Tiberi (R-12-OH).

Comparable policies will be designed as the need is identified.

## 8.2 ACCESS

NBCC's [\*Blueprint for Breast Cancer Deadline 2020\*](#)<sup>®</sup> calls for the development of a global strategy to ensure that individuals with, and at risk of, breast cancer have access to information, quality care and scientific advances. Breast cancer is a disease without borders. Finding the answers to prevention and saving lives will not end breast cancer until everyone, everywhere, has meaningful access to those answers. NBCC is bringing together stakeholders from around the world at all levels, from policy makers to grassroots advocates, and engaging them throughout the process to make certain that location, economic status, and societal factors are not barriers to access.

## Engaging Worldwide Stakeholders

As work continues to progress in the research arena that will result in the scientific advances to be shared worldwide, NBCC is already building relationships and networks in other countries to develop a foundation for global engagement in ending breast cancer.

NBCC has trained women and men from other continents through its various scientific and policy training programs. With networks in place in dozens of countries and an increased investment in electronic communication across the globe, NBCC is working with advocates and scientists in Europe, Africa, Asia and South America and helping to create **Breast Cancer Deadline 2020**<sup>®</sup> continent-wide networks. These networks will expand the existing international breast cancer network in order to improve critical clinical trials research, access to trials and interventions, and engagement in the work to know how to end breast cancer by 2020.

NBCC has increased the representation of stakeholders from other countries in all **Breast Cancer Deadline 2020**<sup>®</sup> activities. The 2013 meeting for the Artemis Project<sup>®</sup> on the causes and prevention of metastasis included a non-US scientist among the 17 who participated. More than ten countries are represented among the organizations endorsing **Breast Cancer Deadline 2020**<sup>®</sup>. Nearly 10% of the advocates in attendance at the Inaugural Advocate Leadership Summit in 2013 were from countries outside of the United States. These leaders are building advocacy campaigns within their countries to gain more support, endorsement and participation from leaders in government and science worldwide.

## 8.3 INFLUENCE

Despite years of campaigns to raise awareness, ever expanding screening programs, increased fundraising efforts and research, breast cancer incidence and mortality have not changed significantly. Media, advocates, researchers, policy makers and others must be educated in order to change the conversation and shift the essential public dialogue about breast cancer from awareness and screening to prevention and saving lives. We must make certain that leaders in government, industry and all areas embrace the deadline with courage and conviction and make ending this disease a priority. We also must mobilize the breast cancer advocacy community so that all those at risk—and all who care about them—join a revolutionary activist movement with the goal of ending breast cancer.

### Media

NBCC is implementing a strategic communications plan to increase influence with reporters, editors and others and provide education to media leaders, in science and policy, so that breast cancer information in the media is grounded in evidence.

Over the past year, NBCC has shared its science-based perspective on stories ranging from Angelina Jolie's decision to undergo a prophylactic mastectomy to the Food and Drug Administration (FDA) approval of Genentech's T-DM1. At the same time, NBCC leadership has been proactive in delivering the message of **Breast Cancer Deadline 2020**<sup>®</sup> through various media channels. NBCC President, Fran Visco, appeared on [The Marie Show](#) and published an op-ed in [The Boston Globe](#). The Coalition's point of view also was featured in major news outlets such as *The New York Times*, NPR's *All Things Considered*, PBS, *Huffington Post*, CBS and Fox News.

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## Policy Makers

NBCC conducts forums for political leaders to explain **Breast Cancer Deadline 2020**<sup>®</sup> and breast cancer in general. Meanwhile, networks of educated constituents are interacting with political leaders to push for appropriate policies and discussions. Strategies include petition drives, the design of legislation that complements the campaign, and advocacy efforts that secure declarations of support from policy leaders.

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During the 2012 presidential election, NBCC once again highlighted breast cancer as a political issue through our Breast Cancer Caucus project.

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**Breast Cancer Caucus:** During the 2012 presidential election, NBCC once again highlighted breast cancer as a political issue through our Breast Cancer Caucus project. NBCC urged the 2012 presidential candidates to see breast cancer as not only a health issue, but a political one as well. NBCC advocates worked tirelessly to

educate the candidates on the importance of ending breast cancer and making it a national priority. Through NBCC's website, Breast Cancer Caucus 2012, thousands of NBCC advocates reached out to the candidates and asked them to support **Breast Cancer Deadline 2020**<sup>®</sup>.

**Presidential Petition:** NBCC asked constituents nationwide to sign a petition to the President asking him to make the end of breast cancer by January 1, 2020 a national priority. NBCC advocates all across the country mobilized their efforts to gather tens of thousands of signatures on petitions to be delivered to President Obama after his 2013 Inauguration. To maximize efforts, advocates issued challenges to breast cancer support groups, launched innovative social media efforts, and promoted the petition on their websites.

### **Declaration of Support from Public Officials:**

NBCC advocates asked [national, state and local officials to publicly declare their support](#) for **Breast Cancer Deadline 2020**<sup>®</sup>. At the national level, the primary focus was on securing support for the *Accelerating the End of Breast Cancer Act*. In tandem with the acquisition of more than half of the House of Representatives and more than one quarter of the Senate as cosponsors on the legislation that supports **Breast Cancer Deadline 2020**<sup>®</sup>, advocates also secured dozens of declarations of support. These national endorsements were complemented by state and local efforts which resulted in support from a governor, mayors, state senators and representatives, and others. In 2013, those who attended the Inaugural Advocate Leadership Summit are implementing action plans to obtain numerous endorsements from state and local public officials to add to the list.

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NBCC advocates asked national, state and local officials to publicly declare their support for **Breast Cancer Deadline 2020**<sup>®</sup>.

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## Scientific Community

By engaging researchers in the Artemis Project<sup>®</sup> collaborations, the scientific conversation is already changing. NBCC is also reaching out to leaders in the scientific community by speaking and exhibiting at breast cancer scientific conferences and meeting with various scientific associations. At the end of 2012, *Nature* published an editorial questioning the goals of **Breast Cancer Deadline 2020**<sup>®</sup>. The journal published a response from NBCC. In addition, a supportive response was published from Stephen Johnston, Director for the Center for Innovations in Medicine (CIM), a Professor in the School of Life Sciences, and Director of the Biological



Design Graduate Program at The Biodesign Institute at Arizona State University. The editorial prompted a [larger story in \*The Cancer Letter\*](#), which provided NBCC President Fran Visco with a forum to promote the strategic action plan for achieving **Breast Cancer Deadline 2020®** and the support the campaign already has received from the scientific community. Visco also brought the message about the deadline to the 2013 ASCO Annual Conference, where she sat on a panel discussing standards for real progress in clinical trials and delivered a talk entitled, *The Appearance of Progress: Resisting the Siren Song of Modest Benefits*. In addition, NBCC was also represented at the 2<sup>nd</sup> Collaborative Summit on Breast Cancer Research. At the Summit, NBCC advocate Laura Nikolaides addressed the largest research funders in the private and public arenas and challenged them to re-envision the breast cancer research enterprise, based on the goals of **Breast Cancer Deadline 2020®**.

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## Breast Cancer Advocacy Education

The Center for NBCC Advocacy Training has been a leader in supplying the education, tools, training and action that enable breast cancer survivors and other advocates to take leadership roles in clinical, scientific, policy and legislative decision making that affects breast cancer research and public policy. Programs include NBCC's science training Project LEAD®, Advocate Summits, and online trainings, all of which involve international advocates.

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**20<sup>th</sup> Annual Advocate Summit:** The NBCC Annual Advocate Summit, formerly the Annual Advocacy Training Conference, was held May 5 – May 7, 2012. The theme of the Summit was “It’s Time....To Make Your Voice Heard, To Get on the Clock, To End Breast Cancer.” There were nearly 600 participants at the Summit, which included 13 international attendees from five countries: Canada, Nigeria, South Africa, Venezuela, and Virgin Islands. The Summit opened with an inspiring and energizing rally where advocates shared their **Breast Cancer Deadline 2020®** work with those in attendance. Advocates unable to attend the Summit in person followed the event through NBCC's social media outlets on Facebook and Twitter. On the last day of the Summit, advocates attended a State Action Planning Workshop where they worked collaboratively to develop regional plans for action to implement **Breast Cancer Deadline 2020®** in their local communities across the country and around the globe.

**Inaugural Advocate Leadership Summit:** To strengthen our grassroots leadership across the country, we convened a [unique summit of leaders](#) for the Inaugural Advocate Leadership Summit, held May 4 – May 6, 2013. The meeting provided attendees with life-long leadership skills and just-in-time strategies as well as big ideas and advanced learning. They also experienced small group interactions with researchers and thought leaders. Advocates who attended developed personal action plans for the year ahead and returned to their communities to grow the base of support for **Breast Cancer Deadline 2020®**.

**Project LEAD® Institute:** NBCC held the [Project LEAD® Institute](#) in the summer of 2012 and again in 2013. The advocates who attended the intensive science training course studied molecular biology, genetics, mutations, epidemiology, research design and much more. Advocates with the critical ability to ask the right questions and work alongside scientists to help focus research are a crucial part of the strategy for achieving the mission of **Breast Cancer Deadline 2020®**. Throughout the week-long program, students heard lectures from a renowned group of scientists, clinicians and researchers from institutions around the country.

Advocate mentors and scientists, clinicians and researchers worked with students in large presentations and smaller seminar settings, and facilitated small study sessions throughout the course. As students progressed and began to build a solid foundation, they attended a number of advanced sessions such as *Epigenetics and Breast Cancer* and *Prevention of Metastasis*. They also worked closely with carefully selected mentors who helped them develop Graduate Action Plans and who support their implementation throughout the coming year. Crucial to their learning was the importance of developing skills to read the scientific literature and then be able to critically question everything from findings to study design.

**Online Center:** Debuting in October 2012, NBCC launched the [Online Center for NBCC Advocacy Training](#) to give advocates from around the world an opportunity to receive training through webinars and LEADcasts and to re-live or experience for the first time some of the great highlights and sought-after speakers featured at NBCC's events. The Online Center hosts regularly scheduled webinars called LEADcasts on advanced topics related to recently published research studies and relevant, new items in the field. Webinar training is provided for the general public and has included advocacy training for Emerging Leaders, discussions of clinical trial design issues for a new class of agents T-DM1, and a

Twitter 101 session for novices in social media. Advocates are able to receive sophisticated online training on the Washington political landscape and NBCC legislative priorities in advance of Lobby Day. And visitors to NBCC's Online Center can tune into cutting-edge lectures and workshops by some of the best thinkers in the world of breast cancer who have presented at NBCC courses, Summits and other live events. These include sessions with breast surgeon and activist Dr. Susan Love, pioneer researcher Dr. Dennis Slamon, astrophysicist Dr. Paul Davies and Dr. Nancy Snyderman of NBC News.

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**Team Leader Training:** On March 17, 2013, more than 50 of NBCC's most active advocate leaders came to Washington, DC to attend the annual Team Leader Training for an update on NBCC's legislative and public policy priorities. This workshop provided a unique opportunity to engage with NBCC leadership on the details of our legislative priorities, hear about key players on Capitol Hill who are critical to our success, and learn how to communicate our positions effectively. Team Leaders then returned to their communities to create effective outreach plans to support NBCC's legislative agenda.

**Continuing Education:** NBCC provides Project LEAD® graduates with [additional educational opportunities](#) throughout the year to gain advanced advocacy training. LEADcasts, part of our online continuing education lecture series, are scheduled throughout the year for Project LEAD® graduates. Each year, NBCC hosts 3 to 6 advanced, online continuing education events with 90 to 120 graduates participating in each webinar. In addition, NBCC offers Advanced Topics classes at the advocate summits and at the San Antonio Breast Cancer Symposium. Topics covered in LEADcasts and Advanced Topics sessions during the past year include *Early Phase Clinical Trials: What are they for and why do they need to be better?* and *Breast Cancer and the Environment*.

## Breast Cancer Advocacy Engagement & Mobilization

**Organization Endorsements:** To reach the goal of knowing how to end breast cancer by January 1, 2020, the campaign must gain support from a diverse set of groups and organizations—not just those focused on

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The list of endorsing organizations has grown to several hundred, representing many of the 50 states, as well as a half dozen countries.

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breast cancer but all who care about and understand the importance of this issue. State and local, as well as global, efforts to increase the number of organizations endorsing **Breast Cancer Deadline 2020**<sup>®</sup> gained momentum as advocates expanded their outreach to breast cancer support groups, women's health and advocacy groups and businesses in their communities. A concerted global outreach

strategy to gain increased international organizational endorsements was initiated with outreach targeting the many organizations worldwide that have been impacted through NBCC trainings and collaborations. The [list of endorsing organizations](#) has grown to several hundred, representing many of the 50 states, as well as a half dozen countries.

**Local Networks:** NBCC advocates are building **Breast Cancer Deadline 2020**<sup>®</sup> Action Networks in local communities around the country to organize and work collectively to maximize the important work being done to build support, energy and momentum for **Breast Cancer Deadline 2020**<sup>®</sup>. Through the grassroots mobilization workshops held during the Advocate Summit, NBCC identified leadership and membership for networks in nearly every state. These groups are developing and implementing action plans to engage and mobilize new advocates to broaden the reach for **Breast Cancer Deadline 2020**<sup>®</sup> within their states or regions, expand local outreach efforts and broaden the base of supporters willing to push the envelope and demand actions to know how to end breast cancer by the end of the decade.

**International Networks:** NBCC's advocates from outside the United States are building networks within their countries and across continents to galvanize global support for **Breast Cancer Deadline 2020**<sup>®</sup>. Advocates representing 11 countries have begun outreach and engagement efforts to grow networks in their communities.

**Emerging Leaders:** NBCC's [Emerging Leaders program](#) seeks to involve individuals, ages 18-35, in **Breast Cancer Deadline 2020**<sup>®</sup>. An online network gives participants a place to communicate, share resources, and connect with one another and with NBCC so they can continue to act on important efforts toward ending breast cancer. Nearly 1 in 10 participants in the Inaugural Advocate Leadership Summit were Emerging Leaders. Capitalizing on this group's strength, Emerging Leaders have been tasked with expanding the presence of **Breast Cancer Deadline 2020**<sup>®</sup> in the various social media platforms—particularly [Twitter](#) and [Facebook](#). To facilitate the effort, a special webinar was held to discuss the NBCC brand and strategize on ways to increase the visibility of **Breast Cancer Deadline 2020**<sup>®</sup> in social media.

## Information & Outreach for the General Public

NBCC continues to inform and activate the public through online messaging, print publications and presentations at events related to breast cancer.

**Outreach:** NBCC continues to expand our network and change the conversation around breast cancer to a dialogue about knowing how to end the disease by 2020. To achieve this objective, NBCC conducts extensive grassroots outreach to share materials and messaging via major science and research conferences, fundraising events, member organizations, charity fairs, community events and volunteer events.

**Online Information Campaigns:** NBCC's website and social media pages deliver information about the current state of breast cancer and the **Breast Cancer Deadline 2020**<sup>®</sup> plan of action to end the disease. In 2012, NBCC launched a **Breast Cancer Deadline 2020**<sup>®</sup> blog that features advocates talking about the work they are doing to reach our goal of knowing how to end breast cancer. These first-person accounts of activism in the breast cancer community highlight the roles of advocates in science, research, public policy and grassroots outreach. NBCC

continues to maintain an active presence on [Facebook](#), [Twitter](#) and [YouTube](#), enabling us to communicate effectively with these audiences. These sites reach new audiences with information about NBCC programs and events, as well as important facts about breast cancer. Social media campaigns during the past year built around major holidays like Mother's Day and Independence Day highlighted the campaign's message of knowing how to end breast cancer and save lives by using personal stories, photos and videos. In addition, NBCC President, Fran Visco, blogs at *Huffington Post* regularly to help promote the **Breast Cancer Deadline 2020**<sup>®</sup> campaign.

**Progress Reports:** Transparency and accountability are integral components of the campaign and necessary to changing the conversation. Beginning with a [baseline report in May 2011](#), NBCC is issuing annual progress reports that summarize the state of breast cancer as well as the status of NBCC's work to end breast cancer. In August 2012, NBCC released its [Second Annual Progress Report](#) summarizing the state of breast cancer and the status of **Breast Cancer Deadline 2020**<sup>®</sup>. The report was an update to the 2011 Baseline Report, which described the lack of adequate progress despite billions of dollars in public and private resources directed at the disease. The new report found no breakthroughs in breast cancer diagnosis or treatment in the prior year. While there were new ways to treat the disease, there was little progress on preventing the incidence of breast cancer and making certain no one dies of it. The report also included analyses of breast cancer public policy, research spending on breast cancer and media coverage of the disease. All Progress Reports are available on NBCC's website.

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In the three years since the launch of **Breast Cancer Deadline 2020**<sup>®</sup>, NBCC has laid a strong foundation upon which to build in the years ahead. From new research collaborations to public policy initiatives and efforts to change the conversation in the media and to mobilize the global advocacy community, NBCC is making progress.

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## 8.4 CONCLUSION

The tools, information, resources and wisdom now exist to create a global strategy to know how to end breast cancer by 2020. NBCC has developed a strategic plan of action that will catalyze the change required to speed progress toward an end to breast cancer. The *Blueprint for **Breast Cancer Deadline 2020***<sup>®</sup> lays out some of the strategies NBCC will follow to achieve its mission. In the three years since the launch of **Breast Cancer Deadline 2020**<sup>®</sup>, NBCC has laid a strong foundation upon which to build in the years

ahead. From new research collaborations to public policy initiatives and efforts to change the conversation in the media and to mobilize the global advocacy community, NBCC is making progress. But, as is made clear in the *Blueprint*, it will take all of us working together to change years of incremental progress and inspire a decade of unparalleled achievement. NBCC will continue to seek to harness the energy, resources and leadership around the world to achieve **Breast Cancer Deadline 2020**<sup>®</sup>. Ultimately, success will depend upon those outside NBCC: leaders, researchers, public officials, the philanthropic and funding community, breast cancer advocates, and the general public.

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2020

2019

2018

2017

2016

2015

2014

**2013**

2012

2011

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## 3 | BREAST CANCER TREATMENT

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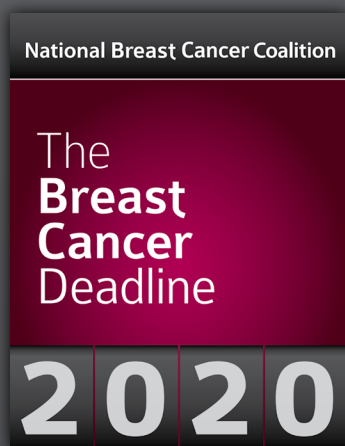
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