

June 26, 2019

Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***Re: Docket No. FDA-2013-N-0134—Mammography Quality Standards Act; Amendments to Part 900 Regulations***

Dear Sir or Madam:

Our organizations individually represent millions of women who have mammograms, and we are keenly interested in improving the delivery of this service to women in the United States. Our interest in breast screening to detect cancer earlier and concern for women's health are the impetus for us to collectively submit the enclosed comments in response to the U.S. Food and Drug Administration's ("FDA" or "the Agency") March 28, 2019, Federal Register notice and request for comments on proposed updates to the *Mammography Quality Standards Act*.

We commend the Agency's efforts to modernize the mammography regulations set forth in 21 C.F.R. Part 900 and to help empower patients with more information to inform important decisions related to their breast health care. As noted by then-Commissioner Gottlieb, "[b]reast cancer is one of the most worrisome health concerns facing women," and is the second leading cause of cancer death in American women, after lung cancer. As patient advocates, we applaud FDA's efforts to improve the delivery of this critical service, and we suggest some clarifications that we think can build on what the Agency has proposed.

FDA's proposed rule appropriately seeks to improve communication and medical decision-making by adding certain information related to breast density in the mammography lay summary letter provided to patients. Specifically, FDA proposes to amend 21 C.F.R. § 900.12 as follows:

(c)(2) . . .

*(iii) If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the lay summary shall include "Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is low, not high. Follow the recommendations in this letter, and talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."*

*(iv) If the mammography report identifies the breast density as “The breasts are heterogeneously dense, which may obscure small masses” or “The breasts are extremely dense, which lowers the sensitivity of mammography,” the lay summary shall include “Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is high. Some patients with high breast density may need other imaging tests in addition to mammograms. Follow the recommendations in this letter, and talk to your healthcare provider about high breast density and how it relates to breast cancer risk, and your individual situation.”*

We agree that it is critically important for patients to receive clear, concise, and accurate information to help them understand the results of their mammograms. It is also important for this information to identify possible next steps for patients, without creating undue alarm. In our view, this is particularly important in regard to breast density. Patients should be educated about breast density, to include the fact that dense breast tissue is very common and is not abnormal. At the same time, patients should be encouraged and empowered to discuss their mammography findings with their physician, to determine whether additional tests may be beneficial in their specific circumstances.

In light of the above, we recommend that the proposed changes to 21 C.F.R. § 900.12(c)(2)(iv), be revised to read as follows:

*(c)(2)(iii) If the mammography report identifies the patient's breast density as “The breasts are almost entirely fatty” or “There are scattered areas of fibroglandular density,” the lay summary shall include “Breast tissue density can be low or high. This depends on how much fat and dense tissue is present in the breast. High density tissue makes it harder to find cancer on a mammogram. **Your breast tissue density is low and is categorized as {fatty OR scattered}**, and your breasts are not considered dense. Follow the advice in this letter and talk to your healthcare provider about your risks for breast cancer and the recommended screening for your individual situation. It is important to continue with routine screening mammograms as risk factors can change and should be reviewed from time to time.”*

*(iv) If the mammography report identifies the breast density as “The breasts are heterogeneously dense, which may obscure small masses” or “The breasts are extremely dense, which lowers the sensitivity of mammography,” the lay summary shall include “Breast tissue density can be low or high. This depends on how much fat and dense tissue is present in the breast. **Your breast tissue density is high and is categorized as {heterogeneously OR extremely} dense**, which makes it harder to find breast cancer on a mammogram. As a result, other imaging tests after your mammogram may be appropriate. Dense breasts are normal, but may raise your risk for getting breast cancer. Follow the advice in this letter and talk to your health care provider about high breast density, your other risk factors, and breast screening for your specific situation. It is important to continue with routine screening mammograms as breast density and other risk factors can change and should be reviewed from time to time.”*

We believe this information will ensure that all women are adequately informed about breast density, which can change over time. We also believe this language will minimize confusion and alarm associated with mammography findings, while continuing to stress the importance of routine screening mammograms for all patients. (We extend special thanks to DenseBreast-info.Org for their leadership in the development of the recommended language.)

Improving how patients communicate with their providers can only enhance patient understanding of their care. The information patients share with their provider needs to be improved as we better understand risk, for example, women should also be sharing their family cancer history with their providers as this could raise awareness of increased cancer risk. We propose that mammography facilities collect family cancer history via an evidence-based tool and refer women to a health care provider with experience in cancer genetics and/or a genetic counselor for further evaluation as needed.

With these additional clarifications, we support FDA's efforts to improve the delivery of mammography services in the United States.

If you have any questions about this letter, please contact Marilyn Yager at [marilyn.yager@alston.com](mailto:marilyn.yager@alston.com), (202) 239-3341.

Respectfully Submitted,

Black Women's Health Imperative  
Breast Friends  
Brem Foundation to Defeat Breast Cancer  
Bright Pink  
Don't be a Chump! Check for a Lump!  
FORCE: Facing Our Risk of Cancer Empowered  
HealthyWomen  
Living Beyond Breast Cancer  
Men Against Breast Cancer  
National Association of Nurse Practitioners in Women's Health  
National Black Nurse Association  
National Hispanic Medical Association  
Prevent Cancer Foundation  
Sharsheret  
Susan G. Komen  
Tigerlily Foundation