

Doctor tells FDA to change rules; says mammogram won't spot cancer in some

November 7 2011, By Lindy Washburn

A woman's mammography results should tell her if she has dense breasts, so that she'll know the test may miss a breast cancer diagnosis, a Ridgewood, N.J., radiologist told a federal advisory panel on mammography Friday.

Women with dense breasts are more likely to develop breast cancer, and their cancers may be more aggressive, recent research has found. Those who've already had breast cancer are more likely to have a recurrence if they have dense breasts.

But [tumor cells](#) may be impossible to distinguish from normal cells on mammograms of women with dense breasts because both show up as white areas.

"With dense tissue, cancers big and small are often not visible on the mammogram," Dr. Lisa Weinstock, the founder of Women's Digital Imaging in Ridgewood, told the FDA's National Mammography Quality Assurance Advisory Committee at their meeting on Friday in Maryland.

Cancers may be visible with other types of imaging, such as ultrasound.

"Educating patients directly about the risks of dense tissue and the limits of mammography is imperative," she said.

Currently, two reports are produced after a mammogram: one for the referring doctor and one for the patient. The doctor gets information

about breast density but the patient doesn't. Weinstock and others advocate that the information also be included in the report to patients.

The committee meets regularly to hear from the public and give advice and recommendations to the federal [Food and Drug Administration](#), which inspects mammography facilities and enforces the law about mammography quality and standards. It was not expected to vote on a recommendation at Friday's meeting.

"Without this information, the patient letter is misleading and may have fatal consequences," said Nancy Capello, a Connecticut woman who founded the [advocacy group](#) "Are You Dense?" Capello testified before the committee on Friday.

Capello was diagnosed with Stage 3 breast cancer, which had spread to 13 lymph nodes, in 2004 - after 11 annual mammograms, including one two months earlier, had found nothing. She did not know that she had dense breasts, which reduce the sensitivity of mammograms, she said.

"We have too many women like me, who end up with an advanced stage of cancer," she said, in a phone interview outside the hearing room in Gaithersburg, Md. With better early detection, she believes that fewer women at first diagnosis will learn that their [breast cancer](#) has already spread, she said.

A 52-year-old Teaneck, N.J., woman, who asked that her name not be used, also testified.

"I had gone to different radiologists in the past, and nobody told me I had dense breasts," she said.

Weinstock told her she had dense breasts and scheduled ultrasound screenings between her annual [mammograms](#), she said.

It was the ultrasound that found a small invasive lobular cancer diagnosed earlier this year. Even knowing that the tumor was there, it could not be seen on a subsequent mammogram, she said. She underwent surgery and has fully recovered.

The American College of Radiology, in a position statement, said that it recognizes that greater breast density leads to lower sensitivity for mammography. While information on breast density is helpful for physicians, it said, "It is less clear how the typical patient would interpret or understand the same information."

Patients with dense breasts might demand additional alternative forms of screening, such as ultrasounds or MRIs, which would lead to more false positives and unnecessary breast biopsies.

If the alternate forms of screening were not covered by insurance, that might lead to "an unfortunate disparity" between those who could pay for it themselves and those who couldn't. And women without dense breasts might develop a false sense of security, the policy statement said.

The advocacy group, Are You Dense? estimates that 40 percent of women have dense breasts - two-thirds of those before menopause and one-fourth of those after menopause, but no population studies have been done.

Two states - Connecticut and Texas - have enacted laws requiring that reports to patients contain information about [breast density](#), and legislation is pending in New York State. A Connecticut congresswoman also introduced federal legislation last month to require such reports.

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