

Trends in Breast Cancer Drugs Approved by the US Food and Drug Administration, 1980-2024

HPR 107



SCHOOL OF PHARMACY

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BACKGROUND

- ➤ Breast cancer is the most commonly diagnosed cancer among women in the United States, accounting for approximately 30% of all new cancer cases in women annually.
- As of 2024, the lifetime risk for a woman in the U.S. developing breast cancer is approximately 1 in 8 (12.5%). It remains the second leading cause of cancer-related death among women, contributing to about 15% of all female cancer deaths nationwide.
- The pharmacological options for breast cancer include chemotherapy, hormone therapy, targeted therapy, and immunotherapy, which are used for treatment of breast cancer.

OBJECTIVE

To analyze trends in the FDA approval of breast cancer drugs from 1980 to 2024, focusing on regulatory pathways, approval speeds, and disease-specific targeting strategies.

METHODS

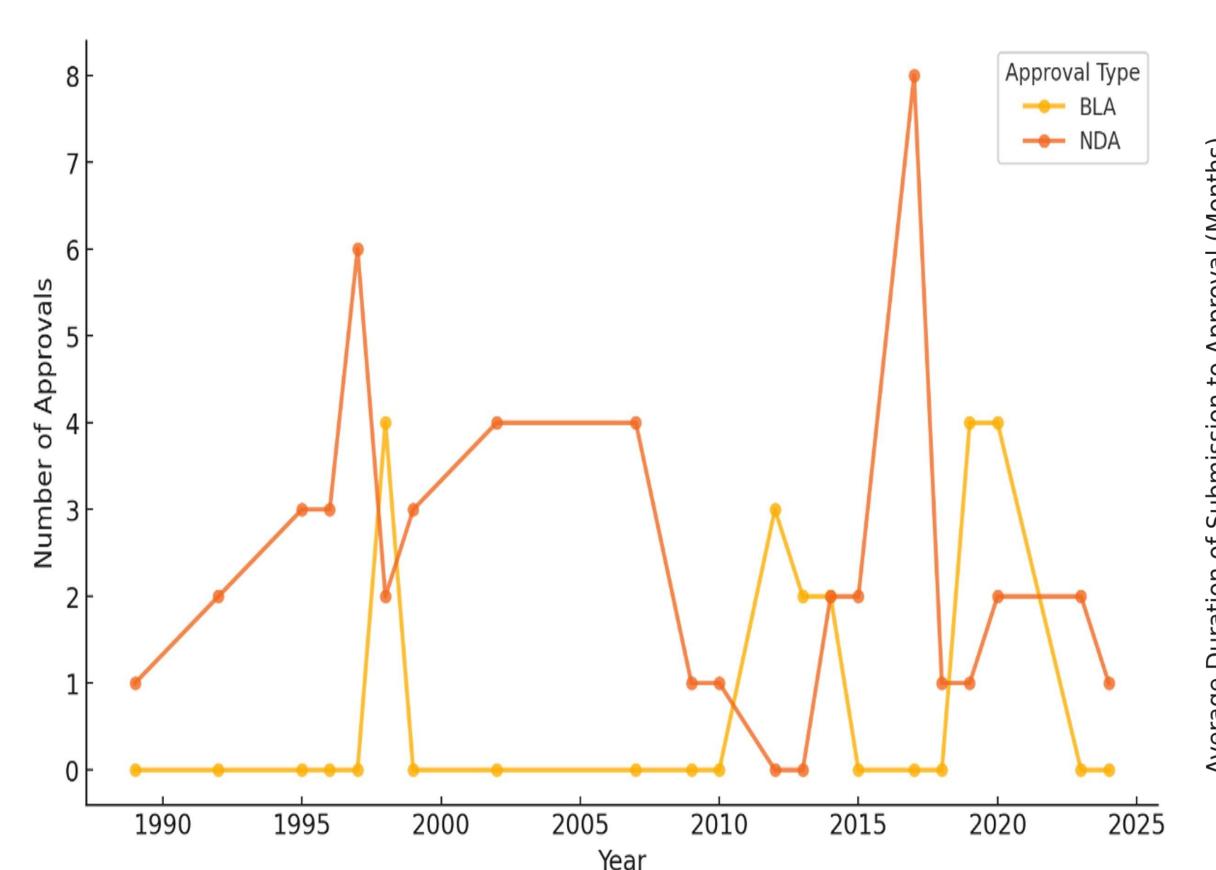
- ➤ We collected regulatory information from the drugs@FDA, FDA Label Search, and DailyMeds databases.
- To gather detailed information on breast cancer therapeutics, we utilized the FDA Label Search database, which provided the foundation for our analysis.
- ➤ We assessed trends in the number of approvals, FDA review time, and regulatory procedures and designations analyses using Microsoft Excel and Python 3.13.1

Table 1. Descriptive Statistics

	Orphan	FDA NDA	Accelerated
Metric	Drug NME	Review Priority	Approval NME
Percentage of			
drugs (%)	13.230	67.640	22.050
Standard			
Error	0.041	0.057	0.050
Standard			
Deviation	0.341	0.471	0.418
Sample			
Variance	0.117	0.222	0.174
Kurtosis			
	2.708	-1.431	-0.184
Skewness			
	2.169	-0.754	1.348
Sum	9	46	15
Count	68	68	68
Confidence			
Level (95%)	±8.3	± 11.4	± 10.1

Figure 3. Approval Trends of BLA vs NDA

RESULTS



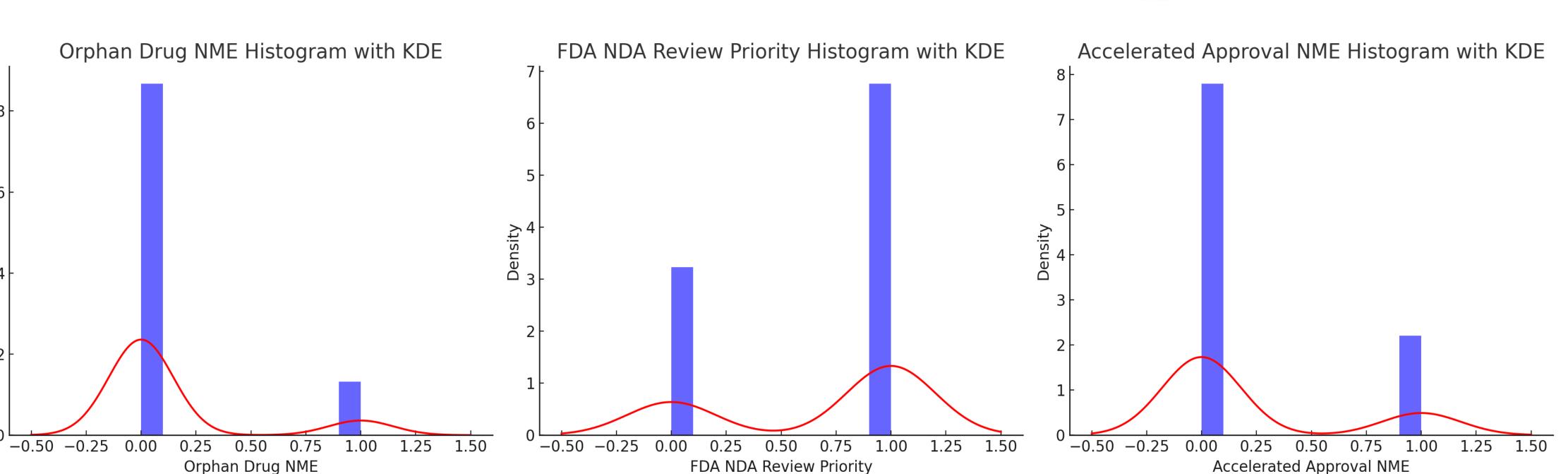


Figure 1. Mapping FDA-Approved Breast Cancer Drugs by MOA and Targeted Receptor Subtype

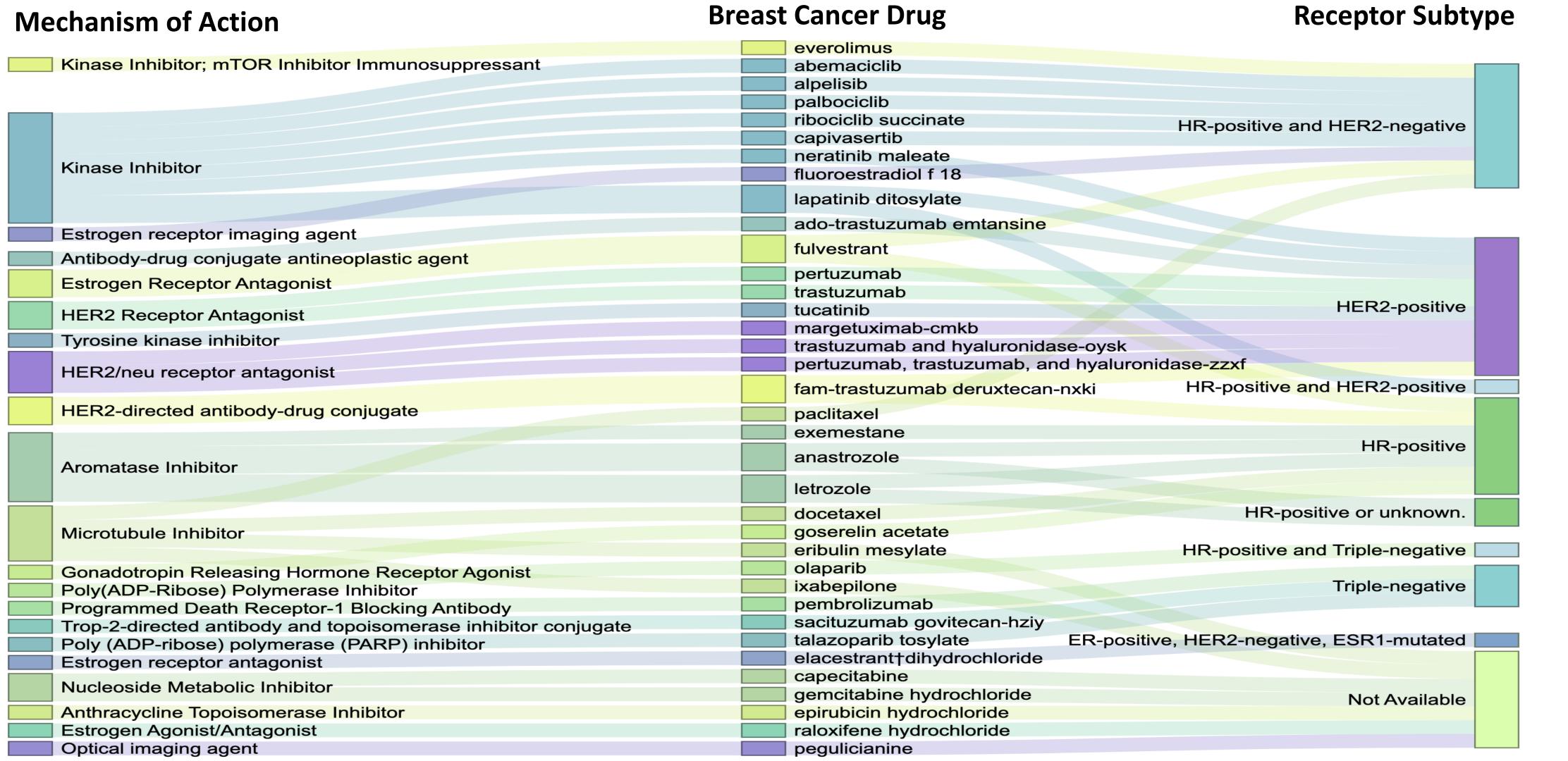


Figure 4. FDA Approval By Cancer Stage

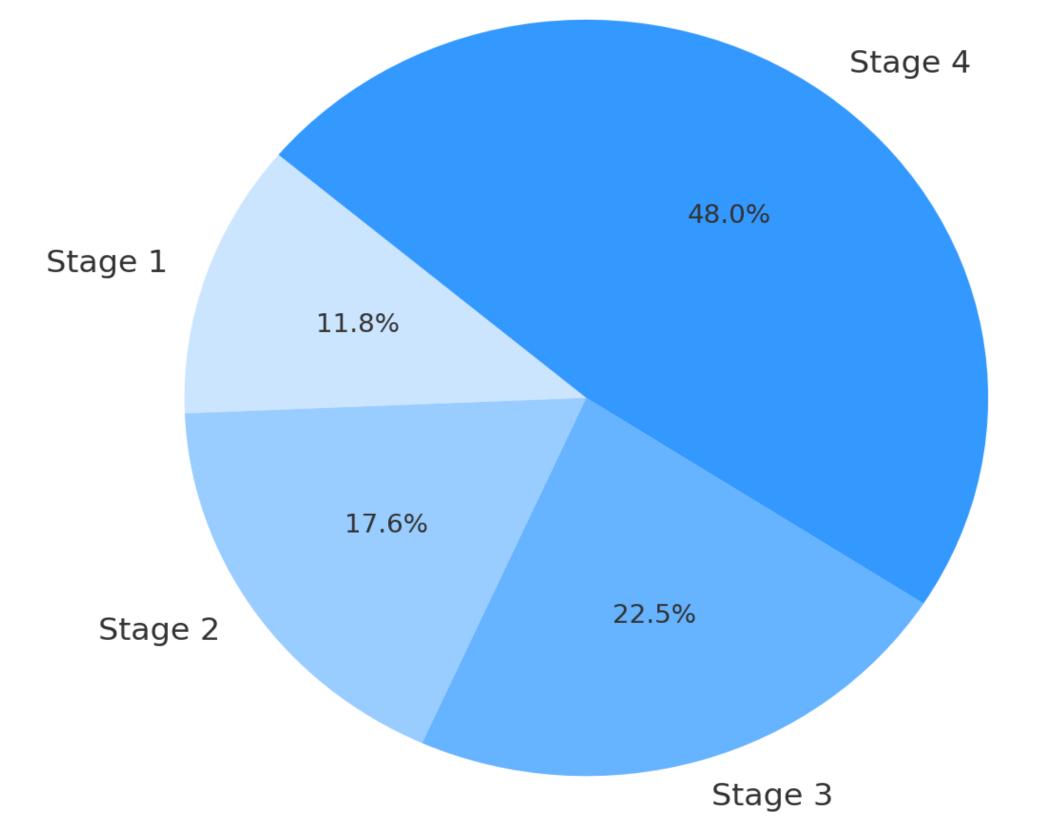
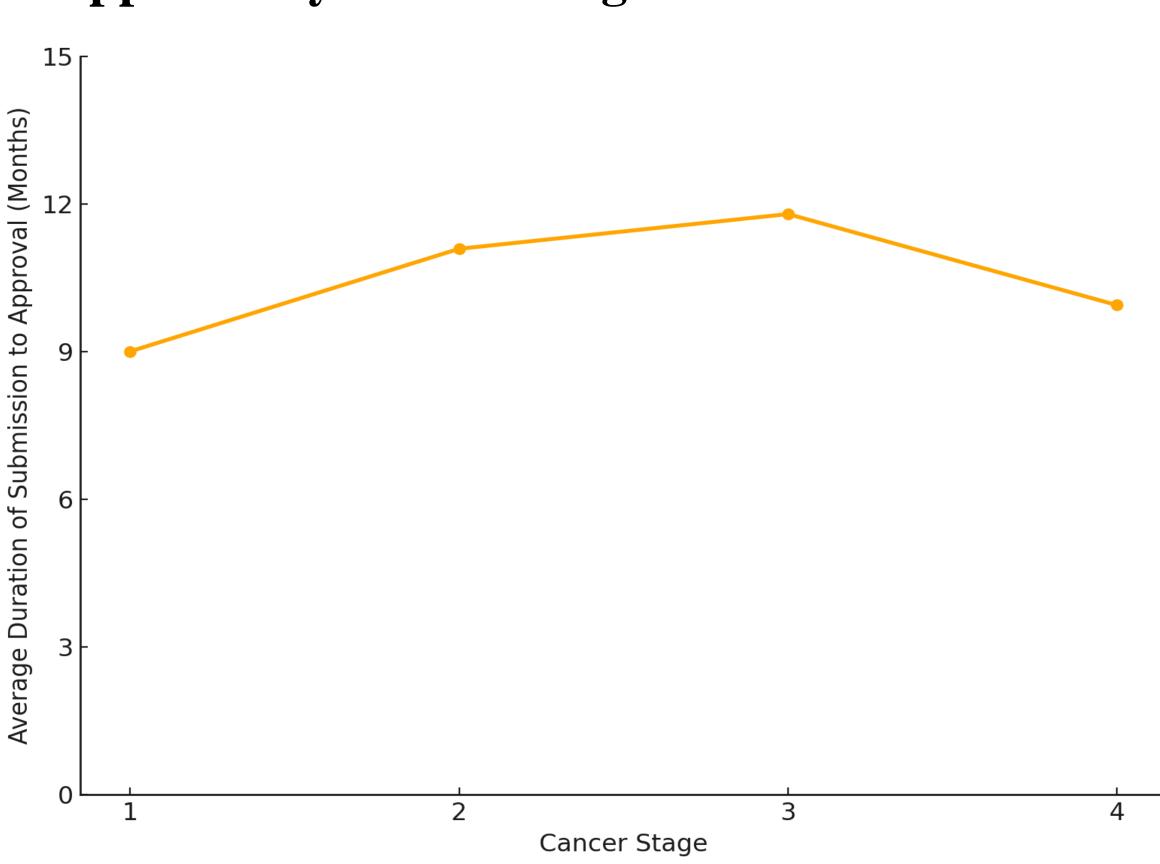


Figure 5. Duration from Submission to FDA Approval by Cancer Stage



DISCUSSION

- ➤ Between 1980 and 2024, the U.S. FDA approved a total of 68 drugs for breast cancer treatment. A significant portion of these approvals were new molecular entities (n = 49) and new biologics (n = 19), reflecting continued innovation in drug development.
- Notably, 67.6% of the drugs (n = 46) were approved via priority review designation, indicating their potential to offer significant improvements over existing treatments.
- Additionally, 22.1% (n = 15) of drugs utilized the accelerated approval pathway, while 13.2% (n = 9) were granted orphan drug designation, highlighting efforts to address unmet needs in rare or advanced breast cancer populations.

Limitations

- A drug developed in the 1980s may not have the same regulatory or scientific environment as today, this affects comparability across time periods.
- ➤ Correlation ≠ Causation: An increase in approvals over time does not necessarily mean progress in treatment; it could reflect policy shifts or industry dynamics.

CONCLUSION

There is a significant shift in breast cancer drug approvals, with emphasis on late-stage (stage 4) cancers through expedited regulatory pathways. The rise in BLA approvals post-2010 reflects the growing importance of biologics in addressing breast cancer.