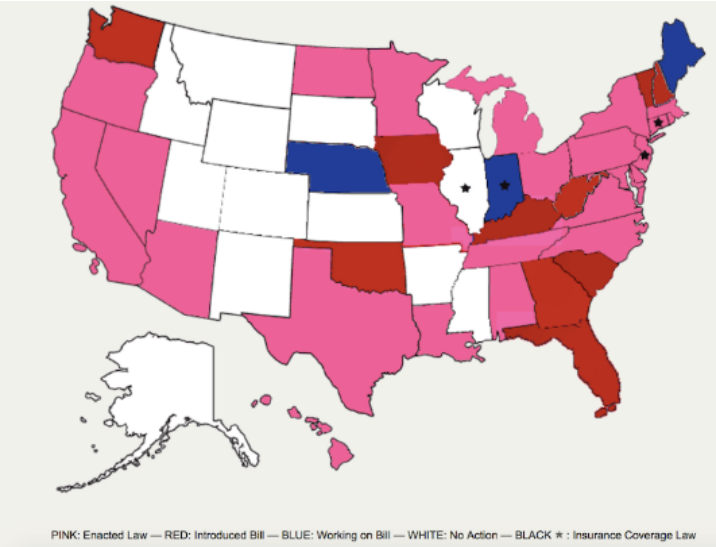
Breast Cancer Screening & Breast Density



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Disclosure

- Dr. **Goldberg** has no Conflict of Interest to disclose
- Dr. **Goldberg** l has no Financial or Scientific disclosures
- Dr. **Goldberg** has no Off-Label disclosures.

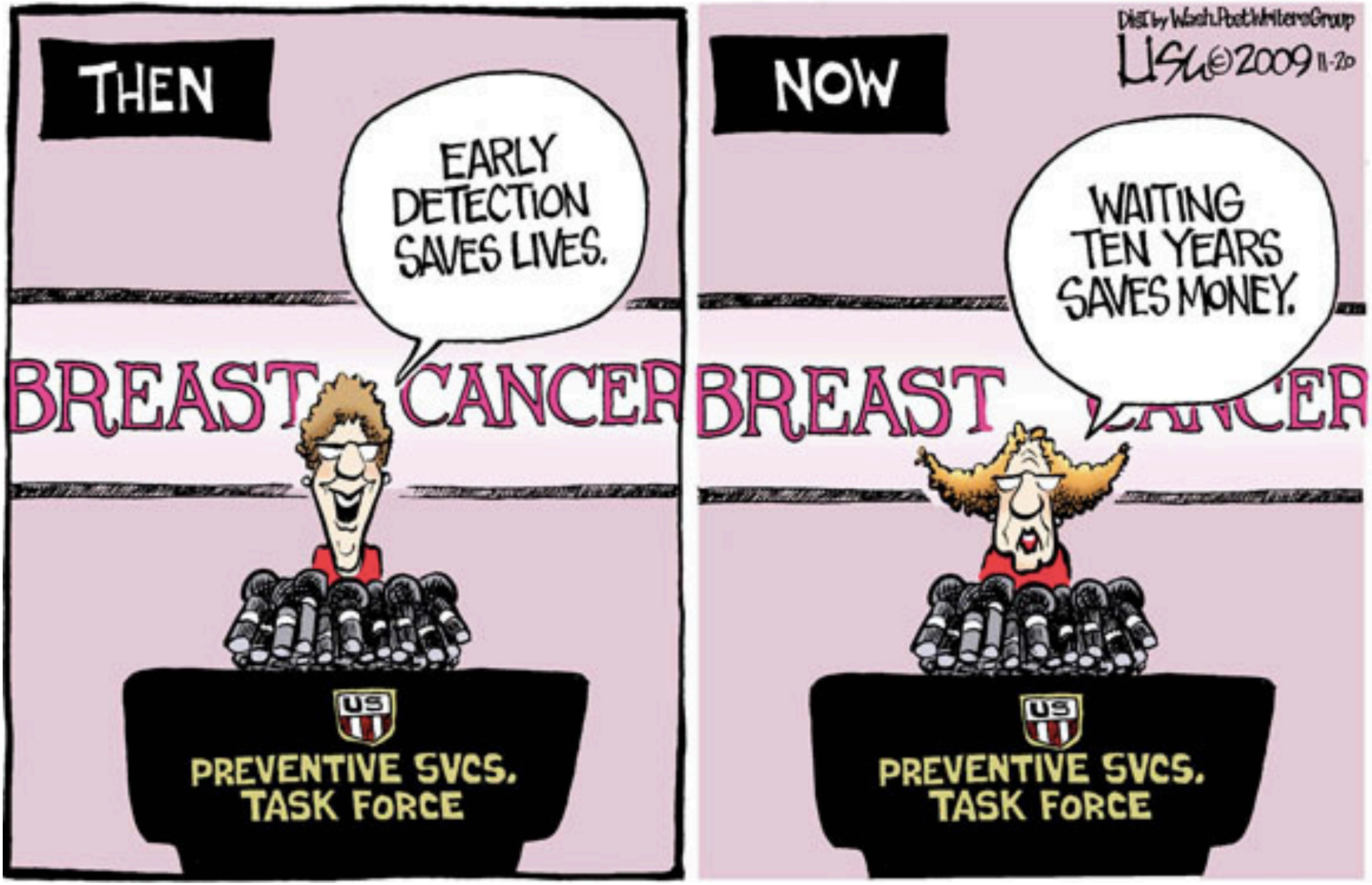
OBJECTIVES

- Describe current recommendations for breast screening.
- Describe increased mammographic breast density.
- Describe strategies to medico-legally comply with mammographic breast density laws.

Screening Mammogram Guidelines

US Preventive Services Task Force (USPSTF) Recommendations

- Women before the age of 50; decision to start regular, biennial screening mammography should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms
- **Women age 50-74**; USPSTF recommends **biennial screening mammography**
- Women age >75; current evidence is insufficient to assess the benefits and harms of screening
- **USPSTF recommends against teaching breast self examination**


THEN
EARLY DETECTION SAVES LIVES.
BREAST CANCER
PREVENTIVE SVCS. TASK FORCE
NOW
WAITING TEN YEARS SAVES MONEY.
BREAST
PREVENTIVE SVCS. TASK FORCE
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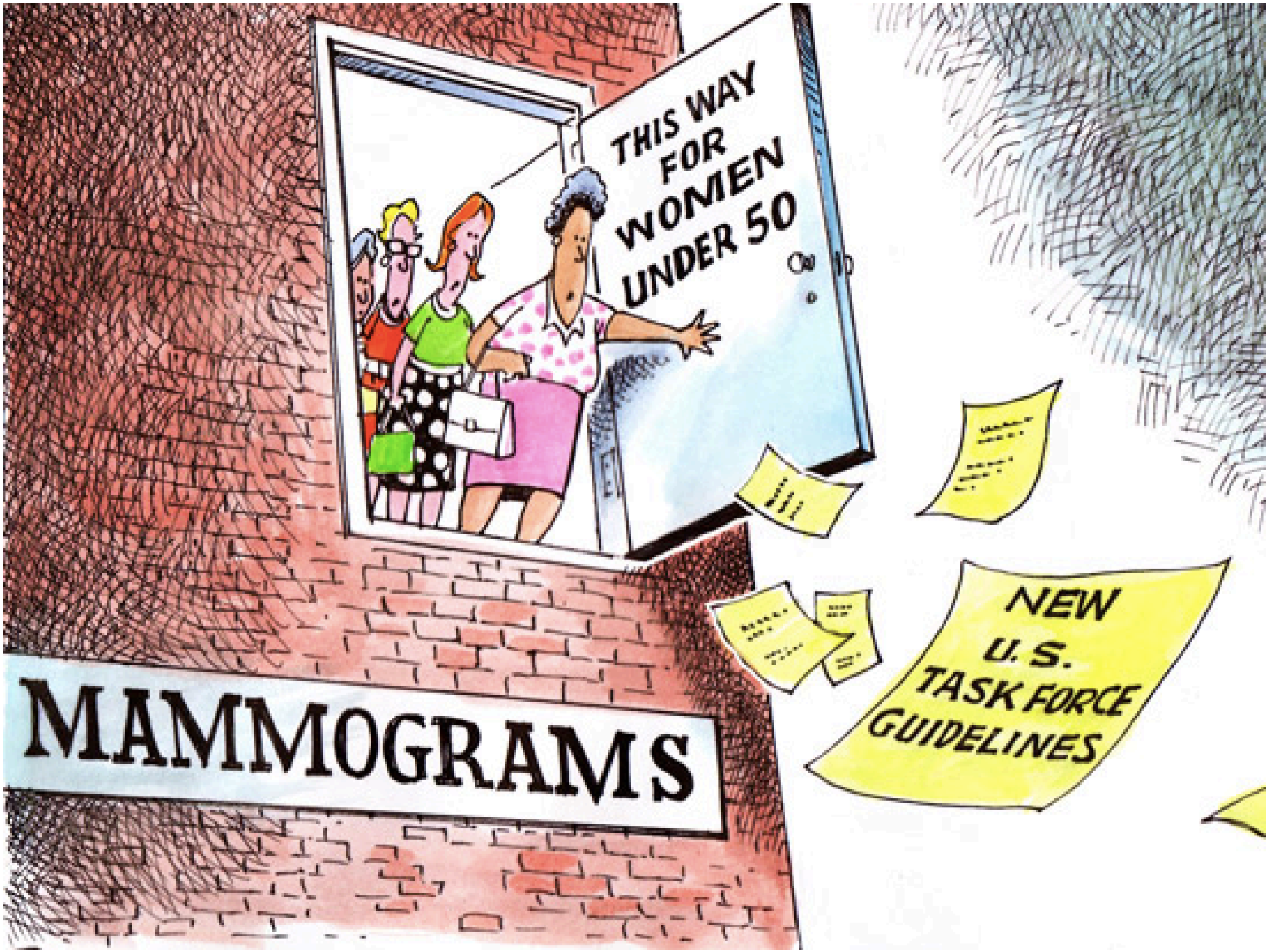
THIS WAY FOR WOMEN UNDER 50
MAMMOGRAMS
NEW U.S. TASK FORCE GUIDELINES

American Cancer Society 2016 Guidelines

- Women with average risk of breast cancer;
  - **Regular screening mammography starting at age 45 years** (strong recommendation), however women should have the opportunity to begin annual screening between the ages of 40 and 44 years
  - **Age 45 to 54 years should be screened annually**
  - **Age 55 years and older should transition to biennial screening** or have the opportunity to continue screening annually
  - **Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer**
  - **Do not recommend clinical breast examination** for breast cancer screening among average-risk women at any age

American College of Radiology (ACR) Recommendations

- **Recommend yearly mammograms starting at age 40**
- **Screening to continue until life expectancy is less than five to seven years**, on the basis of age and co-morbidities

ACOG Practice Bulletin 179
Breast Cancer Risk Assessment and Screening in Average-Risk Women
July 2017

- Clinical breast exam
  - "May be offered* every 1-3 years for women aged 25-39 years and annually for women 40 years and older."

ACOG Practice Bulletin 179 July 2017

- Mammography initiation age
  - Offer starting at age 40 years.
  - Initiate at age 40-49 years after counseling, if patient desires.
  - Recommend by no later than age 50 years if patient has not already initiated.

14 GYNECOLOGIC ONCOLOGY CONSULT: Understand human papillomarvirus. ▪ 16 ENDOMETRIOSIS:

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Mental health lessons
By Dr. Lee S. Cohen

Dr. Elizabeth A. Joy

BUSTING

NEW MAMMOGRAM GUIDELINES

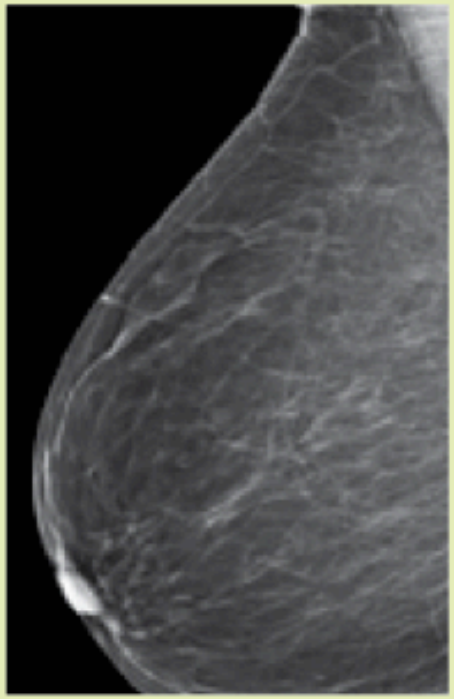
ACOG recommends initiation between 40 and 50 years old

ACOG Practice Bulletin 179 July 2017

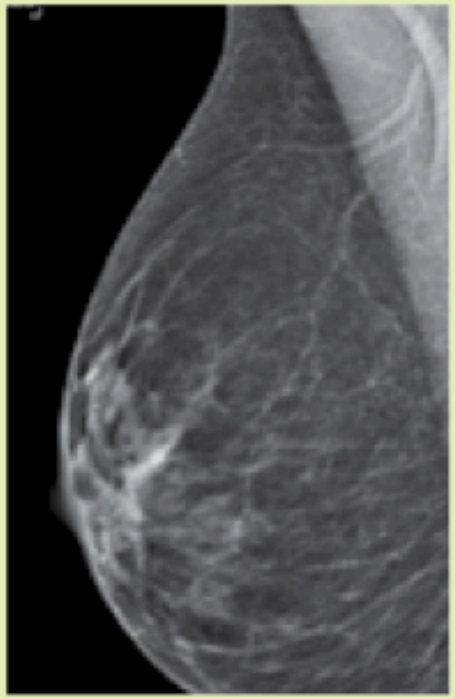
- Mammography screening interval
  - Annual or biennial
- Mammography stop age
  - Continue until age 75. Beyond age 75, the decision to discontinue should be based on a shared decision-making process that includes a discussion of the woman's health status and longevity.

American College of Radiology

Radiologists classify breast density using a 4-level density scale:

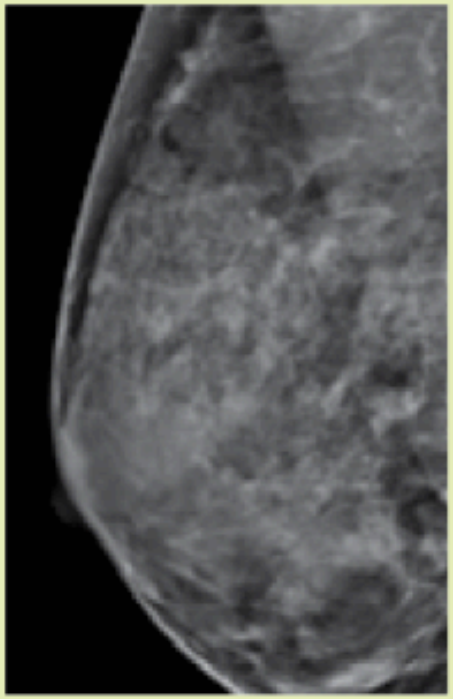


Almost entirely fatty



Scattered areas of fibroglandular density

Heterogeneously dense

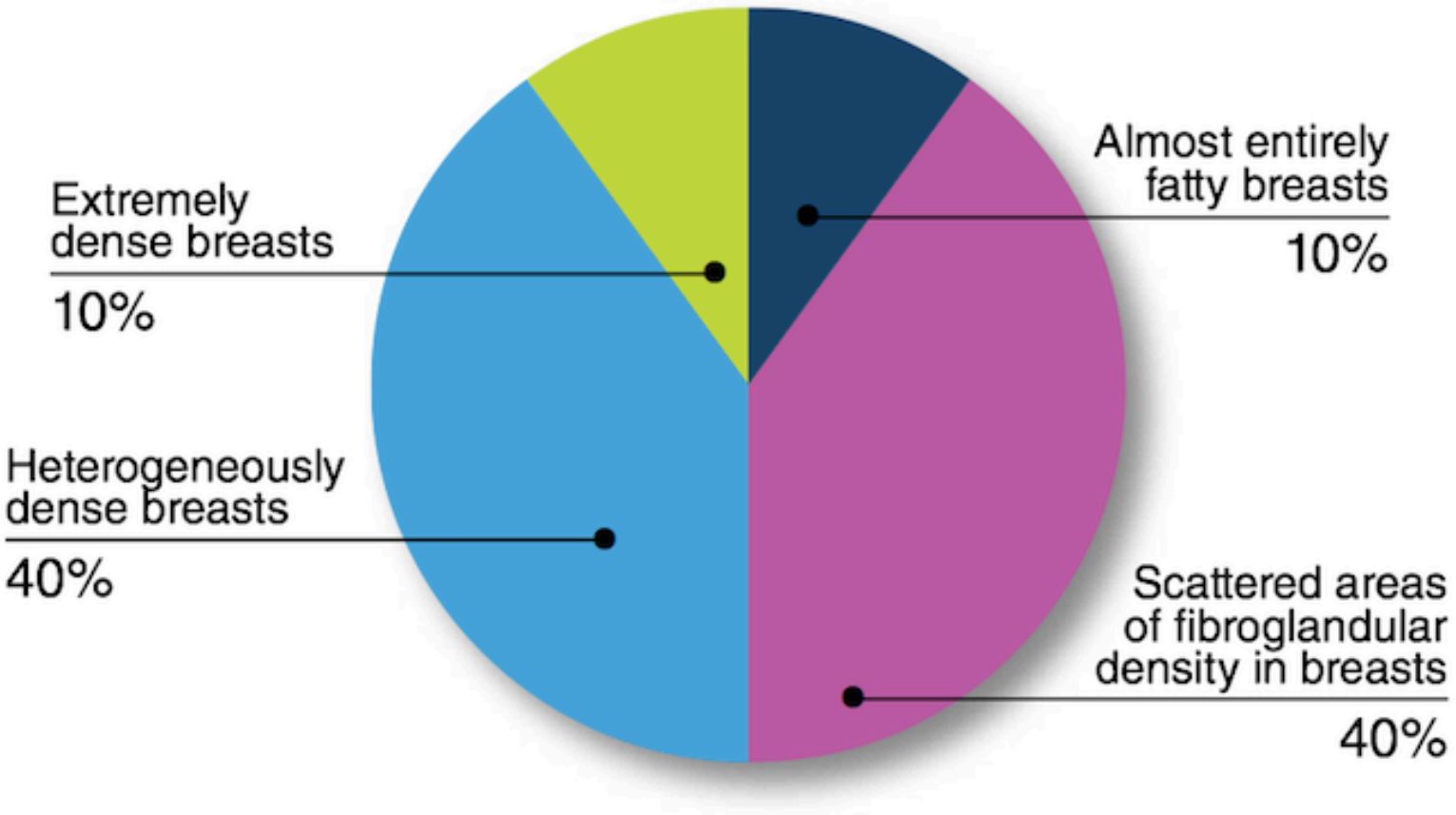


Extremely dense

American College of Radiology

Breast density in the U.S. (See pie chart)

- 10% of women have almost entirely fatty breasts
- 10% have extremely dense breasts
- 80% are classified into one of two middle categories



Increased Mammographic Breast Density
Why does it matter?

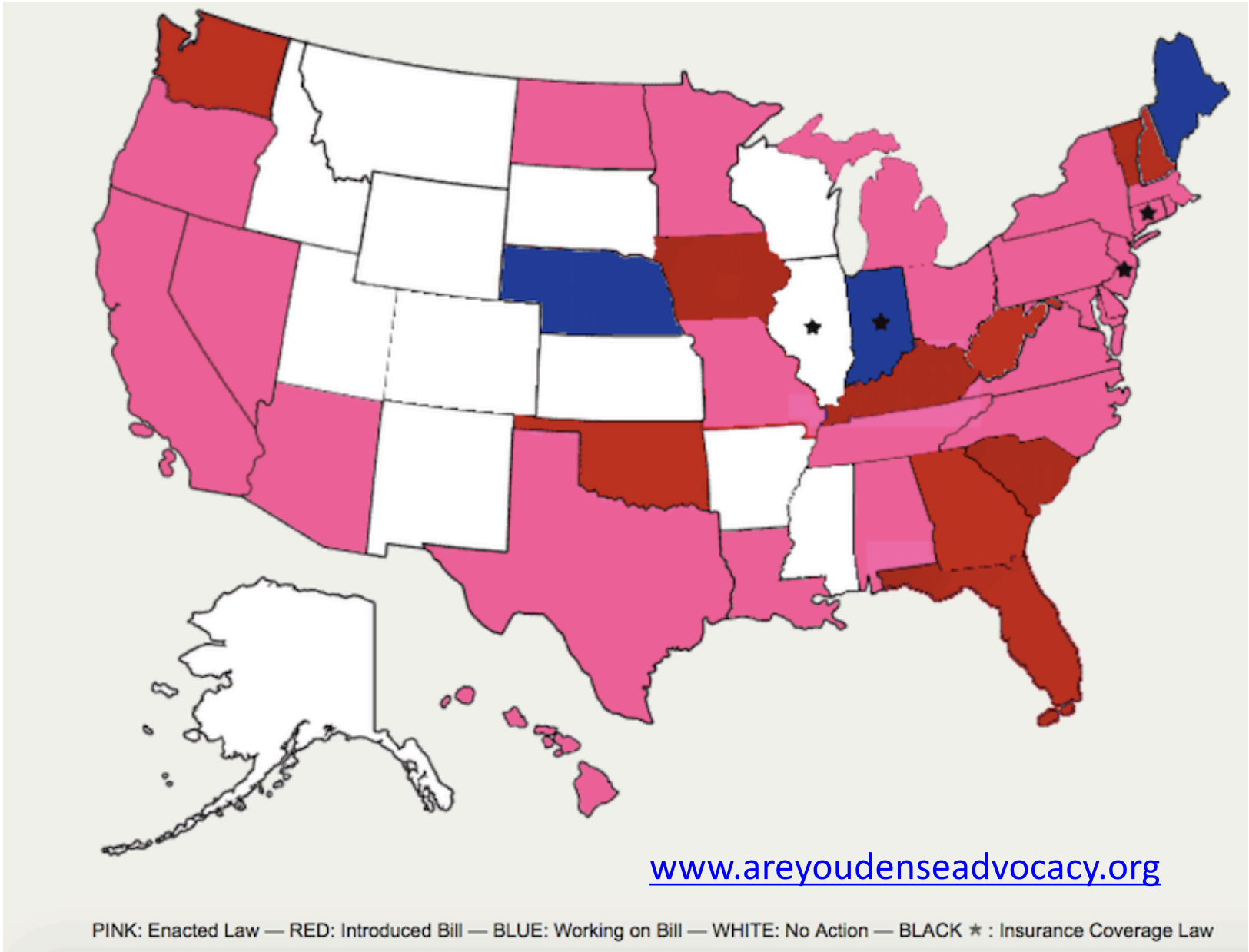
- Dense breast tissue absorbs more radiation during mammography compared with fatty breast tissue.
- This in theory reduces the accuracy of mammography to detect breast cancer.
- Compared to average breast density, the RR of breast cancer in women with heterogeneously dense and extremely dense breasts are increased by factors of 1.2 and 2.1, respectively. (Sickles. *Radiol Clin North Am* 2010)

TABLE Breast Cancer Risk Factors and Their Relative Risks

Relative risk <2	Relative risk 2-4	Relative risk >4
Age 25 to 34 at first live birth	Age >35 at first live birth	Gene mutations (BRCA 1 or 2)
Early menarche	First-degree relative with breast cancer	Lobular carcinoma in situ
Late menopause	Nulliparity	Ductal carcinoma in situ
Proliferative benign disease	Radiation exposure	Atypical hyperplasia
Postmenopausal obesity	Prior breast cancer	
Alcohol use		
Estrogen/ progestogen hormone therapy		

Adapted from: Bilimoria MM, Morrow M. The woman at increased risk for breast cancer: evaluation and management strategies. *CA Cancer J Clin.* 1995;45:263-278.

BREAST DENSITY NOTIFICATION ACTs



Pennsylvania's Breast Density Notification Act

- Enacted 2013
- "This notice contains the results of your recent mammogram, including information about breast density. If your mammogram shows that your breast tissue is dense, you should know that dense breast tissue is a common finding and is not abnormal. Statistics show many women could have dense or highly dense breasts. Dense breast tissue can make it harder to find cancer on a mammogram and may be associated with an increased risk of cancer. **This information about the result of your mammogram is given to you to raise your awareness and to inform your conversations with your physician. Together, you can decide which screening options are right for you based on your mammogram results, individual risk factors or physical examination. A report of your results was sent to your physician."**

ACOG 2015 Committee Opinion 625 Management of Women With Dense Breasts Diagnosed by Mammography

- No studies have demonstrated earlier detection or improved prognosis when additional breast imaging is obtained.
- ACOG advocates against recommending additional breast imaging in otherwise asymptomatic women with increased breast density.
- **Physicians should comply with state laws requiring disclosure of increased mammographic breast density, many mandating offering additional breast imaging.**

"… to inform your conversations with your physician. Together, you can decide which screening options are right for you …"

- **Which screening options are being referred to?**
  - Breast Ultrasound ?
  - Breast MRI ?
  - Breast Tomosynthesis ?
  - Molecular Breast Imaging ?

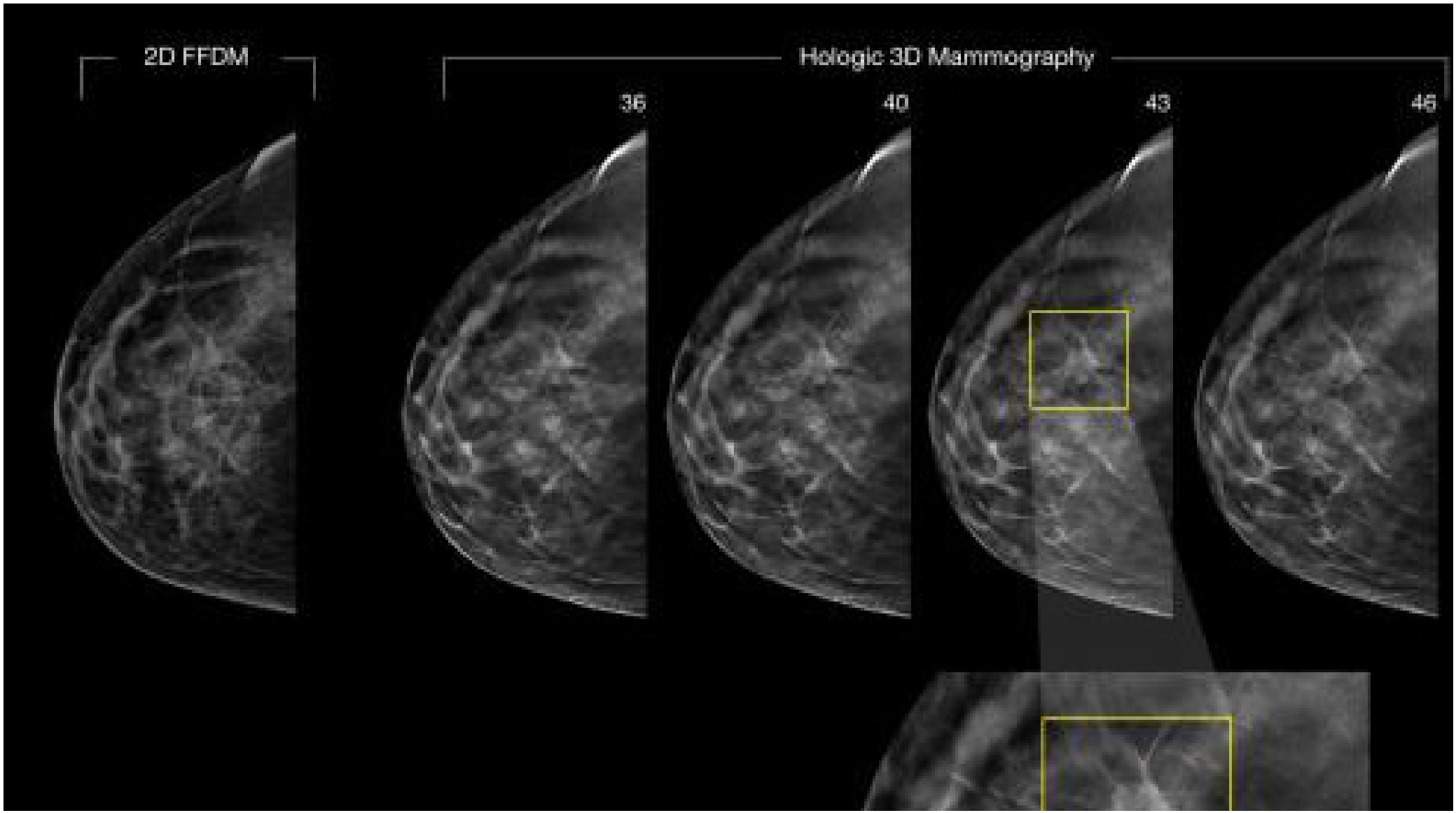
Digital Breast Tomosynthesis

Also called 3-dimensional (3D) Mammography

Low dose radiation and computer reconstruction forms a 3D model of the breasts

Higher cancer detection rates with fewer recalls

Digital Breast Tomosynthesis



Molecular Breast Imaging (MBI)

Your mammographic breast density on today's study is considered dense. Please understand that assessment of breast density is subjective and that variations in breast density from year to year may be of no clinical significance. Dense breast tissue can make it harder to find cancer on a mammogram and may be associated with an increased risk of cancer. Dense Breast tissue in and of itself is a relatively common condition and is normal. This information is not provided to cause undue concern; rather, it is to raise your awareness and promote discussion with your health care provider regarding the presense of dense breast tissue in addition to other risk factors.

Because of your breast density, secondary screening with MBI(Molecular Breast Imaging)is now being offered. To schedule please call (215) 456-3282.

For more information about secondary screening options, please visit www.becertain.info

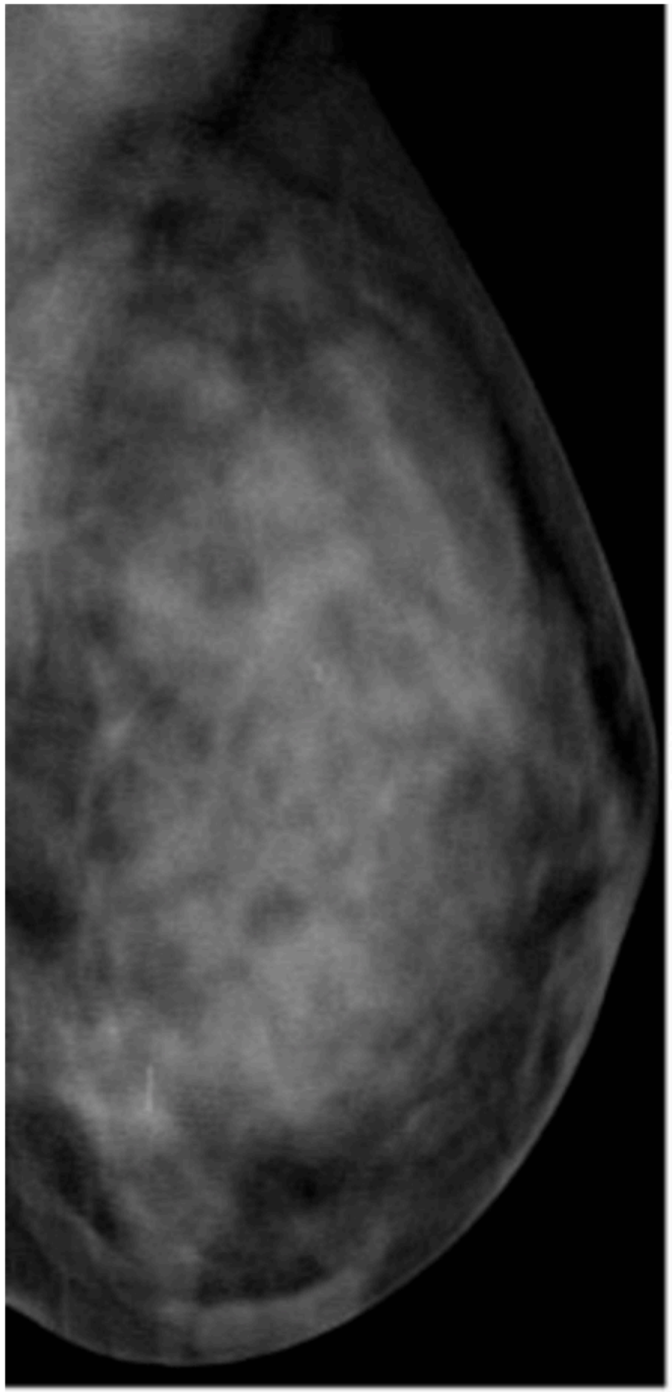
Sincerely,

Einstein Healthcare Network
Department of Radiology
Division of Breast Imaging

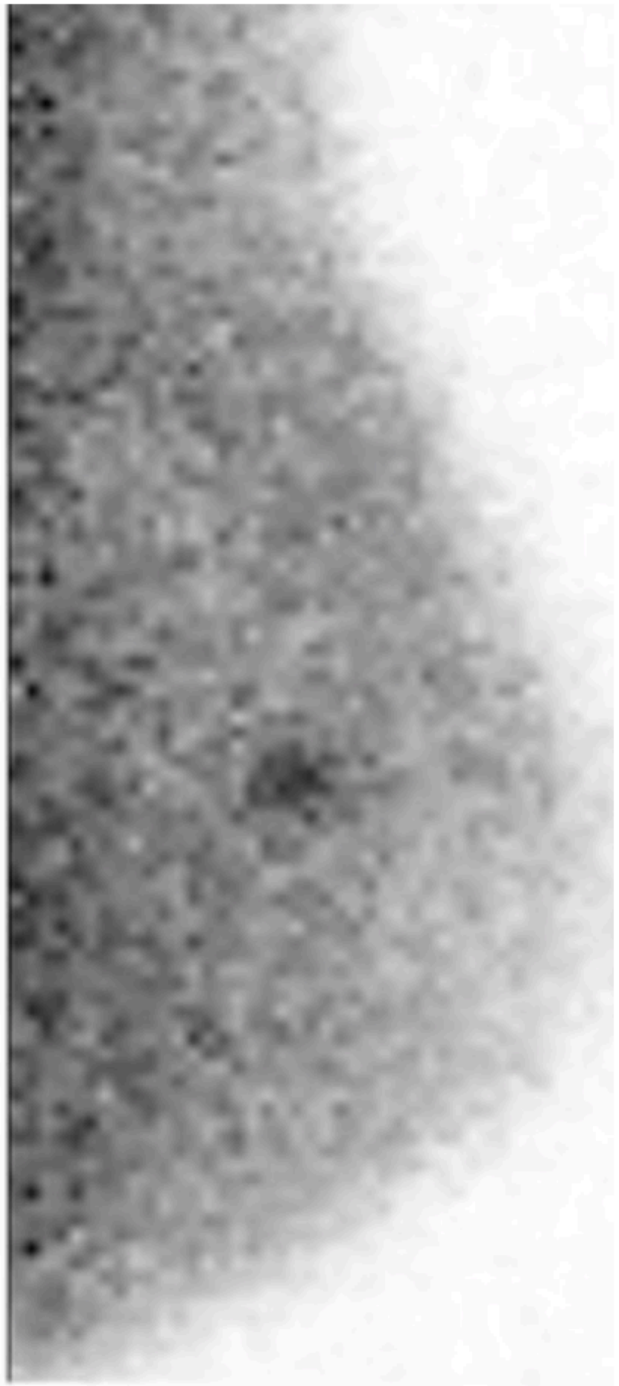
Supplemental Breast Cancer Screening With Molecular Breast Imaging for Women With Dense Breast Tissue

Shermis. *AJR* 2016

- Retrospective study of clinical performance of molecular breast imaging as a supplementary screening tool for women with dense breasts.
- Women with dense breasts and negative mammography subsequently underwent screening with 300 MBq (8 mCi) 99mTc-sestamibi molecular breast imaging



Tomosynthesis scan of woman with dense breast tissue.



Molecular Breast Imaging (MBI) scan of same woman.

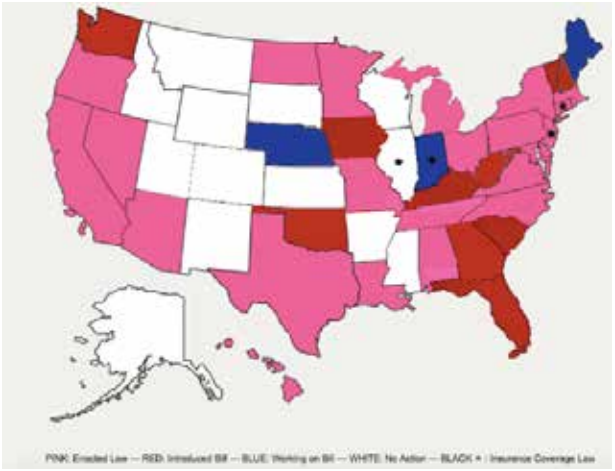
Supplemental Breast Cancer Screening With Molecular Breast Imaging for Women With Dense Breast Tissue

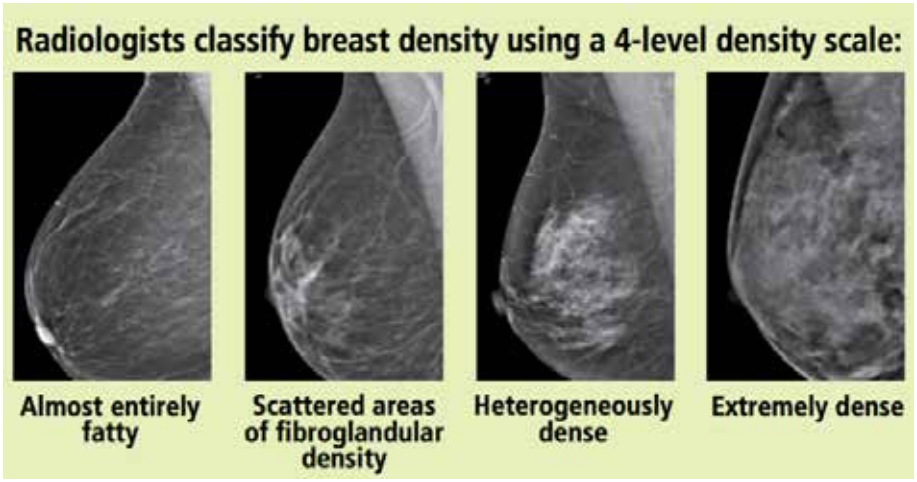
Shermis. *AJR* 2016

- Molecular breast imaging screening of 1,696 women
- Detection of 13 mammographically occult malignancies (11 invasive, 1 node positive).
- Incremental cancer detection rate was 8 %
- Recall rate was 8 %
- Biopsy rate was 4 %
- PPV for recall was 9 %
- PPV for biopsy was 19 %

Breast density laws.
Are you in compliance?

Contemporary OB/GYN 2016





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Einstein Medical Center Philadelphia

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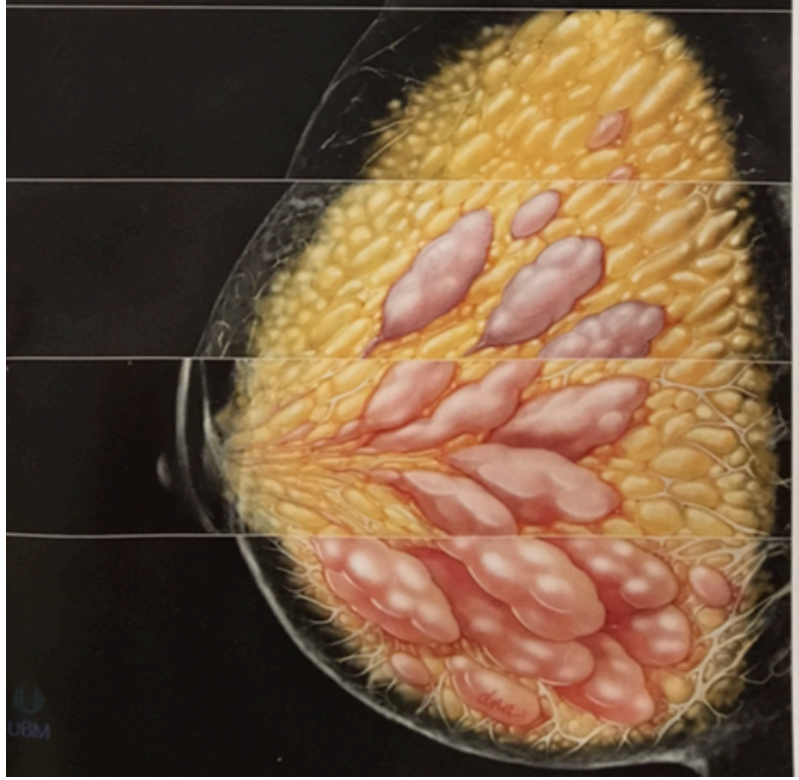

Care after sexual assault

Pessaries for preterm birth prevention?

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Delivery for intrahepatic cholestasis

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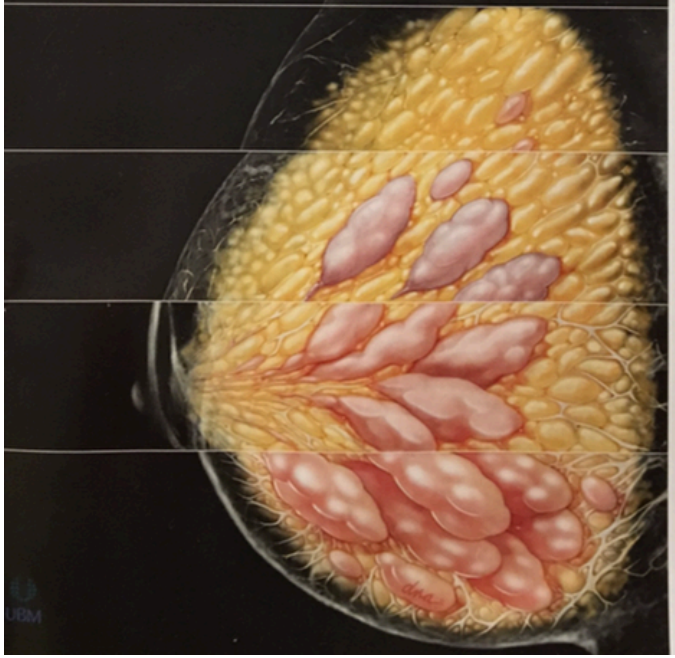

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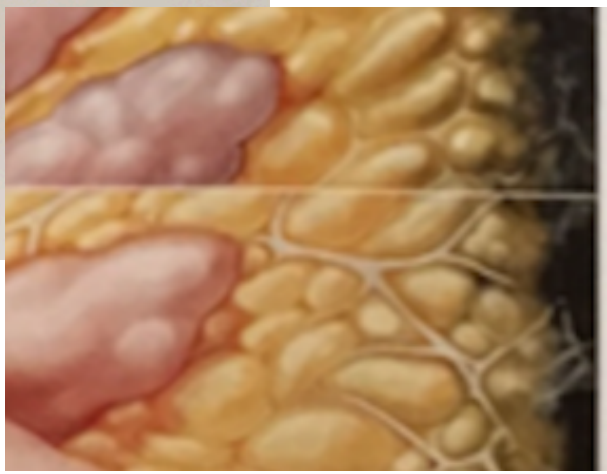

DR LOCKWOOD
President Trump and healthcare

Provider Density Survey

- 79% unaware of the 4 density categories
- 68% unaware of Breast Density Notification Act
- 64% focus on “Impression/Recommendation” section of mammogram report
- 85% rely on radiology to determine if additional imaging is needed

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HEALTHCARE NETWORK

Provider Density Survey

- When aware of increased density on a screening mammogram:
  - 60% take no action
  - 19% personally notify the woman
  - **21% personally notify the woman and discuss the option of additional breast imaging**

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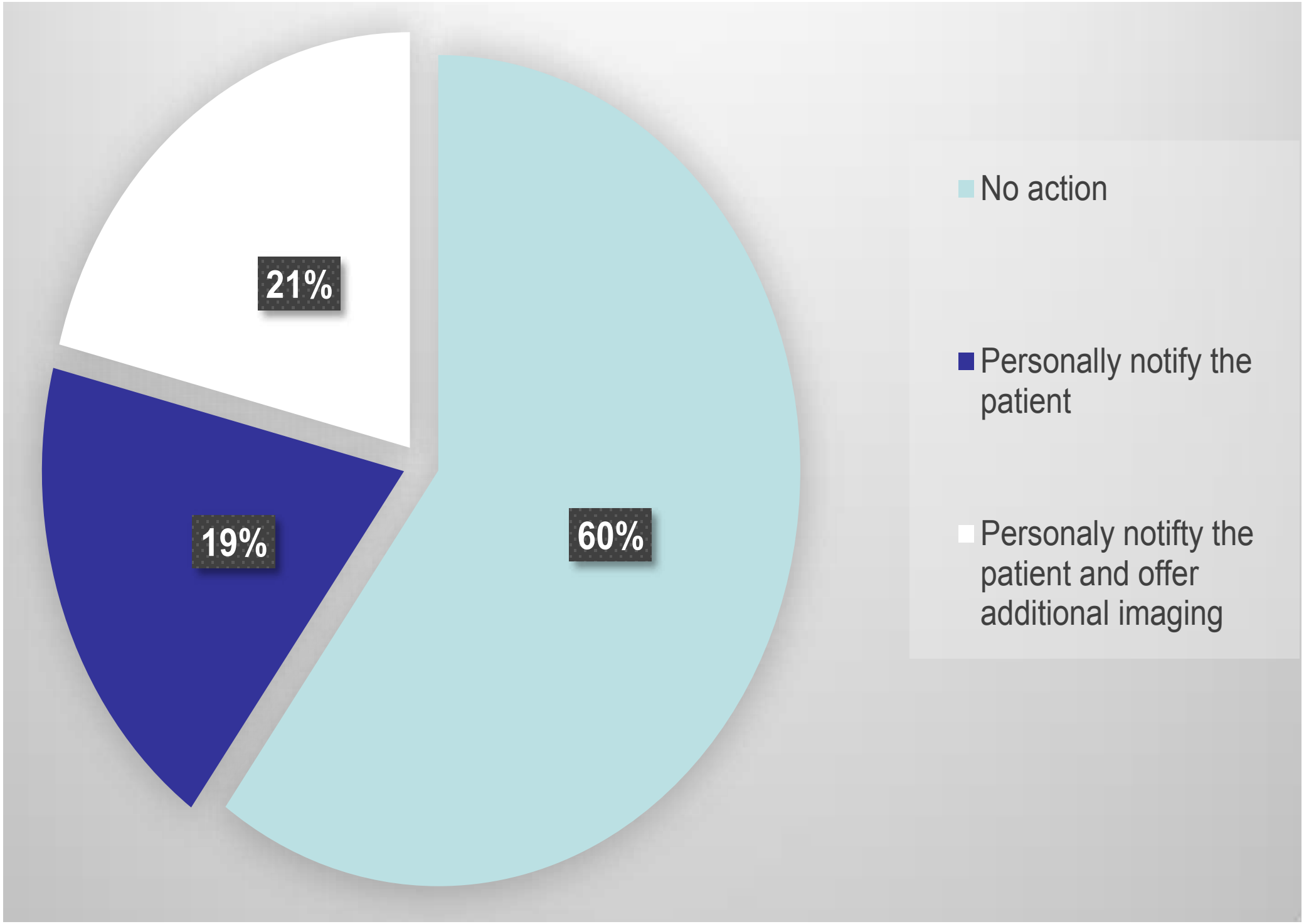
21%
19%
60%
No action
Personally notify the patient
Personaly notifty the patient and offer additional imaging

Patient Density Survey

- 72% unaware of Breast Density Notification Act
- 40% would be anxious if notified of increased density
- **84% would request additional imaging if 100% covered by insurance**
- **44% would pay out of pocket if not covered**
- 88% believed PA law economically discriminates

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Risk Management Interventions

- Providers education regarding the significance of increased breast density on mammography and the corresponding state law.

- Mammogram reports sent to ordering providers have been reformatted so that the breast density category is now more obvious, being listed in the "**Impression/Recommendations**" section.

Radiology result letters sent to patients now contain the following:

- "*The American College of Obstetricians and Gynecologists has addressed increased breast density, noting that no research studies have demonstrated earlier cancer detection or improved prognosis when additional breast imaging is obtained. ACOG advocates against routinely recommending additional breast imaging in otherwise asymptomatic women with increased breast density on mammogram.* ***Some patients, however, wish to discuss increased breast density further or are interested in obtaining additional breast imaging. If you also do, given the complexity of the issue, you should schedule a breast density consult with your provider.***"

Further Areas of Confusion

- Is written notification from the radiologist or health care provider legally acceptable or must a discussion regarding breast density occur?

- If a woman's breast density is not reported as significantly changed from year to year, are providers legally required to repeat a discussion regarding increased mammographic density and possibly offer additional imaging every time that a screening mammogram is performed?

Further Areas of Confusion

- What is the economic cost to insurers and women?
- Do the breast density notification laws actually lead to the earlier detection and treatment of more breast cancers, as well as improved survival?
- Do these laws lead to more unnecessary benign breast biopsies and at what emotional toll for the 50% of women being notified of their increased breast density?

Case 1

- A 49-year-old asymptomatic woman with a recent normal check-up, including a breast exam, obtained a referral for a screening bilateral mammogram from her PCP/GYN/NP/CNM/PA.

- The bilateral screening mammogram was performed.

- The patient later received a letter from the radiology center stating in bold at the top of the page **"*We wish to inform you that the results of your recent mammography examination are normal*."**
- "*Your mammographic breast density is considered dense. Dense breast tissue is a common finding and is not abnormal. A report of your results was sent to your physician*."

- The ordering provider received a mammography report:

  "*BIRADS 1: Negative evaluation.*

  Impression:

  1) No mammographic evidence of malignancy in either breast.

  2*) A bilateral mammogram is recommended in one year*."

- Hidden within the report "*The breast tissue is heterogenously dense*."

- The patient, believing that her "*normal*" mammogram required no additional action, did not contact the ordering physician for further discussion.

- No further action was taken by the ordering provider.

- One year later, after newly appearing microcalcifications were noted on her next screening mammogram, a biopsy found invasive ductal breast carcinoma.

- Unilateral mastectomy, axillary node dissection, chemotherapy, and radiation treatment for a Stage II breast cancer.

- Lawsuit: Provider negligently failed to comply with the state's breast density notification act.
- The woman stated that she would have elected to undergo a breast MRI if offered due to her increased breast density.
- The Complaint alleged that a breast MRI would have led to earlier diagnosis and treatment of her breast cancer, as well as a greater likelihood of survival.

Case 2

- 45-year-old woman with no complaints has a normal GYN check-up including a normal breast examination
- A screening mammogram is ordered

- The patient later received a letter from the radiology center **“*We wish to inform you that the results of your recent mammography examination are normal*.”**

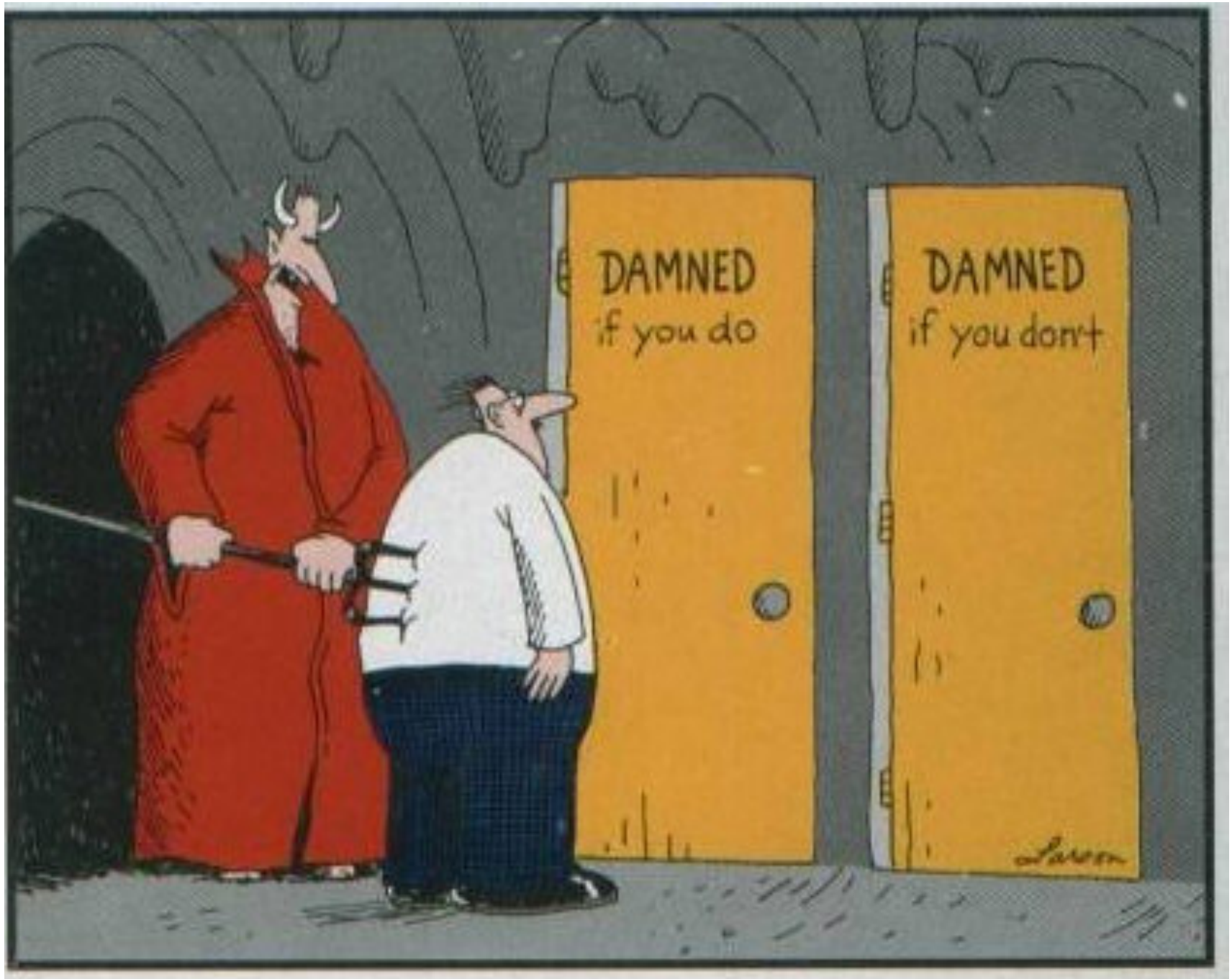
- “*Your mammographic breast density is considered dense. Dense breast tissue is a common finding and is not abnormal. A report of your results was sent to your physician*.”

- The provider's report: "*BIRADS 1: Negative evaluation.*"
- "*Impression: 1) No mammographic evidence of malignancy in either breast*. and *2) A bilateral mammogram is recommended in one year*."
- Hidden within the report "*The breast tissue is extremely dense*."

- The patient, believing that her "*normal*" mammogram required no additional action, did not contact the ordering physician for further discussion.

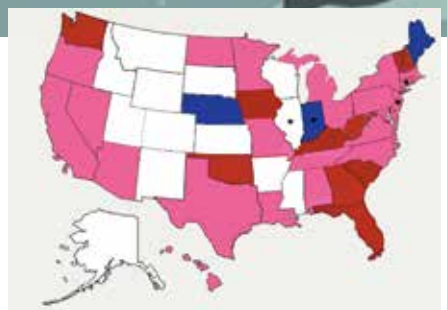
- Her provider, aware of the Breast Density Notification Act, searches through the screening mammogram report, noting increased density.
- The provider calls her, notifies her of her increased density, and offers additional breast imaging.
- The patient, previously believing her screening MXR was completely normal, is very confused.

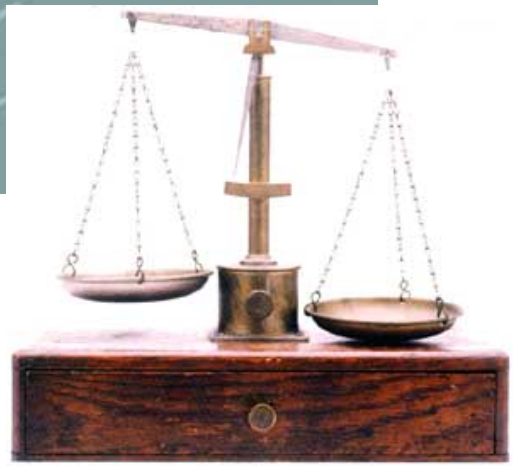
- After 3 phone calls with her provider, the patient requests additional breast imaging.
- Her insurer declines coverage.
- Out of pocket costs:
  - **$2400 breast MRI**
  - **$250 breast ultrasound**
- The patient cannot afford the additional testing
- Significant anxiety



"C'mon, c'mon — it's either one or the other."

Breast Density Notification Acts





Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Over-Diagnosis

Jorgensen. *Annals of Internal Medicine* 2017

- Effective breast cancer screening should detect early-stage cancer and prevent advanced disease.
- Objective: To assess the association between screening and the size of detected tumors and to estimate over-diagnosis (detection of tumors that would not become clinically relevant).

Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Overdiagnosis

Jorgensen. *Annals of Internal Medicine* 2017

- Screening programs offering biennial mammography for women aged 50 to 69. Compared screened vs. nonscreened.
- Incidence of advanced (>20 mm) and nonadvanced (≤20 mm) breast cancer tumors in screened and nonscreened women.
- **Screening was not associated with lower incidence of advanced tumors.**
- Incidence of nonadvanced tumors increased in the screening vs. prescreening periods (1.49 [95% CI, 1.43 to 1.54]). Over-diagnosis rate of 24% [including DCIS] and 15% [excluding DCIS]).
- In women younger than the screening age, over-diagnosis rate of 48% [including DCIS] and 30% [excluding DCIS]).

Breast Cancer Screening in Denmark: A Cohort Study of Tumor Size and Overdiagnosis

Jorgensen. *Annals of Internal Medicine* 2017

- Conclusion: Breast cancer screening was not associated with a reduction in the incidence of advanced cancer. 1 in every 3 invasive tumors and cases of DCIS diagnosed in women offered screening represent over-diagnosis (incidence increase of 48%).

If Women controlled medicine

The Manogram

SUMMARY

- New mammography screening recommendations
- 4 categories of mammographic breast density
- Mammographic breast density laws are not evidence based
- Providers not complying with mammographic breast density laws may face medico-legal consequences


HEALTH
NEW BREAST EXAM STANDARD
START AT 50
YEAH, WE KNOW WE SAID 40, BUT NOW IT'S 50...
LOOK, WHAT'S SO HARD TO UNDERSTAND?
JOHN COLE