

## PROTECTING THE CONSUMER FROM MISSED, DELAYED & ADVANCED STAGE BREAST CANCER

Nancy M Cappello, Ph.D. Founder and Executive Director  
Are You Dense Inc. & Are You Dense Advocacy Inc.

FDA/MQSA Meeting  
September 15, 2016

# Disclosure

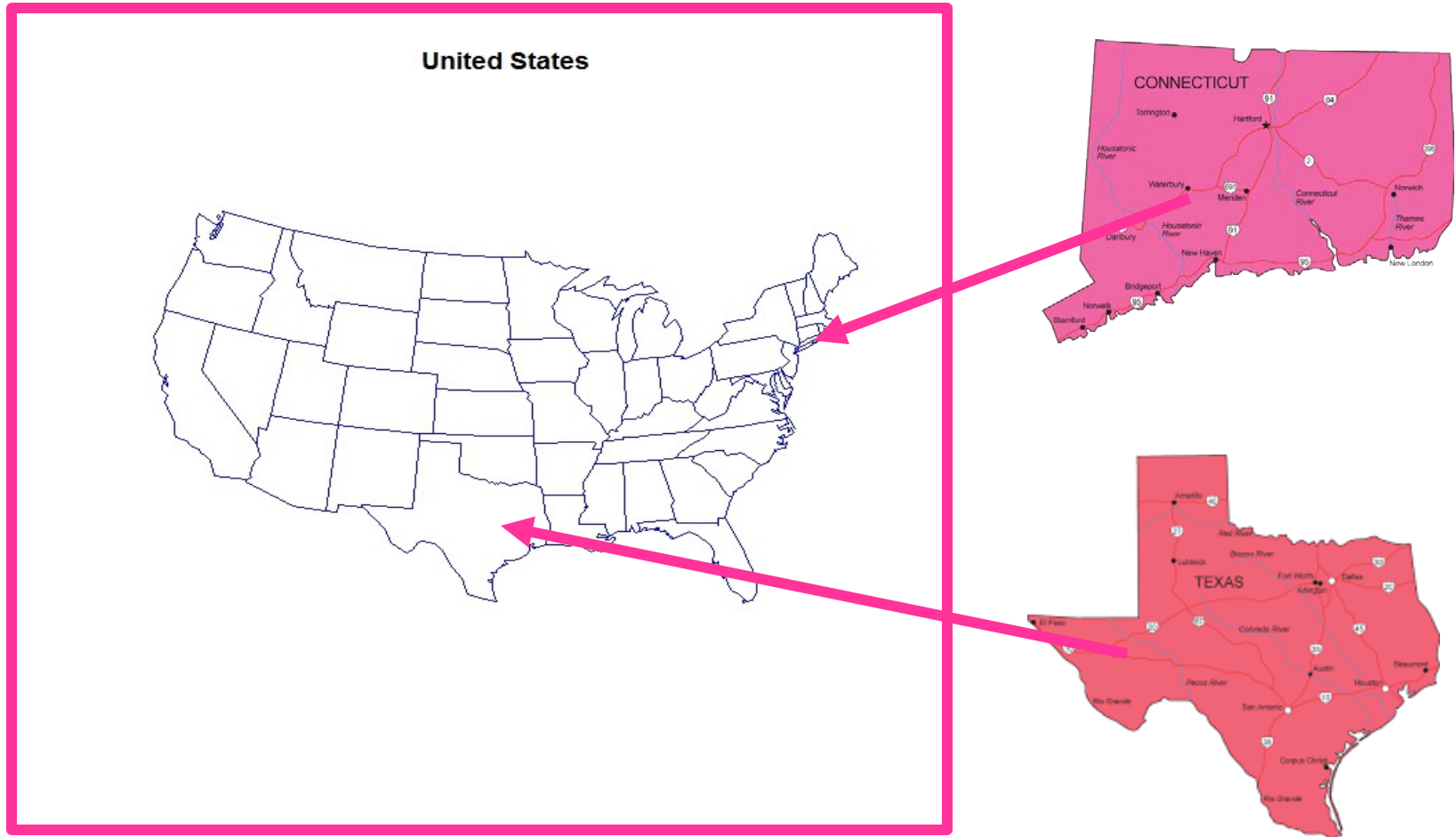
Are You Dense Inc. and Are You Dense Advocacy Inc. are nonprofit organizations that receive sponsorships and grants from imaging facilities, manufacturers, hospitals and health care businesses.

# MQSA Committee Meeting



November 4, 2011

# Connecticut (2009) Texas (2011)





# Federal Breast Density and Mammography Reporting Act (HR 716/S370)

Reintroduced in House/Introduced in Senate  
Feb 4, 2015 w/bipartisan support



# Does *Early* Matter?

## Highlights of Research Since 2011

- Saadatmand et al. BMJ: 9-4-15 Tumor stage at diagnosis still influences overall survival significantly in the current era of effective systemic therapy. Mortality increased with progressing tumor size and positive lymph nodes. **Diagnosis of breast cancer at an early tumor stage remains VITAL.**
- Tabar et Al. The Breast Journal 9-2-14 “Going forward breast cancer screening programs should embrace the opportunity to **TAILOR imaging to provide the greatest benefit to all women to reduce advanced disease.** It is only through a more sensitive screening tool than mammography or multi-modal screening will the equality of reliable breast cancer screening to reduce advanced disease and mortality be achieved.”
- Tagliagico et al. Journal of Clinical Oncology. March, 2016. ASTOUND “Our findings could be taken to suggest that **tomosyntheses** is detecting breast cancer that would have been otherwise masked on 2D but seems **LESS THAN CAPABLE than ultrasound at finding cancers that are entirely masked by mammography-dense tissue.**”

*“In women who have no significant other risk than density, combining a bilateral screening mammogram with a bilateral breast ultrasound is perhaps **the best way we have for finding early cancer.**”*

*Jean Weigert, M.D. Hospital of Central Connecticut.*

*“We’re finding **small, mammographically occult** cancers at a significant rate & we’re able to do that & still be efficient.”*

*Regina Hooley, M.D. Yale Medical Center.*

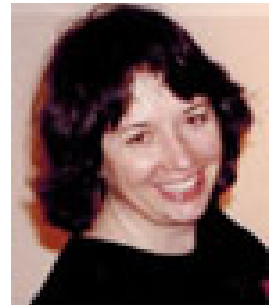
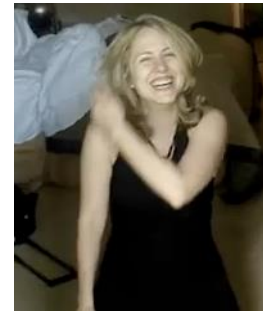
**“All the issues that are concerning to the profession cannot be solved by withholding a woman’s dense tissue composition from her.”**

Cappello, N. J Am Coll Radiol 2013;10:903-908. The HappyGram Decade of Normal Mammography Reports



# *In Honor of*

*Lori (MI) Roberta (CA) Theresa (NY) Hallie (NY) Ellen (MA)*



*Laura (OR) Hope (SC) Cheri (NE) Cindy (PA) Cathryn (VA)*





# A Call to Action

## Learning from History of MQSA

### *A Possible requirement for reporting Breast Density?*

## Take Home Points

Cappello, N. J Am Coll Radiol 2013;10:903-908. The HappyGram Decade of Normal Mammography Reports

- Breast Density is the strongest predictor of the failure of mammography screening to detect cancer.
- To withhold a woman's breast density composition from her, which may affect her health care, is denying her the right to make an informed decision.
- The doctrine of informed consent exists independent of a consensus to the challenges of detecting early invasive cancers in dense breasts.
- There is no research to suggest that cancers, not visible by mammogram and detected by other screening tests, are less clinically significant.

- Voluntary measures will not ensure that every woman receives this critical breast health information

#DenseBreasts

Let's Continue w/MQSA's Important Mission