

Breast Density Legislation and Clinical Evidence

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KEYWORDS

• Ultrasound • Screening • Density • Legislation • Breast • Cancer • Risk

KEY POINTS

- Breast density legislation is increasing in popularity, and more than half of the United States have enacted such laws since 2009.
- Dense breast tissue is common and is associated with decreased mammographic sensitivity, as well as increased breast cancer risk.
- Supplemental screening with ultrasound, tomosynthesis, and MRI are complimentary to mammography, although each modality is associated with its own limitations.

INTRODUCTION

Connecticut passed the first breast density awareness notification law in 2009, and now over half of the United States has also followed. Although radiologists have been aware of the significance of breast density and its impact on the sensitivity of mammography for decades, most primary care physicians and women undergoing screening mammography were previously unaware of differences in breast density along with its relationship to breast cancer risk and mammographic accuracy. Breast density is now a hot topic and is fueled primarily by the successful grassroots efforts of patient advocates behind breast density inform legislation.

Women are diagnosed with dense breast tissue based on the amount of fibroglandular tissue relative to fatty tissue present on mammography. Women with dense breast tissue may opt for supplemental screening, usually with ultrasound or MRI. Radiologists are on the forefront of the breast density platform, since they are responsible for diagnosing women with dense breast tissue and, increasingly, offering women—either by choice or

by law—a discussion over the implications of having dense breast tissue and the options regarding supplemental screening. Therefore, radiologists must be knowledgeable of the current evidence related to optimal breast density determination, its effect on mammography and breast cancer risk, and the associated risks and benefits of different supplemental screening tests.

BREAST DENSITY LEGISLATION *The Origins of Breast Density Legislation*

In 2004, Nancy Cappello self-palpated a breast lump only 6 weeks after having a normal mammogram. Ultrasound subsequently revealed a 2.5 cm suspicious breast mass, and she was ultimately diagnosed with stage IIIC breast cancer metastatic to 13 axillary lymph nodes.¹ Cappello was surprised by her diagnosis of late-stage cancer, particularly since she faithfully had annual mammography. Moreover, she was bewildered when multiple doctors were unsurprised by her diagnosis, because, they explained, she had dense breast tissue as was clearly and consistently described on all of her mammogram reports.

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Cappello searched lay publications but found no information about dense breast tissue. Having a PhD in psychology, Cappello then easily searched the scientific and medical literature, discovering that not only is dense breast tissue common,^{2,3} but also represents a risk factor for breast cancer^{5,6} and is the strongest predictor of the failure of mammography screening.⁷⁻⁹ She also found multiple studies showing that supplemental screening ultrasound performed in the addition to mammography could find early stage mammographically occult invasive cancers.¹⁰⁻¹⁵

Overwhelmed by this information, Cappello decided to take action. At first she believed that providing access to screening breast ultrasound would allow more women to choose supplemental screening. A former chief of special education in Connecticut, she successfully helped craft legislation to mandate insurance coverage for screening whole breast ultrasound (SWBUS), which easily passed state legislation in 2005. She spread her message during speaking engagements throughout Connecticut, but soon discovered that the initial legislation was unsuccessful, because many women were still not given the option to choose SWBUS; additionally, most doctors remained dismissive about the importance of dense breasts. As a result, Cappello worked with her state senators to craft new legislation designed to provide standardized communication to women regarding the findings of dense breast tissue on their mammography reports. The initial legislation failed in 2007, as only a single community radiologist testified in its favor, and multiple radiologists, including members of the Connecticut Radiology Society, testified against it. In response, Cappello founded AreYouDense.org, which is also linked to a nonprofit organization. The website provided a path to efficient widespread community outreach and support.

In a second attempt, CT 09-41 “An Act Requiring Communication of Mammographic Density Information to Patients,” was introduced in 2009. By then the multi-institutional results of the ACRIN 6666 were published, showing that SWBUS could detect an additional 4.2 cancers per 1000 women screened in women with dense breasts, elevated risk, and a negative mammogram.¹⁶ Fueled with this new scientific evidence and more community support, the bill easily passed. Despite initial opposition, the Connecticut Radiology Society supported the bill in the closing hours to help influence the verbiage of the final legislation. On May 20, 2009, Governor Jodi Rell, herself diagnosed with breast cancer a few years earlier while in office, signed the landmark legislation that went on to spark a nationwide breast density inform grassroots effort.

Texas, New York, Virginia, and California soon followed Connecticut’s lead, enacting similar breast density inform legislation by early 2013. Despite the success of the initial breast density inform laws, there were numerous early opponents including the American College of Obstetricians and Gynecologists (ACOG), Planned Parenthood, insurance companies, and many state radiology societies. Opponents cited concerns about the lack of strong scientific evidence proving mortality reduction related to providing patients breast density information and supplemental screening. There were also concerns about increased patient anxiety, false-positive results, and increased health care costs generated by additional diagnostic testing.

The Current Status of Breast Density Legislation

There are 27 states with mandatory breast density inform laws in effect, as of this writing. These laws require patients receive some level of information about their breast density present on their mammogram. However, breast density reporting is variable by state, and although some state laws are similar, there is no nationwide standard.¹⁷ For example, the Connecticut law specifically states that supplemental screening with ultrasound or MRI could be beneficial, while the California and Pennsylvania laws do not specifically mention the option of supplemental screening. Three states have also passed breast density inform related bills suggesting, but not mandating, that patients be informed of their breast density (**Table 1**).

Five states have insurance mandates for screening ultrasound, but only 3 states with insurance mandates also have active breast density laws. New Jersey law mandates insurance coverage for SWBUS in women with a normal mammogram and extremely dense breasts only, while Connecticut requires insurance coverage for all women with dense breasts subject to an individual’s deductible, plus a maximum copay of \$20. In mid-2016, New York passed a broad law mandating insurance coverage without copay or any patient cost sharing for SWBUS, mammography, or MRI for the detection of breast cancer. A Connecticut bill introduced by Cappello in 2016 designed to eliminate all patient cost sharing for SWBUS failed.

The Future of Breast Density Notification

Passage of state breast density notification laws continues to gain momentum throughout the country, but patient advocates ultimately strive

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