

**COMMENTS SUBMITTED TO  
THE NATIONAL MAMMOGRAPHY QUALITY ASSURANCE  
ADVISORY COMMITTEE**

By  
The American Society of Breast Surgeons

Regarding  
Regulation of “Interventional Mammography”

October 5, 2007

**INTRODUCTION**

The American Society of Breast Surgeons submits these comments pursuant to the notice published in the Federal Register of September 11, 2007, (72 Fed. Reg. 51,823) regarding the meeting of the National Mammography Quality Assurance Advisory Committee (the Committee) scheduled for November 5, 2007.

That notice states that the subject of the meeting is “possible regulation of interventional mammography.” FDA uses the term “interventional mammography” to refer to the use of breast radiography for localization in invasive procedures such as stereotactic biopsy, as distinct from screening and diagnostic mammography.<sup>1</sup>

We oppose FDA regulation of invasive medical procedures under the Mammography Quality Standards Act (MQSA)<sup>2</sup> because such regulation would be an impediment to good patient care and because there is no evidence-based justification for federal regulation of invasive procedures. Invasive procedures guided by radiological imaging are far different from the screening and diagnostic mammography that Congress addressed in the MQSA. Such procedures include stereotactic biopsy, which was the subject of discussion at the Committee’s last meeting, and which surgeons propose to address at the upcoming meeting.<sup>3</sup>

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<sup>1</sup> FDA Policy Guidance Help System, “Prohibited Equipment” (Aug. 10, 2007).

<sup>2</sup> 42 U.S.C. 263b.

<sup>3</sup> Surgeons did not participate in the last Advisory Committee meeting at which the Committee considered and voted on a proposal that FDA regulate stereotactic biopsy under MQSA. Because of a series of miscommunications between the major surgical groups and FDA personnel, surgeons were not aware of the subject of the meeting until it was too late to submit materials or request to speak.

## DISCUSSION

### A. The Regulation of “Interventional Mammography” Would Thrust FDA into a New Role as Regulator of Invasive Medical Procedures.

When Congress passed MQSA it determined that federal regulation was warranted based on specific findings of a public health issue related to screening and diagnosis from mammograms. Congress thus limited regulation under MQSA to “facilities” that “conduct[ ] breast cancer *screening or diagnosis* through mammography activities.”<sup>4</sup> Congress did not address the use of radiographic imaging for localization in invasive medical procedures.

The difference is important. The most common technology for localization of breast tissue is stereotaxis, which involves stereographic images of a small area of the breast for guidance in invasive procedures, which do not involve screening or diagnosis from a mammogram.<sup>5</sup> Federal regulation of stereotaxis-guided medical procedures would ultimately involve the government in regulating not only biopsy procedures, but also procedures involving the treatment of pathologic breast tissue, such as the following:

- Laser ablation, in which a probe with a laser-emitting optic fiber is used to destroy tissue with heat<sup>6</sup>
- Cryoablation, in which temperature probes are used to freeze tissue<sup>7</sup>
- Radiofrequency ablation, in which a probe is used to deploy prongs that emit high frequency alternating current flows, which in turn emit heat<sup>8</sup>

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<sup>4</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.

42 U.S.C. 363b(a)(3)(A) (emphasis added).

<sup>5</sup> 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. *The American Heritage® Stedman’s Medical Dictionary* (Houghton Mifflin Co. 2002).
- “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.” *Id.*
- “Localization” involves “[t]he determination of the location of a pathological process.” *Id.*

<sup>6</sup> See Kambiz Dowlathshahi et al., *Stereotactically Guided Laser Therapy of Occult Breast Tumors: Work-in-Progress Report*, 135 Arch. Surg. 1345, 1345-1352 (2000) (Tab A); Michael S. Sabel, *Locoregional Therapy of Breast Cancer: Maximizing Control, Minimizing Morbidity*, 6 Expert Rev. Anticancer Ther. 1261 (2006) (Tab B).

<sup>7</sup> See Sabel, *supra* note 8.

<sup>8</sup> *Id.*

- Mechanical probes, which are used to cut tissue and remove tissue through a combination of suction and mechanical cutting<sup>9</sup>
- Placement of radiation catheters for delivery of accelerated partial breast irradiation.<sup>10</sup>

**B. Federal Regulation of Stereotaxis-Guided Procedures Would Be Detrimental to Health Care.**

FDA regulation of procedures guided by stereotactic localization would harm patients. In the case of stereotactic biopsy, it would impose a barrier for surgeons that would impede availability for patients. Stereotactic biopsies are preferable to surgical biopsies in terms of cost, comfort, convenience, and morbidity. It is important to avoid regulatory constraints that would inevitably make it more difficult for surgeons to offer stereotactic biopsies to their patients.

Even without a new regulatory regime, surgeons face impediments to offering this procedure to their patients. There is extensive reporting among surgeons of efforts by radiologists to deny them access to stereotactic imaging equipment in the hospital setting. A recent survey of breast surgeons conducted by the American Society of Breast Surgeons revealed that 46% of the respondents performed stereotactic biopsy procedures. Of the 54% of respondents who did not perform the procedure, the survey revealed that 37% had attempted to perform the procedure but were prevented by lack of access to the technology. Almost all of these surgeons reported that radiologists played a role in denying them access. These restraints on access to the technology have had an effect on the ability of surgeons to offer stereotactic biopsy to their patients. The percentage of stereotactic biopsy procedures conducted by surgeons has declined over the past few years, while the percentage of such procedures conducted by radiologists has grown. Further, regulatory constraints will only make things worse.

It is also important to consider that, as noted above, regulation of stereotaxis-guided procedures would ultimately mean regulation of therapeutic procedures for removal or ablation of pathologic tissue. This would impede the availability of stereotactic therapy by discouraging surgeons who do not have the resources for such regulatory regimes. It would also discourage innovation in the use of stereotactic localization in practice of surgery, as well as in the use of other radiographic imaging techniques. Patients would suffer the consequences.

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<sup>9</sup> See Anita T. Johnson et al., *Percutaneous Excisional Breast Biopsy*, 184 Am. J. Surg. 550, 550-54 (2002) (Tab C).

<sup>10</sup> FDA has recently granted a 510(k) clearance to such a device (MammoTest®, No. K042095).

**C. There Must Be an Evidence-Based Justification for Regulation of “Interventional Mammography.”**

FDA has acknowledged that it would be inappropriate to extend MQSA regulation to invasive procedures in the absence of a scientific, evidence-based justification for federal standards.<sup>11</sup> There can be no scientific, evidence-based justification for regulation of stereotaxis-guided procedures in the absence of two determinations:

**1. That There Is a Clinically Significant, Mammography-Related Problem.**

Proponents of regulation must demonstrate that there is a clinically significant negative outcome that is related to the use of stereotactic imaging.

**2. That There Are Mammography Standards that Can Resolve or Ameliorate the Problem.** Proponents of regulation must demonstrate that there are MQSA standards related to stereotaxis that will have a significant effect on the negative clinical outcome.

**D. There Is No Evidence-Based Justification for Regulation of Stereotaxis-Guided Procedures.**

**1. There Is No Evidence of an Image-Related Problem.**

Although there have been calls from the American College of Radiology (ACR) and others to regulate stereotactic-guided invasive procedures, no one has brought forward evidence of an imaging problem, or indeed of any clinically significant problem whatsoever, associated with such procedures.<sup>12</sup> While an ACR representative testified at the last Committee meeting that there was a high failure rate in the ACR accreditation program for stereotactic biopsy,<sup>13</sup> that failure rate was not shown to be clinically relevant. Some failures were based on equipment and radiation exposure.<sup>14</sup> While most failures related to image quality,<sup>15</sup> the ACR standards for image quality do not correlate with real-world clinical outcome, and bear no established or even suggested relationship to any clinical problem. ACR reported a failure rate of 35% (or perhaps higher). It is generally reported in the literature, however, that false-negative rates associated with stereotactic biopsy range from 0% to 4%, which is comparable to the 2.8% miss rate of surgical (needle localized) biopsy.<sup>16</sup>

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<sup>11</sup> 61 Fed. Reg. 14,856, 14,862 (1996)

<sup>12</sup> See, e.g., IOM, *Improving Breast Imaging Quality Report*, 104-105 (2005) (calling for regulation of stereotactic breast biopsy without citation to any evidence of a mammography-related problem, or any other clinical issue involving stereotactic biopsy).

<sup>13</sup> National Mammography Quality Assurance Advisory Committee Meeting Transcript, 54-57 (Sept. 29, 2006) [hereinafter NMQAAC Transcript].

<sup>14</sup> *Id.* at 16-17.

<sup>15</sup> *Id.*

<sup>16</sup> See R. Phillip Burns et al., *Stereotactic Core-Needle Breast Biopsy by Surgeons: Minimum 2-Year Follow-Up of Benign Lesions*, 232 *Ann. Surg.* 542, 543-44 (2001) (Tab D); see also Richard C. Frazee et al., *Open Versus Stereotactic Breast Biopsy*, 172 *Am. J. Surg.* 491, 491-95 (1996) (Tab E). A more recent study involving vacuum-assisted biopsy (see *infra* note 21) found a negative predictive value of 99.95%. Ute Kettritz

And, although there seemed to be some interest at the Committee's last meeting in the rate of discordance between pathology diagnosis from biopsy specimen and the originating mammography diagnosis,<sup>17</sup> that rate is also very low (probably less than 2%).<sup>18</sup>

We question whether discordance is meaningful in this context. Discordance in stereotactic biopsy (as in surgical biopsy) is not in and of itself a negative clinical outcome. It informs the physician that more information, generally a further biopsy or, in some cases, further mammography may be necessary for a proper diagnosis.

Furthermore, even if such discordance in stereotactic biopsy were clinically relevant – which is not the case – it would not demonstrate a *mammography*-related issue. There is no evidence that the discordance rate results from problems in stereotactic imaging. The most significant factors associated with discordance are biopsy method (related to size of needle and vacuum technique), substantial bleeding during biopsy, number of specimens per lesion, and breast density.<sup>19</sup> It has also been associated with the number of biopsies performed by the physician.<sup>20</sup> Although discordance may in some instances result from mistargeting in the biopsy, such mistargeting has been associated with patient movement and “snowplow effect” (movement of tissue caused by movement of the probe).<sup>21</sup>

## **2. There Is No Evidence-Based Mammography Standard for FDA to Impose.**

To be rational, any initiative under the MQSA to regulate an invasive procedure must be based on a standard that will improve clinical outcome *by improving the performance of the mammography component* of that procedure. No such standard has been proposed, or can be proposed, because no one has identified a significant clinical problem related to stereotactic imaging to be addressed by such a standard. There is, by definition, no clinically relevant standard to impose in the absence of evidence that a standard will improve clinical outcome.

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et al., *Stereotactic Vacuum-Assisted Breast Biopsy in 2874 Patients*, 100 *Cancer* 245, 249 (2004) (Tab F).

<sup>17</sup> This definition was used at the NMQAAC meeting and is commonly used in the literature. See, e.g., NMQAAC Transcript, *supra* note 16, at 51-52.

<sup>18</sup> The published reports going back to 1996 generally range from 0.8% to 6.2%. There is general agreement that the rates have been trending toward the lower number based on the use of larger needles (11-gauge and lower) and vacuum-assisted technology, which are associated with reported rates of 0.8% to 1.7% and which are now utilized in almost all stereotactic breast biopsies. See Elizabeth S. Burnside et al., *A Probabilistic Expert System that Provides Automated Mammographic–Histologic Correlation: Initial Experience*, 182 *AJR* 481, 481-488 (2004) and sources cited therein (Tab G); Laura Liberman et al., *Imaging-Histologic Discordance at Percutaneous Breast Biopsy: An Indicator of Missed Cancer*, 89 *Cancer* 2538, 2544 tbl.4 (2000) and sources cited therein (Tab H).

<sup>19</sup> Roger J. Jackman et al., *Breast Microcalcifications: Retrieval Failure at Prone Stereotactic Core and Vacuum Breast Biopsy – Frequency, Causes and Outcome*, 239 *Radiology* 61, 64 (2006) (Tab I).

<sup>20</sup> Liberman, *supra* note 21; Anna K. Koskela, *Learning Curve for Add-on Stereotactic Core Needle Breast Biopsy*, 47 *Acta Radiologica* 454, 454-460 (2006) (Tab J).

<sup>21</sup> See, e.g., Burns, *supra* note 19.

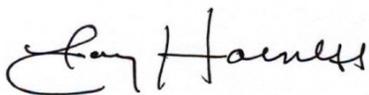
**E. Professional Programs Ensure Safe and Effective Use of Stereotaxis in Biopsy Procedures.**

Patients are now protected by professional standards, accreditation programs, and educational programs. The American Society of Breast Surgeons provides Performance and Practice Guidelines for Stereotactic Breast Procedures,<sup>22</sup> and has recently instituted its Stereotactic Certification Program, which will provide a certification to surgeons who intend to perform such procedures.<sup>23</sup> This program, modeled after the Society's Ultrasound Certification Program, will ensure proper training and provide high professional standards for surgeons performing stereotactic procedures. The Society has also developed an accreditation program for surgical facilities performing stereotactic biopsy, which the Society hopes to present to Advisory Committee at the upcoming meeting. While not required by law, the certification and accreditation programs are likely to become necessary for surgeons based on requirements of secondary payors, hospital privileges, and malpractice liability. We note also that the American College of Surgeons has long played a major role in ensuring quality medical care for patients undergoing these types of invasive procedures, and has participated in the Joint Task Force of the American College of Radiology, American College of Surgeons, and College of American Pathologists, which developed joint standards for facilities that perform stereotactic biopsy

**CONCLUSION**

There is no rationale under the MQSA for regulating stereotaxis, or any other radiographic imaging technology, that is used for localization in invasive medical procedures. This is not screening or diagnostic mammography. There is, moreover, no evidence-based justification for regulation of such procedures. There is no evidence of a mammography-related problem in such procedures; nor is there a clinically relevant mammography standard to impose. The certification and accreditation programs offer a reasonable alternative to federal regulation and will better protect patients by encouraging rather than discouraging the development and use of stereotaxis-guided procedures by surgeons.

Respectfully submitted,



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<sup>22</sup> Tab K.

<sup>23</sup> See Certification Application for Stereotactic Breast Procedures (Tab L).