

## WRITTEN TESTIMONY

**TO: NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY  
COMMITTEE (NMQAAC)**

**BY: Shawna Willey, MD, FACS**

**RE: REGULATION OF INVASIVE PROCEDURES... POSSIBLE  
MODIFICATION OF THE DEFINITION OF MAMMOGRAPHY... UNDER THE  
MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA)**

**November 5, 2007**

Chairperson, Dr. Ferguson and distinguished committee members:

On behalf of the 71,000 Fellows of the American College of Surgeons (ACS), thank you for the opportunity to discuss an issue that could be detrimental to the interests of patients in need of breast biopsy and ultimately hurt patient access and patient care. More specifically, federal regulation of interventional medical procedures, such as stereotactic breast biopsy, is unwarranted and inappropriate under the Mammography Quality Standards Act (MQSA), in the absence of a clinically significant mammography-related problem and MQSA standards that can address the problem.<sup>1</sup>

Since ACS was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice, we strongly support efforts to improve access to high quality and cost efficient care. However, the attempted regulation at hand severely falls short of meeting such high standards.

We believe regulation of stereotactic breast biopsy is both inappropriate and insupportable for three reasons: (1) it violates Congressional intent of MQSA; (2) FDA has not identified a clinically significant problem and as proposed, such regulation would limit patient access to needed high quality healthcare; and (3) the NMQAAC Advisory Committee process leading to this decision was severely flawed.

**First, the Congressional intent of the Mammography Quality Standards Act is clear.**

In 1992, Congress passed the Mammography Quality Standards Act (MQSA) to provide a general framework for ensuring national quality standards in facilities performing screening mammography.<sup>2</sup> Under the Act, all facilities that provide screening or diagnostic mammography services, including physician offices, must be credentialed. Examination of the Congressional Record demonstrates that the purpose of

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<sup>1</sup> 42 U.S.C. 263b.

<sup>2</sup> Institute of Medicine and National Research Council, *Improving Breast Imaging Quality Standards*, 2005, page 82

this legislation is to reduce the frequency of false positives and false negatives in these types of mammograms by regulating facilities in the areas of quality, personnel training, equipment evaluation, and medical records and reports.<sup>3</sup> Therefore, it is clear that the regulation of stereotactic biopsy does not fit within this purpose. Congress recognized that the MQSA statute represented an unprecedented federal regulatory initiative into regulating the practice of medicine, and placed clear limits on the statute's scope and purpose. Furthermore, the legislative history of the MQSA defined a national problem related to traditional mammography, which is practiced solely by radiologists and involves producing and interpreting images of the entire breast for screening and diagnosis of cancer.

Specifically, Congress determined that federal regulation was warranted based on specific findings of a public health issue related to differing and inadequate standards for this arena of mammography practice, and Congress worked with radiologists to develop appropriate federal quality standards for cancer screening and diagnosis from mammograms.<sup>4</sup> Consistent with this determination and approach, Congress limited regulation under the MQSA to "facilities" that "conduct [ ] breast cancer *screening or diagnosis* through mammography activities."<sup>5</sup> By limiting regulation to *facilities* engaged in screening or diagnosing from mammograms, Congress made clear that other, nontraditional uses of mammographic imaging were *not intended to be regulated under the MQSA*.

Furthermore, Congress did not address newer, non-traditional forms and uses of mammography such as stereotactic imaging, which involves stereographic images of a small area of the breast for purposes of *localization* in other, invasive procedures carried out by surgeons (and, in the case of biopsy procedures, radiologists as well). In these invasive procedures, there is no screening or diagnosis of cancer based on a mammogram. The imaging is conducted solely for localization as an integral part of a procedure intended to obtain a specimen or achieve a therapeutic outcome through removal or ablation of tissue. Moreover, the imaging is "mammographic" only insofar as it involves imaging of a small area of tissue within the breast. To the extent that such imaging can be termed "mammography," it is a completely different modality that serves a different purpose in a different medical procedure - a procedure that was neither contemplated by Congress nor included in the wording of the MQSA.

Disregarding clear Congressional intent, FDA has suggested authority under the MQSA to regulate surgeons (and radiologists) in their performance of invasive procedures when they utilize stereotactic localization as a guidance mechanism. The agency nowhere explains how the MQSA authorizes intrusion into this arena of medical practice in light of the clear distinctions (1) between stereotactic localization and traditional mammograms, (2) between the use of radiographic images for localization and the use of

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<sup>3</sup> Congressional Record, September 18-23, 1992

<sup>4</sup> H.R. Rep. No. 102-889 (1992); S. Rep. No. 102-448 (1992).

<sup>5</sup> The statute limits federal regulation to "facilities" and defines "facility" as follows:

The term "facility" means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that *conducts breast cancer screening or diagnosis* through mammography activities.

radiographic images for screening and diagnosis, and (3) between invasive procedures and the traditional practice of mammography.<sup>6</sup>

While we recognize, the purpose of stereotactic biopsy is to obtain a tissue sample for further procedures, including pathological analysis and ultimately, diagnosis of cancer, stereotactic biopsy cannot by any stretch of imagination be deemed a “diagnosis through mammography activities” within the meaning set out by MQSA. The procedure is not, and does not involve, a diagnosis, from a mammogram or otherwise.

The terms "screening" and "diagnosis" (used by Congress to define the scope of regulation under the MQSA) and the term "localization" have clearly distinct meanings.

"Screening" involves "[t]he examination of a group of usually asymptomatic individuals to detect those with a high probability of having or developing a given disease . . . [t]he initial evaluation of an individual, intended to determine suitability for a particular treatment modality;

"Diagnosis" involves "[t]he act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data; and

"Localization" involves "[t]he determination of the location of a pathological process.

The process of localization in an invasive procedure is thus distinct from diagnosis. To describe the surgeon's localization in an invasive procedure as a "diagnosis" would be to describe surgical procedures generally *as* "diagnoses of where to cut." Such a construction of the statute cannot be squared with its wording, with the practice of medicine, or with common sense. It would be subject to judicial challenge and would not likely survive scrutiny by the courts.

Stereotactic breast biopsy is an important diagnostic tool for breast surgeons and their patients. It is much less invasive than the traditional open biopsy that uses a three-dimensional coordinates system to locate small targets inside the body and to perform a procedure such as ablation, biopsy, injection, simulation, or implantation. In addition, 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

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<sup>6</sup> The agency's regulations suggest a possible misinterpretation of the statute. Although the statutory definition of the regulated "facility" is limited to an entity that "conducts breast cancer *screening or diagnosis* through mammography activities" (emphasis added), the agency's regulation is much broader, applying to any entity that "conducts mammography activities." 21 C.F.R. 900.2(q). The agency addresses stereotactic localization in the regulations by exempting it from the definition of "mammography," 21 C.F.R. 900.2(aa)(I). The agency thus appears to view the jurisdictional question as whether stereotactic localization falls within the definition of "mammography," whereas the more relevant jurisdictional question is whether the definition of "facility" covers the use of radiography for purposes of localization, as distinct from screening and diagnosis.

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."

Most importantly, while imaging is used in stereotactic breast biopsy to guide the biopsy instrument, it is not a screening or diagnostic mammogram, as described above. In fact, almost all patients who are having stereotactic breast biopsy have already had a screening and diagnostic mammography, which has led to the need for a biopsy. In stereotactic breast biopsy, the imaging modality itself is not being used to screen or diagnose breast cancer, but it is instead merely the avenue used to provide the surgeon the visual access needed to perform an interventional procedure.

Similarly, the American College of Surgeons strongly believe that the imaging platform used in stereotactic breast biopsy does not meet the definition of mammography as intended in the MQSA and, therefore, cannot be regulated under the MQSA. The current FDA regulations on the MQSA recognize there is a difference between a screening or diagnostic mammography and the imaging techniques used when performing invasive procedures like stereotactic breast biopsy. The FDA regulations define mammography in the following manner:

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

We agree with this definition and do not believe it should be changed.

**Secondly, FDA has presented no evidence-based justification for regulation of Stereotactic Biopsy under MQSA.**

Not only has the FDA not presented any evidence-based justification for this regulatory initiative, the FDA has already acknowledged that it would be inappropriate to extend MQSA regulation to invasive procedures based solely on the use in the procedure of a radiographic of the breast. Furthermore, the agency has appropriately rejected such intrusion into the practice of medicine in the absence of such findings.<sup>7</sup>

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<sup>7</sup> 61 Fed. Reg. 14,856, 14,862 (1996)

In order to make such a finding, the agency must make the following two determinations:

**(1) The FDA must identify a Clinically Significant, Mammography-Related Problem.**

FDA must make an evidence-based determination that there is a clinically significant negative outcome from the procedure that is caused, or likely to cause, in whole or in part by the mammography element of the procedure.

**(2) The FDA must identify Mammography Standards that can Resolve or Ameliorate the Problem.**

FDA must make an evidence-based determination that there are reasonable standards that can be implemented under MQSA with regard to the mammography element of the procedure that will have a significant effect on the negative clinical outcome associated with mammography.

To date, FDA has not identified such a mammography related problem.

We are confident that no such mammography-related problem exists. In fact, in our review of more than 600 articles on stereotactic breast biopsy published in peer review journals in the past 10 years reveals no evidence of mammography-related quality issues when performing this procedure. In fact, almost every single article written in the past 10 years concludes stereotactic breast biopsy is a safe and effective procedure with a very low rate of discordant outcomes regardless of cause. We have included for you review Attachment A, which lists major articles on stereotactic breast biopsy.

Moreover, the few problems that have been identified in the literature involve patient selection for the procedure, and not use of equipment or mammographic technique. For example, stereotactic breast biopsy is not the preferred biopsy choice for cystic or liquid masses, but is the preferred method for microcalcifications. There is no evidence or basis in science for concluding that regulation of stereotactic breast biopsy under the MQSA would help physicians select the best biopsy choice for an individual patient or otherwise reduce the low discordance rate associated with this procedure. It would instead reduce the likelihood that the patient would receive the most optimal procedure by reducing the availability of the stereotactic breast biopsy.

ACS would further make note that, regulation of stereotactic breast biopsy will hurt patient access to these procedures as well as development of the entire field of image guided surgery. The implementation of regulations will cause many physicians, especially surgeons, to stop performing stereotactic breast biopsy because they will not accept the administrative burden of the credentialing process. These surgeons will have no choice but to revert to open biopsy procedures. In addition, there is already a shortage of physicians willing to perform breast procedures and unnecessary regulations are going to fuel this problem.

Image guided surgery is an ever-changing field. While once stereotactic imaging was limited to vacuum assisted biopsies, today surgeons across the country are using stereotactic imaging for laser ablation, placement of needle localization wires and placement of brachytherapy catheters for treatment of breast cancer after surgery. We strongly believe these examples are only a mere hint at what the future will bring and believe greater use of image guidance will lead to better outcomes, less invasive procedures and higher patient satisfaction. We are concerned that regulation of stereotactic breast biopsy under the MQSA will have a chilling affect on these advancements, which are almost always discovered by surgeons who are forever searching for new methods to improve old techniques. Finally, we note that x-rays are only a small aspect of the field of image guided surgery, which includes ultrasound, MRIs and other imaging techniques, and we believe limiting use of one type of imaging modality through regulations could hamper advancements in other areas.

We acknowledge that several prestigious organizations have recently called for the regulation of stereotactic breast biopsy under the MQSA, including the Institutes of Medicine and the American Cancer Society. However, we note that none of these organizations have identified any quality problems with stereotactic breast biopsy, much less a problem that could be addressed by mammography standards under the MQSA.

**Lastly, the NMQAAC Advisory Committee Process was severely flawed.**

We are deeply concerned by the process leading up to the vote at the September 2006 NMQAAC meeting. Surgeons were not adequately informed of the purpose of the meeting and did not have an adequate opportunity to participate and present their views.

On the eve of the September 2006 NMQAAC meeting, both the American Society of Breast Surgeons and the ACS were surprised to learn that the meeting would involve presentations and a vote on, regulation of stereotactic biopsy under the MQSA. Neither organization was able to participate at that point.

Although Dr. David Winchester of ACS had previously been invited to present at the meeting and had prepared materials for the presentation, he was informed prior to the meeting that he would not be able to present because of his status as a consultant. Dr. Winchester understood, however, that Dr. Phillip Israel, a surgeon and a new member of the NMQAAC, would be able to present the materials. At the meeting, however, Dr. Israel was not provided an opportunity to deliver his presentation and his materials were not made a part of the record.

The American College of Radiology (ACR), on the other hand, delivered a presentation at the meeting and, to the surprise of the ACS (which has been cooperating with the ACR on a joint standards program), proposed that ACR accreditation standards be imposed on all physicians conducting stereotactic biopsy, including surgeons. Although, the ACR representative mentioned the joint program with ACS, he did not present the differing views on the part of ACS with regard to regulation of stereotactic biopsy. Effectively excluding the contrary views of ACS.

ACS is completely committed to providing the best possible care to patients in need of breast biopsy. Our goal is to provide the most accurate and appropriate type of biopsy required in the most expeditious manner possible. Therefore, we most make note of the unintended consequences of regulating stereotactic breast biopsy through the MQSA. Such regulation would significantly reduce access to safe and high quality care, especially, 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. For example, in Laredo, Texas, where the physician (not a radiologist) performs all stereotactic biopsies, if such regulation were implemented, the only other specialist that performs stereotactic biopsy is located 150 miles away. This would have a detrimental impact on patients receiving appropriate, safe and quality health care services in mammography in a timely manner.

In closing, the American College of Surgeons strongly supports the MQSA and believes it has improved the quality of screening and diagnostic mammograms. However, we do not believe the intention of the MQSA is the regulation of surgical procedures like stereotactic breast biopsy and believe the FDA's current regulations reflect this. We do not believe the regulatory changes suggested by the Advisory Committee will improve quality and will instead just regulate for the purpose of regulating. Furthermore, we strongly believe additional regulations will hurt patient access to this valuable procedure and will have a chilling affect on future advances in this field. We urge the FDA to maintain the current definition of mammography in its regulations.

Thank you for providing ACS this opportunity to share our views and concerns about this potential regulation of stereotactic breast biopsy procedures by the FDA. Please do not hesitate to contact Christal E. Edwards at the American College of Surgeons ([cedwards@facs.org](mailto:cedwards@facs.org) or 202.672.1510) with any questions or concerns.

Sincerely,

**American College of Surgeons**