

Congress of the United States
House of Representatives
Washington, DC 20515

April 8, 2015

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
The Food and Drug Administration
10903 New Hampshire Avenue
White Oak, RM 322346
Silver Springs, MD 20993

Dear Acting Commissioner Ostroff,

We are writing to inquire as to the status of the implementation of the Food and Drug Administration (FDA) decision to include breast tissue composition in mammography reporting results. It has been nearly four years since the Mammography Quality Standards Act (MQSA) committee of the FDA recommended standardized notification of a patient's breast tissue composition in the "lay" letter women receive after they have a mammogram, and there has been little progress in the implementation of this change.

While mammograms are important for the early detection of breast cancer, studies have shown that they miss half of the cancers in women with dense breasts. More than forty percent of all women have dense breasts and are often unaware of their risk.

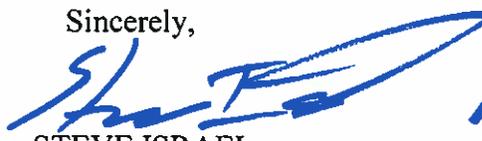
Currently, there is no federal requirement for the inclusion of density information in the letter women receive after their mammograms. Without the knowledge that their breasts are dense, women are unable to advocate effectively for their health. Research demonstrates that adding ultrasound to mammography in women with dense breast tissue nearly doubles the detection of small, invasive cancers. If these cancers are found early, they are often treatable, survivable, and less costly for the healthcare system to treat.

In December 2013 an amendment was scheduled to be issued as a Notice of Proposed Rulemaking, yet FDA has not moved forward with a rule.

We urge you to expedite the implementation of this regulatory change as soon as possible. Women should have access to this critical and potentially lifesaving information.

Sincerely,


ROSA L. DeLAURO
Member of Congress


STEVE ISRAEL
Member of Congress


MICHAEL FITZPATRICK
Member of Congress