



## **YSC Responds to FDA Panel Recommendations and Recent Legislation**

On April 11, 2012, the FDA Radiological Devices Advisory Panel (“the Advisory Panel”), unanimously voted in support of the use of automated breast ultrasound device (ABUS)<sup>i</sup> for breast cancer screening, after a negative mammogram in women with dense breasts.<sup>ii</sup> The recommendation specifically excluded the use of ABUS for screening in women who have had prior “breast intervention,” which includes breast biopsy or breast cancer treatment.<sup>iii</sup> The FDA has not yet decided whether to accept the recommendations of the Advisory Panel. The meeting’s summary can be viewed [here](#).

We do not believe that this recent Advisory Panel recommendation affects most of our YSC constituents, who are young women diagnosed with breast cancer under the age of 40. Screening occurs in healthy women who are not yet showing any symptoms of breast cancer and current screening recommendations suggest that women age 40 and older should have a mammogram every year.<sup>iv</sup> Screening for the disease before a symptom of breast cancer is seen or felt is not warranted in young women unless she is at high risk for breast cancer.<sup>v</sup> The Advisory Panel recommendation would also not apply to young breast cancer survivors who have one or more breasts remaining as it specifically excludes women with prior breast intervention.

Breast density is also a topic of recently enacted or proposed legislation throughout the country. These laws, including New York Bill No. A09586 require insurers to provide coverage for “supplementary screening tests” when a mammogram shows dense breast tissue.<sup>vi</sup> The laws also require written notification to the patient informing them of their dense breasts.<sup>vii</sup> Again, because these laws are directed to the population of healthy women receiving breast cancer screening, we do not believe they are directed at or will affect most of our YSC constituents.

YSC will continue to monitor this situation on both the potential FDA approval of the ABUS for screening as well as the breast density laws to see the potential implications for our young women diagnosed with breast cancer. Both of these topics highlight the issues facing young women today. While over 11,000 women under 40 in the United States are diagnosed with breast cancer annually, there is still no reliable or proven screening method for early detection of breast cancer in young women. Accordingly, YSC urges all young women to be familiar with their bodies, know their own personal risk factors for breast cancer, be aware of the signs of breast malignancies and to consult promptly with their health provider if they have any concerns.

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<sup>i</sup> The specific device is the sono-v Automated Breast Ultrasound System (ABUS) manufactured by U-Systems, Inc. of California. It is currently approved by the FDA for diagnosing breast cancer in conjunction with mammography. On April 11<sup>th</sup>, the Panel considered whether or not the ABUS could be used for screening as well.

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<sup>ii</sup> “Dense breasts” are defined as having a Breast Imaging Reporting and Data System (BI-RADS) composition density of 3 or 4, which means that over 50% of the breast is dense.

<sup>iii</sup> Phend, Crystal, “FDA Panel OKs Ultrasound to Screen Dense Breasts,” MedPage Today, Apr. 13, 2012 (available at [www.medpagetoday.com/HematologyOncology/BreastCancer/32149](http://www.medpagetoday.com/HematologyOncology/BreastCancer/32149)). The Panel included this restriction because the studies submitted in support of the expanded indication excluded such women.

<sup>iv</sup> American Cancer Society recommends starting at age 40 with annual mammograms, <http://www.cancer.org/Cancer/BreastCancer/MoreInformation/BreastCancerEarlyDetection/breast-cancer-early-detection-acs-recs>, while the U.S. Preventive Services Task Force recommended mammography screening every other year starting at age 50. [www.uspreventiveservicestaskforce.org/uspstf09/breastcancer/brcanrs.htm](http://www.uspreventiveservicestaskforce.org/uspstf09/breastcancer/brcanrs.htm). Please see YSC’s response to new mammography guidelines, dated November 17, 2009. [http://www.youngsurvival.org/uploaded\\_files/tiny\\_mce/PDFs/YSC\\_Mammography\\_Guidelines\\_Response\\_Nov\\_17\\_2009.pdf](http://www.youngsurvival.org/uploaded_files/tiny_mce/PDFs/YSC_Mammography_Guidelines_Response_Nov_17_2009.pdf)

<sup>v</sup> Some things that put a young woman at increased risk include: a previous history of breast cancer; a first-degree relative who has had breast or ovarian cancer, especially if it was diagnosed pre-menopause; having a mutation in BRCA1 or BRCA2 gene; and having radiation treatment to the chest during childhood or adolescence. If you are a high-risk young woman, being sent for screening mammograms, you should ask your doctor whether the addition of ABUS to mammography is warranted.

<sup>vi</sup> See N.Y. Bill No. A9586, Memo (found at [www.assembly.state.ny.us/leg/?default\\_fld=&bn=A09586&term=2011&Summary=Y&Memo=Y](http://www.assembly.state.ny.us/leg/?default_fld=&bn=A09586&term=2011&Summary=Y&Memo=Y) ). Three states have passed breast density laws so far, with 12 other states endorsing it and 4 states working on it. See [www.areyoudenseadvocacy.org/dense/](http://www.areyoudenseadvocacy.org/dense/) A national bill, H.R. 3102, has also been introduced in the US House of Representatives. A study performed after the Connecticut breast density law was passed found that adding ultrasound to mammography screening increased the ability to detect cancer in dense breasts. This study will be published in The Breast Journal, but is not yet available. See <http://health.myrecordjournal.com/vitalsigns/ultrasound-testing-found-valuable-if-breasts-dense>.

<sup>vii</sup> The American College of Radiology, Susan G. Komen for the Cure, and American Cancer Society are “neutral” on this legislation while the American Medical Association and American College of Obstetricians and Gynecologists oppose it.