Journal of the National Cancer Institute CAD Study Drawer Statement - July 2011

The Journal of the National Cancer Institute released a study titled: "Effectiveness of Computer-Aided Detection in Community Mammography Practice," on July 27, 2011. The study used data from the Breast Cancer Surveillance Consortium and found that CAD used during film-screen screening mammography in the United States is associated with decreased specificity but no improvement in the detection rate or prognostic characteristics of invasive breast cancer.

iCAD, Inc. is an industry-leading provider of mammography CAD solutions, including digital and film based solutions. The Company was not involved with this study.

The current study builds on an initial assessment of CAD technology from lead investigator Joshua J. Fenton, MD, MPH, the results of which were published in the New England Journal of Medicine (NEJM) in April 2007. This latest study uses a similar longitudinal study design as the NEJM study, which was criticized by industry experts, as having a flawed methodology. Additionally, critics of the research findings in the NEJM said that study was based on use of an older version of CAD technology, and so did not accurately reflect its usefulness.

- The current study was limited to film mammography and Full Field Digital Mammography (FFDM) was excluded. FFDM is becoming increasingly popular as the standard of care for mammography screenings in the U.S.
- The study only looks at whether CAD improved breast cancer detection when used by community radiologists
- The BCSC does not collect data on the specific CAD product used by individual facilities. (address this when asked if iCAD technology was used in the study)

As the paper acknowledges, "US breast cancer incidence declined in mid-2002 when many women stopped using HT (hormone therapy) following the publication of Women's Health Initiative findings demonstrating a link between HT and breast cancer."

- Most of the pre-CAD data was collected prior to this reduction in breast cancer incidence (1998-2002) and most of the after-CAD data was collected after this reduction in breast cancer incidence (2003-2006).
- Thus, the before-CAD vs. after-CAD sensitivity, specificity, PPV and breast cancer size
 and stage may be influenced by this reduction in breast cancer incidence, making it
 difficult or impossible to assess the impact of CAD on these measures of breast cancer
 screening.

iCAD advises customers and anyone concerned with this study to contact the Company with questions. (Please contact Jeff Hoffmeister at 310-433-9013 or jhoffmeister@icadmed.com; or John DeLucia at 937-431-7945 or jdelucia@icadmed.com.)