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September 14, 2007

Michael D. Maves, MD, MBA, FACS
Executive Vice President
American Medical Association
515 North State Street
Chicago, IL 60610

Mike
Dear Dr. Maves:

This letter follows up on my recent appearance before the AMA Board of Trustees to express surgery's thoughts and concerns about the potential regulation of stereotactic breast biopsy procedures by the Food and Drug Administration (FDA) under the Mammography Quality Standards Act (MQSA). I think we had a very good, thorough, and respectful discussion of the issue, and I look forward to continued dialogue with you and the Board as this issue plays out with the FDA. In addition to reviewing some of the College's concerns about this issue, I want to bring you up-to-date on some recent developments.

As you know, I requested the opportunity to meet with the BOT following action taken by the House of Delegates in June on Resolution 513. Sponsored by the American Society of General Surgeons and eventually referred for decision, this resolution asked the AMA to oppose FDA regulation of stereotactic breast biopsy.

During testimony in reference committee on Resolution 513, an FDA representative stated that the agency was not planning to regulate this procedure under the MQSA. However, subsequent meetings between the College, the American Society of Breast Surgeons, the Society of Surgical Oncology, the American Society of General Surgeons, and the FDA staff who would be involved in development of regulations clearly indicated the agency's desire to pursue regulation of this procedure. I was told by those who participated in the meeting that when confronted with the view that the statute does not grant the authority to regulate these procedures, FDA staff observed that "this can be changed." We take this observation to mean that because the MQSA is, in fact, due for reauthorization, language to permit such regulation could be proposed to Congress by interested parties.



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Two days after I met with the BOT on this issue, the FDA published a notice in the *Federal Register* that the National Mammography Quality Assurance Advisory Committee will be meeting on November 5, 2007, to discuss issues related to possible regulation of interventional mammography (i.e., stereotactic breast biopsy) and to receive input from professional organizations. We believe this is a very important meeting, given the fact that the College was invited to a similar meeting last fall, only to have that invitation withdrawn on short notice. As a result, the advisory committee heard only one viewpoint on this issue last year, prior to recommending that the agency consider regulating this procedure.

We all support access to safe, high quality care. However, the unintended consequences of regulating stereotactic breast biopsy through the MQSA would be to reduce access to care since MQSA effectively limits interpretation of mammograms to radiologists. Limiting delivery of image guided biopsy services or clinical diagnostic ultrasound to one specialty would immediately decrease access to image guided breast biopsy because in many parts of the country women have access to these services only because they are provided by qualified surgeons.

Stereotactic breast biopsy is an important diagnostic tool for breast surgeons and their patients. It is much less invasive than the traditional open biopsy, and with the newer vacuum-assisted biopsy, data is used from the patient's mammogram (provided by a radiologist) and entered into a computer as part of the procedure. The computer coordinates help the surgeon guide the needle to the correct area in the breast, and ultrasound makes it possible to watch the needle on the monitor to help guide it to the area of concern. This is quickly becoming the procedure of choice by both surgeons and patients. However, depending on patient characteristics, stereotactic breast biopsy may not be the most appropriate procedure to use, which is why we believe it is important to assure that breast cancer patients retain access to general surgeon specialists who have more than one "tool in their box."

Specialty societies can and should implement accreditation and certification standards for their members. The ACS and the American College of Radiology developed physician qualifications for stereotactic breast biopsy many years ago. Since 2004, the ACS Stereotactic Breast Biopsy Accreditation Program has been in place to offer surgeons the opportunity for peer review and evaluation of their facility's staff qualifications, equipment, quality control and quality assurance programs, image quality, and breast dose. It should also be noted that the American Society of Breast Surgeons sponsors a certification program in breast ultrasound and in stereotactic breast procedures for individual surgeons. Guidelines are available for both on the ASBS website.



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In addition, the College is starting up a breast center accreditation program (similar to our bariatric surgery accreditation program) in collaboration with other surgical organizations, with expected implementation early next year. Over 310 cancer centers nationwide are on the waiting list for the National Accreditation Program for Breast Centers, with some currently participating in the pilot phase of this initiative. Various program standards address issues such as center leadership, clinical management, research, data collection, professional education, community outreach, and quality improvement. Stereotactic breast biopsy and other imaging services will be an integral part of the standards for clinical management.

One point I must reiterate (as I did during the BOT meeting) has to do with the problem of limiting the use of imaging modalities to any particular specialty. This really departs from the future development of medicine and surgery, where I believe physicians and surgeons will be organized around cycles of care and disease management, and competency will depend on the ability to use imaging and image-based procedures as a platform for treating disease. Without access to imaging modalities it will not be possible to manipulate tissues in the manner that will be commonplace in the future. Technology is driving us all together, and while training is key, we can no longer take the position that only one specialty is competent or qualified to use a certain imaging technology.

The College is asking FDA for time to express its views at the November 5 meeting, and I hope that the AMA will be able to participate, as well. I would ask that our respective staff work together to develop formal comments within the parameters of our respective organizational policies relating to stereotactic breast biopsy, and to the use of imaging technology by appropriately trained physicians.

Thank you as always for being receptive to the College's views.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

TRR:jhs

cc: Cynthia Brown

*Mike - As we discussed, there
now is a timeframe and
date. J.*