

## The Last Word

"We are pleased to inform you that the results of your mammogram are "normal". Within 6 weeks of my "Happy Gram", after a palpable ridge, an ultrasound revealed a quarter-size lesion not seen by mammogram. Pathology confirmed a stage 3C breast cancer with 13 metastasized lymph nodes. During this terrifying time, I learned that "extremely" dense tissue was why my mammograms did not detect my cancer. Puzzled and afraid, I searched the medical journals for answers.

Yearly, 45,000 U.S. women receive "normal" mammography reports yet have a hidden "invasive" cancer which, most likely once detected, will be at a later stage.<sup>123</sup> That's a sold out "Wrigley Field" filled with moms, sisters, daughters, and grandmothers.

Armed with science and compelled to action, my husband and I began working with the CT legislature. It resulted in the landmark breast density notification bill in 2009. Currently, there are 11 states following Connecticut's lead. Women, sharing their personal tragedies of missed cancers, are educating state officials about this public health hazard. Interestingly, three of these state bills were initiated by radiologists – those on the front line of screening challenges created by dense tissue.

After signing Connecticut's bill in 2009, Governor Rell remarked "This law is a no brainer." Her words ring in my ears daily as we face opposition to legislation from medical organizations like the ACR, AMA, and ACOG.

So, what's the opposition saying? **There is not enough science:** Though the challenge of cancer detection in dense tissue and limitation of mammography would seem reason enough to include "inform" language in reports to patients, the number of peer reviewed published studies on the masking and causal risk of dense breast tissue have been around for decades and continues to grow.<sup>456789</sup>

**Measurement of density is subjective:** Variability for breast density is not different from other BI-RADS features in mammographic interpretation.<sup>10</sup> There is substantiation that training of radiologists dramatically reduces

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<sup>1</sup> US Food & Drug Administration: MQSA National Statistics

<sup>2</sup> Steenbergen S, & Weigert, J, "The Connecticut Experiment: The Role of Ultrasound in the Screening of Dense Breasts," Radiological Society of North America 2011 Scientific Assembly and Annual Meeting.

<sup>3</sup> Berg WA, Blume JD, Cormack JB, et al. Combined screening with ultrasound and mammography vs mammography alone in women at elevated risk of breast cancer. *JAMA* 2008; 299(18):2151-63.

<sup>4</sup> Boyd NF, Guo H, Martin LJ, et al. Mammographic density and the risk and detection of breast cancer. *N Engl J Med.* 2007; 356(3):227-36.

<sup>5</sup> Yaghjyan L, Colditz GA, Collins, LC et al. Mammographic breast density and subsequent risk of breast cancer in postmenopausal women according to tumor characteristics. *J Natl Cancer Institute* 2011; 103:1-11.

<sup>6</sup> Chui SY, Duffy S, Yen AM, Tabar L, et al. The effect of baseline breast density on breast cancer incidence, Stage mortality and screening parameters: 25-year follow-up of a Swedish mammographic screening. *Cancer Epidemiol Biomarkers Prev.* 2010; 19(5):1219-28.

<sup>7</sup> Stomper, P, D'Souza, D, DiNitto, P, & Arrendondo, M. Analysis of parenchymal density on mammograms in 1353 women 25-79 years old. *American Roentgen Ray Society*, 1996; 167:1261-1265

<sup>8</sup> Mandelson, M.T., Oestreicher, N, Porter PL., et al. "Breast Density as a predictor of mammographic detection: Comparison of interval and screen-detected cancers," *Journal of the National Cancer Institute* 92:13 (2000): 1081-1087.

<sup>9</sup> Kolb TM, Lichy J, Newhouse JH. Comparison of the performance of screening mammography, physical examination and breast US and evaluation of factors that influence them: an analysis of 27,825 patient evaluations. *Radiology* 2002; 225(1):165-75.

<sup>10</sup> Berg WA, Campassi C, Langenberg P, Sexton MJ. Breast Imaging Reporting and Data System: inter- and intraobserver variability in feature analysis and final assessment. *AJR Am J Roentgenol* 2000; 174:1769-1777.

density assessment variability.<sup>11</sup> Additionally, there are currently two FDA cleared volumetric density assessment tools that are commercially available.<sup>12</sup>

**False positives, resulting from adjuvant screening, will scare women:** A recent national survey found that 90% of women would return for screening the following year, even after experiencing a false positive.<sup>13</sup> Women are more concerned with a MISSED positive than a false one.

**We don't want government to mandate practice as technology is constantly changing.** Enacted and proposed legislation does *not* mandate any technology. It *does* ensure ALL women receive critical information about their breast composition so they are informed participants in their health care. Right now women have to rely upon luck for an early breast cancer diagnosis as less than one in ten women learn about their dense breast tissue from their physician.<sup>14</sup>

In addition to 11 state bills, Federal Bill HR3102 has been introduced. While the process of enacting a federal bill moves forward, access to early detection becomes state dependant as a woman's zip code determines whether she receives critical information about her density which may affect her destiny. What is needed is a single, national notification. The ACR, whose mission statement includes, improving the quality of patient care, should take the lead. A revision in ACR's mammography accreditation standards to include patient breast density in the "lay" letter is the most expeditious way forward.<sup>15</sup> It accomplishes in one fell swoop what would otherwise take years. This simple change would result in density notification to nearly 90% of U.S. women.

Each year, we have a stadium filled with women that already have two strikes against them – cancer missed by mammogram and cancer that will most likely be detected when palpable, thus at a later stage. These women, faithful in their screening regimen, yet denied equal access to early detection, have fewer treatment options and worse survival outcomes.<sup>16</sup> One more strike left. How much longer can we wait to inform women of the risks and challenges of their dense tissue? This is a no brainer.

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<sup>11</sup> Martin K, Helvie M, Chou Z, et al: Mammographic density measured with quantitative computer-aided method: Comparison with radiologists' estimates and BI-RADS categories. *Radiology* 2006; 240(3): 656-65.

<sup>12</sup> Quantra Volumetric Assessment by Hologic & Volpara Breast Imaging Software

<sup>13</sup> National Survey by *Research Now* commissioned by Are You Dense, Inc. Woodbury, CT: Sept., 2011

<sup>14</sup> National Survey by *Harris Interactive* commissioned by U-Systems, Inc. New York: May, 2010

<sup>15</sup> ACR: Practice Guidelines For Screening & Digital Mammography Page VIII (c) (1)(2008) (retrieved online)

<sup>16</sup> ACS: Breast Cancer Survival Rates by Stage 1/6/2012 (retrieved online)

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