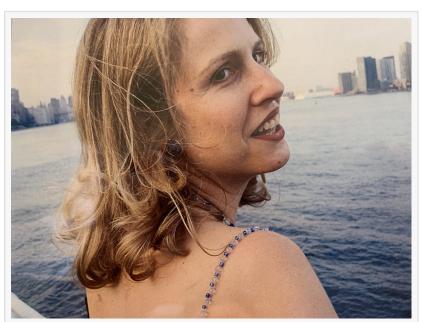


Breast Cancer Advocates From 2015 Documentary Laud New FDA Regulations Mandating Full, Accurate Mammogram Results

Award-winning documentary
'Happygram' exposed practice of
withholding material medical
information from mammogram results
for women with dense breast tissue

NEW YORK, NEW YORK, UNITED STATES, March 24, 2023 /EINPresswire.com/ -- On March 9 of 2023, the FDA announced an update to the Mammography Quality Standards Act (MQSA) of 1992 with a requirement to report breast density information in mammogram results, stating "Approximately half of women over the age of 40 in the U.S. have dense breast tissue, a description of its appearance on a mammogram. Dense breast tissue can make cancers more difficult to



Hallie Leighton successfully lobbied the NY State Assembly to include material medical information in mammogram results.

detect on a mammogram. Additionally, dense breasts have been identified as a risk factor for developing breast cancer. The amendments finalized today provide specific language explaining how breast density can influence the accuracy of mammography."

Filmmakers Hallie Leighton and <u>Julie Marron</u> of Lemon Martini Productions began production on the award-winning film '<u>Happygram</u>' in 2012 when Leighton was diagnosed with late stage breast cancer after several years of normal mammograms.

Despite well-established evidence that mammograms often miss cancer in women with dense breast tissue, Leighton was not informed that she had dense tissue, that her cancer could be obscured by dense tissue on her mammogram, or that she was at greater risk for cancer due to her dense breast tissue. She discovered that many other women were also diagnosed with late stage cancer shortly after receiving what they began to call their "happygram," a mammogram report stating that their mammogram was normal while a malignant tumor remained



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Hallie Leighton

undetected. Many of these women died from breast cancer after relying on inaccurate "normal" mammogram reports for years.

While there are alternate screening methodologies, such as ultrasound, that are more effective at detecting cancer in women with dense breasts, these tools were not widely utilized, stemming in part from the fact that material medical information about breast density was often

withheld from women who had mammograms.

For the past two decades, women advocates have petitioned the FDA to include breast density information in mammogram results. When these efforts met with resistance, advocates began lobbying state legislatures. Along with other advocates, Leighton lobbied the New York State legislature to mandate that mammogram results include material information on breast density.

"This life-saving information about my own body was deliberately withheld from me in my mammogram results," Leighton testified to members of the New York Assembly. She and other advocates celebrated when their efforts resulted in the passage of a New York State law requiring density notification in July of 2012. "It felt great to get that call from the Assemblywoman who had sponsored the legislation that our efforts were successful."

The work of these advocates led to a state by state patchwork of reporting requirements for mammogram results. With the 2023 change nearly twenty years after advocates began their work, the FDA will implement standardized, national reporting requirements for density information. "It is certainly time the FDA supports the consistent reporting of material medical information to women," said Marron. "Unfortunately, the decision to finally implement this change has come too late for many women and their families."

'Happygram,' which tells the stories of women who received "normal" mammogram reports that did not detect their late stage cancer, is available on <u>Amazon Prime Video</u>. The film first aired in August of 2015 at the Rhode Island International Film Festival, where it was awarded First Prize for the Providence Film Festival Award.

Leighton, tragically, never saw the completed film, as she passed away from breast cancer in April of 2013.

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