

# United States Senate

WASHINGTON, DC 20510

July 17, 2018

Dr. Scott Gottlieb  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write to request that the Food and Drug Administration (FDA) include a requirement that patients with dense breast tissue be given this information as part of their mammography report. We are encouraged that FDA has recognized the importance of modernizing mammography quality standards in the Spring 2018 Unified Agenda and that you have also recognized breast density as a risk factor for breast cancer. We appreciate your attention to this critical issue as you proceed with updating regulations issued under the *Mammography Quality Standards Act*.

As you know, dense breast tissue and cancer look similar on a mammogram, which makes cancer harder to detect in women with higher breast tissue density. The dense tissue essentially hides the cancer. Unfortunately, mammogram summaries that women receive after a screening may omit their breast tissue density unless required by the state they live in. Currently, 35 states have density reporting laws, but a federal standard is necessary for all women to receive this important medical information.

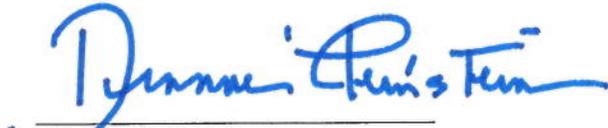
Early detection is critical to increasing the chance of survival for women with breast cancer and patients deserve to know their own medical information in order to make fully informed decisions about their health. We urge that any amendments to regulations governing mammography ensure appropriate information about breast density is included on the mammography summary patients receive. Specifically, these should include, at a minimum:

- A qualitative assessment of the patient's personal breast tissue density;
- An explanation of the effect of breast density in masking the presence of breast cancer on a mammogram; and
- A reminder to patients that individuals with dense breast tissue should talk with their health care provider if they have any questions or concerns about their summary.

We also request information on your progress in developing new regulations related to mammography standards, as well as your timeline for publishing a final rule that addresses providing patients with their own medical information on if they have dense breast tissue.

We appreciate your consideration and look forward to working with you on this important issue.

Sincerely,



Dianne Feinstein  
United States Senator



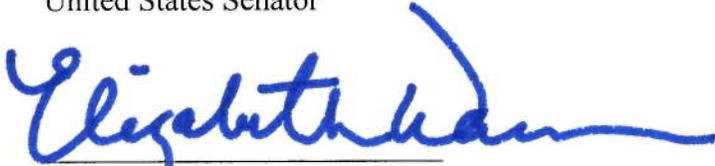
Dean Heller  
United States Senator



Amy Klobuchar  
United States Senator



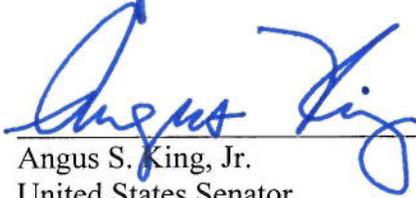
Bill Nelson  
United States Senator



Elizabeth Warren  
United States Senator



Tammy Duckworth  
United States Senator



Angus S. King, Jr.  
United States Senator



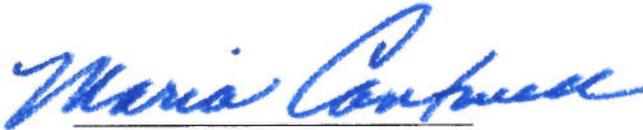
Richard Blumenthal  
United States Senator



Kirsten Gillibrand  
United States Senator



Mazie Hirono  
United States Senator



Maria Cantwell  
United States Senator



Debbie Stabenow  
United States Senator



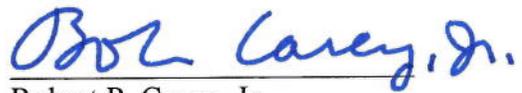
Tammy Baldwin  
United States Senator



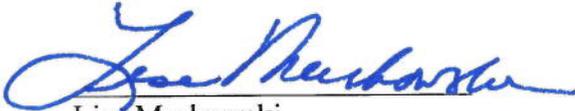
Shelley Moore Capito  
United States Senator



Richard J. Durbin  
United States Senator



Robert P. Casey, Jr.  
United States Senator



Lisa Murkowski  
United States Senator