

UNITED STATES OF AMERICA
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
 CENTER FOR DEVICES AND RADIOLOGIC HEALTH
 NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
 ADVISORY COMMITTEE

MEETING

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Monday, November 5, 2007

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The meeting came to order at 9:00 a.m. in the Ballroom of the Rockville Crowne Plaza, 3 Research Court, Rockville, MD, E. Scott Ferguson, MD, presiding.

PRESENT:

E. SCOTT FERGUSON, MD	CHAIRMAN
DEBRA L. MONTICCIOLO, MD	MEMBER
CAROL J. MOUNT, RT, (R)(M)	MEMBER
WILLIAM A. PASSETTI	MEMBER
DIANE RINELLA, RT, (R)(M)	MEMBER
ERIC L. ROSEN, MD	MEMBER
JULIE E. TIMINS, MD	MEMBER
MARK B. WILLIAMS, PHD	MEMBER
DAVID P. WINCHESTER, MD	CONSULTANT
ROBERT A. UZENOFF	INDUSTRY REP.
JEFFREY W. BYNG, PHD	INDUSTRY REP.
JANE B. SEGELKEN	CONSUMER REP.
JACQUELIN S. HOLLAND, RN, CRNP	CONSUMER REP.
NANCY A. FINKEN, MA	CONSUMER REP.
NANCY WYNNE	EXEC. SEC.
CHARLES FINDER, MD	FDA REP.

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P-R-O-C-E-E-D-I-N-G-S

9:01 a.m.

CHAIRMAN FERGUSON: I would like to call the meeting to order. I remind everybody to turn your cell phones off. Mine just went off, and it was a good reminder for me. We don't want to have all the disturbances. And we will let Ms. Wynne read the conflict of interest. I'm supposed to tell the Panel Members that the microphone in order to use it, you press it once. The red button will come on. When you are finished, you have to press it again to turn it off. And only four microphones will work at a time.

MS. WYNNE: Good morning. The FDA Conflict of Interest Disclosure statement, particular matters of general applicability National Mammography Quality Assurance Advisory Committee. Date of the meeting, November 5, 2007.

The Food and Drug Administration is convening today's meeting of the National Mammography Quality Assurance Advisory Committee of the Center for Devices and Radiological Health under the authority of the

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Federal Advisory Committee Act of 1972. With the exception of the industry representatives, all Members and consultants of the Committee are special government employees or regular federal employees from other agencies and are subject to federal conflict of interest laws and regulations.

The following information on the status of the Committee's compliance with federal ethics and conflict of interest laws covered by, but not limited to, those found at 18 USC 208 and 712 of the Federal Food, Drug and Cosmetic Act are being provided to participants in today's meeting and to the public.

FDA has determined that Members and consultants of this Committee are in compliance with federal ethics and conflict of interest laws. Under 18 USC 208, Congress has authorized FDA to grant waivers to special government employees who have financial conflicts when it is determined that the Agency's need for a particular individual's service outweighs his or her potential financial conflict of interest.

Under 712 of the FD&C Act, Congress has

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authorized FDA to grant waivers to special government employees and regular government employees with potential financial conflicts when necessary to afford the Committee their essential expertise.

Related to the discussion of today's meeting, members and consultants of this Committee who are special government employees have been screened for potential financial conflict of interest of their own, as well as those imputed to them, including those of their spouses or minor children, and for the purposes of 18 USC and 208, their employers.

These interests may include investments, consulting, expert witness testimony, contract and grants, CRADAs, teaching, speaking, writing, patents and royalties, and also primary employment.

For today's agenda, the Committee will discuss issues related to the possible regulation of interventional mammography and receive input from professional organizations. The Committee will also receive updates on recently approved alternative standards. This is a particular matters meeting during

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which general issues will be discussed.

Based on the agenda and all financial interests reported by the Committee members and consultants, conflict of interest waivers have been issued in accordance with 18 USC 208(b)(3) and 712 of the Food, Drug and Cosmetic Act.

Related to Ms. Carol Mount: Ms. Mount's waivers include a consulting arrangement with the parent of a manufacturer of interventional mammography devices for which she received a direct payment of hotel and airfare expenses made by this firm. The waivers allow the individuals to participate fully in today's deliberation.

FDA's reason for issuing the waivers are described in the waiver documents, which are posted on FDA's website at www.fda.gov/ohrms/dockets/default.htm. Copies of the waivers may also be obtained by submitting a written request to the Agency's Freedom of Information Office, Room 6-30 of the Parklawn Building, Rockville, Maryland.

A copy of this statement will be available

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for review at the registration table during the meeting and will be included in the official transcript of this meeting.

Dr. Robert Uzenoff is serving as the industry representative, acting on behalf of all related industry, and is employed by Fuji Medical Systems USA, Inc. Dr. Jeffrey Byng is also serving as an industry representative, acting on behalf of all related industry. He is employed by Eastman Kodak Company.

Dr. Philip Israel has recused himself from today's deliberation.

We would like to remind members and consultants that if the discussions involve any other products or firms not already on the agenda for which an FDA participant has a personal or imputed financial interest, the participant needs to exclude themselves from such involvement and their exclusion will be noted for the record.

FDA encourages all other participants to advise the Committee of any financial relationships that they may have with any firms at issue. Thank you.

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CHAIRMAN FERGUSON: And I see that we have members present to represent a quorum. And I would like the members to introduce themselves and give their area, their background relative to this Committee.

DR. WINCHESTER: Good morning, I'm Dr. David P. Winchester, Professor of Surgery at Northwestern. I'm a surgical oncologist and a breast surgeon. I am Medical Director for the National Cancer programs at the American College of Surgeons, Commission on Cancer and the American Joint Committee on Cancer and Chairman of the Board of an upcoming program called the National Accreditation Program for Breast Centers.

MR. UZENOFF: My name is Bob Uzenoff. I'm Executive Assistant to the President at Fujifilm Medical Systems in Stamford, Connecticut where one of my responsibilities is the Image Quality Group. I'm interested in image quality and diagnostic imaging and especially mammography. And I'm a Member of the National Electrical Manufacturers Medical Imaging Technology Alliance, where the constituency as an industry representative from which I draw some of the

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information that I'll be responding to this morning.

MEMBER PASSETTI: My name is Bill Passetti. I'm the Director of Florida's Radiation Control Program, which is a regulatory agency in the radiation field.

MS. SEGELKEN: My name is Jane Baker Segelken. I'm a consumer representative on the Panel, and I am a breast cancer survivor.

MEMBER MOUNT: My name is Carol Mount. I'm the Manager of the Breast Imaging and Intervention Department at Mayo Clinic, Rochester, Minnesota.

MEMBER WILLIAMS: I'm Mark Williams, and I'm a Physicist and an Imaging Researcher at the University of Virginia.

MEMBER TIMINS: I'm Julie Timins. I'm a Diagnostic Radiologist. I read mammography. I also chair the New Jersey Commission on Radiation Protection.

MS. WYNNE: I'm Nancy Wynne. I'm currently serving as the Executive Secretary of this Committee. I'm a public health advisor. I have a background in inspection and compliance of mammography facilities and currently serve with the Radiological Health Group for

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CHAIRMAN FERGUSON: I'm Scott Ferguson. I'm from Arkansas. I'm a Diagnostic Radiology. I do a lot of mammography and I'm a Member of the Arkansas certifying body.

MEMBER MONTICCIOLO: I'm Debbie Monticciolo. I'm a Professor of Radiology and Vice Chair for Research at Texas A&M, and I'm Section Chief of Breast at Scott and White Hospital.

DR. BYNG: I'm Jeff Byng, and I'm a Physicist by training, but I work with the Mammography Solutions Business at Care Stream Health. Care Stream Health was the successor to the Kodak Medical Imaging Business. And so perhaps Ms. Wynne can make a correction in that information. Thank you.

MEMBER RINELLA: I'm Diane Rinella. I'm a Mammography Consultant and I specialize also in breast ultrasound from San Juan Capistrano, California.

MS. HOLLAND: I'm Jacquelin Holland. I'm an Advanced Practice Nurse. I work as a consultant for the James Cancer Hospital and Solove Research Institute at

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the Ohio State University Medical Center. And I serve as a consumer representative for this group.

MEMBER ROSEN: I'm Eric Rosen. I'm a Breast Imaging Radiologist. I practice in Washington, Seattle.

MS. FINKEN: I'm Nancy Finken. I'm a consumer representative, Board Member of the Virginia Breast Cancer Foundation, also active with Why Me Breast Cancer Support and the National Breast Cancer Coalition.

DR. FINDER: I'm Dr. Charles Finder. I'm the Associate Director for the Division of Mammography Quality and Radiation Program.

MS. WYNNE: At this time, I would like to recognize Dr. Helen Barr. She is the Director of the Division of Mammography Quality and Radiation Programs in the Office of Communication, Education and Radiation in the Center for Devices and Radiological Health at FDA. Dr. Barr?

DR. BARR: I know you all are smarter than I am, you know how to turn this on. First of all, I wanted to thank Mrs. Wynne for all of her hard work in putting this meeting together. It is not an easy task,

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and I would like to thank my right hand man, we choose him, he is the highest paid administrative assistant in the world, My Associate Director, Charlie Finder.

I would like to welcome you all today and thank you all for the time that you give us with your wealth of expertise. We are specifically holding this meeting today dedicated to discussion of interventional mammography so all of you and all of the public and all of us can be assured that we have heard opinions far and wide on this issue that can inform any decisions that we might make in the future regarding interventional mammography.

I know you are all extremely busy. I actually used to be out in the real world practicing mammography before I came to FDA, so I know how busy you all are, and we really honestly appreciate your input immensely. I know some of you will be leaving the Panel, and we thank you for your service. And particularly, I would like to thank Dr. Ferguson for serving as the Chair of the Committee. And good luck as you begin your work today. Thank you.

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MS. WYNNE: At this time, Dr. Charles Finder will tell us a little bit about approved alternative standards in the recent year.

DR. FINDER: For those not familiar with Section 900.18 of the Regulations, "FDA may approve an alternative to a quality standard under Section 900.12 when the Agency determines the following: (1) That the proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace and the proposed alternative is too limited in its applicability to justify an amendment to the standard or it offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the public, and the granting of the alternative is in keeping with the purpose of Statute 42 USC 263(b)."

Since last September's meeting, the Division has approved six modifications to previously approved alternative standards. One modifies the alternative standard correction period when components of the

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Selenia Full Field Digital Mammography system fail quality control tests by adding automatic exposure control function performance and AEC reproducibility to the group of tests with a 30 day correction period.

This amendment allows the same 30 day period for tests that are the same or similar to those for screen-film tests. The alternative is also consistent with previously approved alternative standards that were granted to other FFDM manufacturers.

The other five modifications deal with testing after software upgrades. The current approved alternative permits the post upgrade testing to be performed under medical physicist oversight, but the manufacturer needed to apply to FDA for each individual software upgrade. Because we have received a large number of requests under this alternative standard, we have now generalized the alternative and allowed it to be used by all manufacturers.

Under the modification, the testing must be done under medical physicist oversight as long as a number of conditions are met. These include that the

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post upgrade testing consist of tests that are normally performed by the technologist, are not required to be done by the medical physicist, and that proper notification and instructions are given to the facility.

These alternative standards in their entirety are available on our website in the policy guidance help system. If anybody has any questions, I would be happy to address them. Okay.

CHAIRMAN FERGUSON: Do you want to go with the directions for discussion?

DR. FINDER: Okay. The main purpose of this meeting is to discuss possible regulation of interventional mammography. This is a topic that has been discussed at several prior NMQAAC meetings, but because of the impact of such regulation, FDA believes it is in the best interest of the public that all viewpoints be expressed in this open forum.

We will begin by having speakers from the public present data and express their views on whether, in their opinion, FDA needs to regulate interventional mammography or stereotactic breast biopsy. After the

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public speakers have given their presentations and the Committee has been given a chance to question the speakers, the Committee will discuss the matter.

After that discussion, we will have Dr. Ferguson ask each of the members and consultants the following questions:

Should FDA regulate stereotactic breast biopsy and the reasons that they believe we should or shouldn't?

And two, should we regulate interventional procedures other than stereotactic and the reasons whether we should or shouldn't.

After the meeting, FDA will take the public speakers and the Committee's comments into consideration and make a determination whether FDA regulation of interventional mammography or stereotactic breast biopsy is required. Again, any questions from the Committee? If not, proceed.

CHAIRMAN FERGUSON: I am required to read the following prior to opening the public hearing. Both the Food and Drug Administration and the public believe in a

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transparent process for information gathering and decision making. To ensure such transparency at the open public meeting session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the Committee of any financial relationship that you may have with the sponsor, its product, and, if known, its direct competitors.

For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at this meeting. Likewise, FDA encourages you at the beginning of your statement to advise the Committee if you do not have any such financial relationships.

If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

And now, I would like to have the open public

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hearing speakers to begin the process.

MS. WYNNE: I would just like to say we don't have you in any scheduled format, so anyone who has preloaded their discussion or their slides into the computer is welcome to come up to the table. Just don't stampede each other. You know, if you have a flash drive or you have been preloaded to the computer here, please feel free to come forward.

CHAIRMAN FERGUSON: Yes, state your name.

DR. DERSHAW: I'm David Dershaw from New York, and I'm here representing the American College of Radiology. The college has paid my travel expenses, but I have no other conflict of interest.

Mr. Chairman, Members of the Committee, Advisory Members of the Committee, members of the public, thank you for this opportunity to address the Committee. On behalf of the college, I would like to state that it is the policy of the American College of Radiology that regulation of stereotactic biopsy under MQSA Regulation is appropriate and should, in fact, begin.

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The college also would like to recommend to the Advisory Panel and to the FDA a program that is formatted on the Mammography Accreditation Program and is currently in use by the college for accreditation of stereotactic biopsy facilities.

Next. Under legislation, mammography is defined as radiology of the breast. As I know you all know, stereotactic biopsy is an imaging-guided technique which uses radiation to create images of the breast before, sometimes during, always, and after sometimes the procedure to facilitate accuracy of the biopsy. Therefore, as with screening or diagnostic mammography stereotactic biopsy uses mammography also.

Next, please, next. Facility as a word that's used in the legislation is generally accepted as an entity that conducts breast cancer screening and/or diagnosis through mammography activities.

Next. And this is a widely accepted definition of facility.

Next. Therefore, under legislation examination or procedure under the MQSA Regulation is

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defined as a facility -- is defined under MQSA Regulation that a facility shall obtain a certificate in order to operate radiological equipment that is used to image the breast.

Next. So should the FDA be regulating stereotactic biopsy?

Next. We feel that there is no doubt that it is not only included under the legislation, but it is appropriate for the FDA to do so.

Next, next, next. The FDA has addressed this issue, as the Chair has stated earlier this morning. Previously and in the past the FDA has decided to at least temporarily exempt interventional procedures including stereotactic biopsy from its regulatory efforts. This was stated as "due to the Agency's belief that science had not advanced to the point where effective national quality standards could be developed."

Next. That was a decade ago, and it is our belief that the status of this has dramatically changed in the last 10 years.

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Next. Ten years ago, the American College of Radiology, along with the American College of Surgeons, agreed on and published guidelines for the physician team, the individual or the group of physicians involved in stereotactic biopsy in order to attain accreditation of the facility in which they worked.

Next. And this could be done, as I have implied, either with a group of physicians, most likely radiologists and surgeons, but not necessarily radiologists and/or surgeons working together.

Next. Or with single physicians working independently. The point was that the physician or the physician team should have a level of experience and education that would be met by a single or multiple physicians.

Next. As part of the program, the American College of Radiology for its program published a stereotactic breast biopsy guide. And among the handouts, the many handouts that you have accumulated here this morning is the Stereotactic Breast Biopsy Accreditation Program requirements, which outlines the

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requirements for accreditation of the program.

The stereotactic breast biopsy guide itself -
- next, please -- addresses issues of image quality and patient radiation. This guide was written largely by physicists but with considerable input from radiologic technologists involved in these procedures and with input from physicians involved in these procedures.

Next. The guide is extremely detailed, comparable to the level of detail that's present in the Mammography Quality Control Program and provides guidance for technologists and medical physicists involved in doing these procedures, outlines quality control procedures that should be routinely included in the Stereotactic Biopsy Program of a facility, and outlines methods of identifying shortcomings and fixing them.

Next. The Stereotactic Breast Biopsy Accreditation Program of the college -- next -- was first offered over a decade ago.

Next. It was modified -- it was modeled on the accreditation program of mammography so that there

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would be as much concordance between these programs as possible.

This meant -- next -- that it assessed the performance of an entire facility, not of any single individual. And it includes elements of qualifications, of professional personnel involved in the program, including physicians, physicists, and technologists. It includes assessment of the clinical performance of the biopsy procedure itself. It includes assessment of the quality control and maintenance of equipment, and it includes assessment of the radiation dose to the patient.

Next. Additionally, the program is involved not -- is dedicated not just to assessing quality as it currently exists, but in recommending to individual facilities feedback to improve the quality of the procedures that they are doing.

Next. The American College of Surgeons also instituted a program for accreditation of stereotactic breast biopsy programs -- next -- and this is a program that was first offered in 1999 -- next -- and has

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aspects that are run by the College of Surgeons, and aspects that are run under contract with the College of Radiology.

Next. Requirements for personnel qualifications, clinical performance, equipment and radiation dose are exactly the same as in the program of the American College of Radiology.

Next. Now, the goal in assessing personnel, as I have stated, is to ascertain, to guarantee for the patient undergoing these procedures, that there is a minimum, but a high level of training and experience in whatever personnel are involved in performing these procedures. And by personnel, we include physicians, the medical technologists who are involved in the procedure, and the medical physicists who are checking the equipment to make sure they are safe and functioning optimally.

The requirements for personnel include initial education experience, and initial hands-on experience in actually doing the procedures, or doing the testing of the procedures. It then requires that

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those involved continue to maintain skill with continuing education, and continuing participation in these procedures.

Next. The assessment of clinical performance by submission of clinical images is designed to determine that the facility, even with the equipment functioning well, can do the procedures that we are accrediting them to do. So case material from a procedure which the facility considers to be among its best quality procedure is submitted to make sure that imaging is appropriate, and that the biopsy probe is correctly located.

The program has been updated over time so that a variety of biopsy probes are included in the program, and the program has included those probes which have been FDA approved, and have been demonstrated as being safe and effective in peer reviewed literature.

Next. Also part of the program is evaluation of exposure of a phantom, and this is to ascertain image quality, proper functioning of the equipment, and also to make certain that the radiation exposure to the

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patient falls within an acceptable range.

Next. The program, as well as being updated with newer equipment as it came out, has also been modified in terms of clinical images that we thought were appropriate and, additionally, has been modified to accommodate the shift away from screen-film to digital imaging.

Next, next, next. Now, the program is, of course, a voluntary program, and one should assume that, because of the time, effort and expense involved in applying for accreditation, that highly motivated facilities, who think they are doing a very good job, would be the ones who would apply, and those who don't fall into that range would not apply.

Despite that self-selection process, 25 percent of all applicants failed to gain approval on their first attempt to be approved during the years 2004 to 2006. The failures were largely due to clinical issues, problems with the clinical images that were submitted, but, as you can see from that pie chart up there, a full 10 percent were due to problems with

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exposure, and with technical issues involved in accreditation.

Next, next. After recommendations by the accreditation program by the reviewers, and after corrective action, the failure rate fell on the second attempt from 25 percent to 6 percent, indicating the educational nature of the accreditation program, and the ability of that program to include facilities rather than exclude facilities.

Next. It is important again to notice that 3 percent of the failures on the initial application were due to excessive radiation dose.

Next. This was mostly due to inappropriate radiologic techniques, which were easily corrected, but may not have been corrected if the facilities had not applied for accreditation.

Next. And I will remind you that there are no failures any more for excessive dose in the Mammography Accreditation Program because of the nature of that program.

Next. Now, it is estimated currently that

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there are about 2,300 mammography units that are in operation in the United States.

Next. And as of the 1st of this month, the College of Radiology had 471 units in 459 facilities accredited -- next -- the College of Surgery had an additional four units in four facilities accredited -- next -- so after 10 years, only about 20 percent of the facilities -- of the equipment in use in the United States is accredited.

Next. Mammography, as some of you may recall, had the same problem before the institution of MQSA -- next -- with less than 50 percent accredited voluntarily -- next -- and 30 percent of units self-excluding themselves because of their poor quality and their inability to obtain accreditation.

Next, next, next. So the American College of Radiology strongly recommends to the Advisory Committee that it recommend to the Food and Drug Administration that a program of regulation of stereotactic biopsy facilities be instituted in the United States to guarantee to all women undergoing these procedures that

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they are safe, that they are as effective as possible, that they are done with the same level of quality that the FDA now guarantees that mammography is done.

Thank you very much. I'll be happy to answer any questions.

CHAIRMAN FERGUSON: Members of the Panel, questions?

MEMBER WILLIAMS: Yes, Dr. Dershaw, since the majority of the failures arose from the clinical images, and then so presumably from localization issues, and secondly, because most of those were correctable after some discussion with the ACR, it seems like an important question to ask, why were the localizations going wrong? I mean, obviously, image guidance for localization is a key question here. And I'm wondering if there were any attempts made to break down what it was that was causing the problem?

DR. DERSHAW: Well, I don't have the breakdown of what the numbers are, but anecdotally, I can share with you the kinds of problems there were. Some were simply the procedure was not being well done.

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Commonly, we had issues with, as the films were submitted, depending upon the biopsy probe that was being used, two sets of films, or one set of film with the probe in place, would be submitted.

As the procedures were being done, there may have been a problem with the target lesion being obscured by anesthesia, or blood, or by the biopsy probe itself. In fact, on occasion, the probe was so well placed that you could no longer see the target lesion. It actually obscured it on the images that were taken.

Those facilities would not pass, because we couldn't see the relationship of the probe to the target. Some facilities failed, despite the fact the procedure was being well done, because the lesion that they were demonstrating as being biopsied was so subtle, it was very, very difficult to see on the printout of the digital images that were submitted for accreditation.

But some facilities failed because one of the two stereo images showed the needle in good position, but the other didn't, so, obviously, they didn't know

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what they were doing. On occasion, facilities would fail because the lesion that they showed us on the mammogram was not the same as the lesion that they were biopsying at the time of the procedure.

So it was the entire spectrum. Some were simply technical, failure to follow instructions. Some were truly an inability to do the procedure well. The policy of the college, however, in assessing those images, was the instructions were, we believed, clear and straightforward, and the facilities had to follow the instructions and had to supply us with what it was that we wanted to see. Otherwise, we would have to make a leap, an assumption, that they were doing it right.

We didn't want to make the leap. We wanted to have the proof. I hope that answers that question.

MEMBER WILLIAMS: Thanks.

DR. WINCHESTER: Dr. Dershaw, earlier in your presentation, you alluded to, if this were to be regulated, that it would be -- should be done within the framework of the ACR Accreditation Program. That accreditation program, as you explained on your slides,

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included the component for ACR verifying that facilities had the right equipment, and technologists and so on, that they would further certify the qualifications for radiologists, and that the American College of Surgeons would verify the qualifications of surgeons who had the experience to do this, as well.

Are you proposing that, if this becomes regulated, that that bilateral agreement between the two colleges would remain intact with respect both to equipment and physicians?

DR. DERSHAW: My proposal was not that the FDA should completely lift the program as it is currently and implement that, any more than it completely lifted the Mammography Accreditation Program from the College of Radiology and implemented that. But this is an example of an accreditation program. It's a template that could be used. There is a high quality accreditation program that is in place, and that the argument that there is no consensus, and the argument that there is no example of a program that currently exists is, in fact, not the situation any more.

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DR. WINCHESTER: Yes. Specifically, what is your viewpoint from the ACR about physicians who should be performing this procedure?

DR. DERSHAW: The program that's currently in place for the College of Radiology has a very high bar for quality for the individual or the team of physicians that are involved in the procedure. We believe that is an appropriate bar, and it should not be lowered.

MS. WYNNE: Thank you, Dr. Dershaw. Would the next speaker -- Dr. Barr, would you like to say something?

DR. BARR: Helen Barr, FDA. Dr. Dershaw, one of your slides showed dramatically that the pass rate improved with education. Why wouldn't an educational type program work to improve results in this procedure, rather than a regulatory program? And then I have another question.

DR. DERSHAW: I think that you need to -- I don't know where I'm supposed to be looking to answer this question. I think that an educational component to the program is certainly important, because the programs

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shouldn't be designed, we don't want the programs to be designed, to eliminate motivated quality facilities in whom the issues are sometimes trivial, and often not profoundly important.

We are concerned, however, that there are facilities out there doing stereotactic biopsy. In fact, I think many of us who are involved in the field see examples of this, unfortunately, not infrequently. We are concerned that there are facilities out there doing these procedures that are of the same core quality as facilities who were doing mammography before the regulation of mammography.

So it's the opinion of the college that we should be accepting of facilities whose quality, through advice and education, can be improved, but, in fact, there should be the ability to close down facilities who do not reach a level of competence as defined by the program.

DR. BARR: Thank you. My other question is, you said that these facilities submit examples of their best work. Now, if I were a facility performing this

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procedure, I would send in a case where, you know, I made the diagnosis that seemed appropriate for the lesion. Isn't the proof of the pudding in whether a diagnosis was made, and not whether there was some obscuration of the lesion by blood, or the needle was a little off? Do you look at the results of the procedure at all? Thank you.

DR. DERSHAW: That's a very interesting question, and actually we pondered that. The clinical images are submitted in an attempt to ascertain whether or not the physician, the medical team that's performing a procedure, knows what they are doing as the procedure is ongoing. We do not look at what the histology results are, because we are not accrediting the pathologist, or the pathology team, and we do not look at what the patient management is.

We are simply looking at whether or not the medical team is in control of the procedure, and appropriately performing the intervention on the patient while it is ongoing. When you are doing the procedure, of course, you don't know what the histology is going to

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be, and you don't know how you are going to manage the patient at that particular point.

So it's not the result that comes back two or three days later that we are trying to evaluate. It's the actual appropriateness of where the needle is being placed inside the breast at that particular point in the procedure. Thank you.

DR. BARR: Thank you very much.

CHAIRMAN FERGUSON: Yes?

MEMBER TIMINS: Dr. Dershaw -- sorry, Julie Timins.

DR. DERSHAW: That's fine, I need the exercise.

MEMBER TIMINS: From the patient's standpoint, what the patient might want to know is how effective the biopsy is in determining whether or not there is indeed breast cancer. In the best hands, what is the concordancy rate?

DR. DERSHAW: By concordancy rate, you mean what?

MEMBER TIMINS: That the -- what is the true

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positive/true negative rate in the best of hands?

DR. DERSHAW: I think there is not a real answer for that. And I will tell you why, and I will tell it to you once again anecdotally. In my facility - I'm at Sloan-Kettering in New York - and we have one facility that does screening, and we have another facility that does diagnostic.

Our patients who come for biopsy from our diagnostic facility are women who have a personal history of breast cancer, who are gene positive, who have high risk histologies on prior biopsies, who are at extremely high risk of any lesion being malignant.

Our patients who come from our screening center downtown are at a much lower risk of having breast cancer. So the numbers for those two facilities, both of which, I believe, I hope appropriately, are high quality facilities, our numbers are very different in those two facilities. What we do look at -- and also our patients who have a previous history of atypical ductal hyperplasia, for example, undergo biopsy for calcifications again, may again have atypical ductal

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hyperplasias.

So whether you call that a true positive, or they go to surgery and then they have cancer, or a false negative, it's kind of difficult to figure out what those numbers mean. We do have numbers on patients who have BIRADS 5 lesions who we have biopsied. We have gotten back some benign histology. We believe it is false, and we think we missed the lesion at the time of stereo biopsy. And we do -- that number is extremely small, 1 percent.

And we do have numbers on patients who have complications during the procedure. And we know that there are, you know, in the literature, the published rate is 2 percent or less for complications. Ours is lower than that, but certainly, if I look at an individual radiologist, and I see that he or she has a 5 percent complication rate, and everybody else has a 2 percent complication rate, I know there is something we need to look at.

But in terms of, are there numbers that are applicable to everybody everywhere, I personally, and

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I'm not speaking on behalf of the college on this, but I personally believe that those numbers are extremely dependent on the population that you are actually looking at. I think it's important that you have -- and I think it's easier to look at the range of variation among the physicians performing the procedure in your individual facility, rather than comparing your facility to another facility, because the physicians within your facility are all dealing, presumably, with the same population, and the physicians from different facilities are dealing with very different populations who may have very, very different numbers.

So unfortunately, I don't have a number that I can give you for that. I hope that's a satisfactory answer.

MEMBER TIMINS: It's the answer you gave.

DR. DERSHAW: Thank you. You're kind. Any other questions? Thank you very much.

MS. WYNNE: At this time, I would like to have the next speaker make their way down to the computer. But I also want to remind you that there is a

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15 minute limitation to your talk, and we have a listing of people who have registered prior to the meeting, and those people will be allowed to speak first. There have been some speakers that have dropped in this morning and requested to speak. They will be allowed to speak as time permits.

So would the next person come forward that wishes to speak and has a slide presentation?

DR. LEE: Sorry -- Mr. Chairman, Members of the Committee, consultants and industry representatives, I appreciate this opportunity to speak in front of you. I am Dr. Carol Lee. I am Professor of Diagnostic Radiology at Yale University, School of Medicine. I am also the President of the Society of Breast Imaging, which has sponsored my travel expenses to this meeting. I'm also an unpaid member of the Scientific Advisory Committee of the Hologic Corporation, which manufactures stereotactic equipment, and they also have, on occasion, sponsored travel expenses to their advisory committee meetings.

Could I have the next slide, please? The

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Society of Breast Imaging was founded in 1985, and it currently consists of a little over 2,000 board-certified radiologists and allied professionals who are involved in breast imaging. Of it's members, 107 have met the qualifications to be granted the status of Fellow. And I think it's important to point out that much of the work, the research, that has been done to establish stereotactic core biopsy as a valid, efficacious, safe alternative to open surgical biopsy, has been the result of work by members and fellows of the SBI.

Next, please. The Society of Breast Imaging supports the inclusion of stereotactic breast biopsy under the mandates of the MQSA.

Next slide. This is some data from a paper looking at the performance of breast biopsy in this country using CMS data that was published in the Journal of American College of Radiology last year. As you can see, the number of breast biopsies in this country is steadily increasing.

Next slide. And when you look at -- again,

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these are procedures only covered by CMS. Of all the breast biopsy procedures, approximately 40 percent of them were image-guided by stereotactics.

Next, please. If you look at the breakdown of who is doing these image-guided breast biopsies, about three-quarters are done by radiologists, about a quarter by surgeons, and the rate of increase in the performance of these biopsies, as you can see, has increased quite dramatically.

Next. Now, compared to open surgical biopsy, it has been demonstrated that stereotactic breast biopsy is associated with less morbidity, it is faster to perform, it's achieved at a lower cost than surgical biopsy, and, when properly performed, it has been shown that the accuracy is comparable to open surgical biopsy.

Next slide. There are challenges and pitfalls associated with the performance, the appropriate performance of this procedure. We run into insufficient or incorrect samples, and this is dependent -- the avoidance of this pitfall is dependent on obtaining high quality images, and performing accurate

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targeting as Dr. Dershaw alluded to.

We need to know the person -- the physician performing the procedure needs to know appropriate management in terms of recognizing which high risk lesions that you get on core biopsy require follow-up surgical excision in order to avoid false negative results. The physician performing the procedure needs to recognize possible imaging, histologic discordance, again, to minimize the possibility of false negatives. And in the literature, in the review of the literature, the false negative rate, and I'm talking about the delayed false negative rate, unrecognized false negatives, range anywhere from well under 1 percent, to up to 4 percent.

Next slide. Now, what are the reasons for not including stereotactic biopsy under MQSA? These are some of the reasons that have been put forward. The regulation would be too burdensome, there has been no demonstrated documented need for this inclusion, and there are voluntary accreditation programs, as you've heard of, that already exist that accredit these

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procedures.

Next slide, next slide. Now, none of us welcomes regulations. Nobody who is involved in, really, anything, welcomes their inspections, and regulations, and paperwork and bureaucracy, but we know from the example of MQSA that it really -- that regulation can affect meaningful and important improvements in practice.

This is a mammogram that was performed in New Haven, Connecticut, in 1985. The patient was referred to us from her surgeon because she had a palpable mass, and had had this mammogram to evaluate the palpable mass. We repeated the mammogram, and here is the cancer here. And again, this is pre-MQSA, pre-ACR voluntary mammographic accreditation.

And what we can accomplish now -- next slide -- is something along these lines, where this tiny little cluster of calcification was detected mammographically, representing a small focus of DCIS with microinvasion.

Next slide. I'm sure you're probably aware

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that, since 1990, breast cancer mortality in this country has dropped by 24 percent. And this is felt to be -- even the biggest skeptics now admit that this is most likely due to a combination of earlier detection through screening mammography, and improved treatment. And the ability to apply improvements in treatment has been largely dependent on the fact that we are picking up tumors at an earlier stage.

Next slide. What about the question of documented need? We have heard that, you know, there is no evidence that there is a problem with stereotactic biopsy. My response to that is, just because it's not on the front page of the New York Times does not mean that there isn't variability in quality, and that all practitioners are performing this procedure with the expertise and the quality standards that we would like to see.

Next slide. This is some anecdotal, and this doesn't project, I'm sorry, but here is a magnification view of a pre-biopsy mammogram showing some fine pleomorphic calcifications. She was advised to have a

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stereotactic biopsy, which she did at another facility, came a year later, here is the follow-up magnification view, and these images are identical.

She had the stereotactic biopsy. She was told that everything was fine, and that she just needed another mammogram in a year. We tried to get the specimen radiograph and the post-procedure mammogram to determine whether or not these calcifications had adequately been sampled, or whether perhaps she needed a repeat stereotactic biopsy. And we were told by the facility that they didn't routinely obtain specimen radiographs or follow-up mammograms. And this was just -- this case was about two years old.

Next slide. This is another -- this is a direct quote from a report of a stereotactic biopsy procedure where they report that they did the procedure, they were successful in retrieving the calcifications, but the conclusion pathology is pending. So when we called this facility and asked, were they going to issue an addendum once the pathology report was available giving the results and making the recommendation, the

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response was that they did not do that, that they left it up to the referring physician to determine what the appropriate management was.

So this is anecdotal, but I suspect that -- you know, I came across these examples fairly easily, and I suspect that other facilities have also found this.

Next. In terms of published literature on the variable performance, and this comes back to Dr. Timins, your question. These are a different populations. These are papers that were published a year apart, and the technique was very similar. The study design was very similar. What they did was they followed-up their benign stereotactic biopsy -- their benign concordant stereotactic biopsies.

And you can see that, in this study, there was a delayed false negative rate of 1.2 percent, as opposed to this study, that had a delayed false negative rate of 4.3 percent. So there is variability -- and these are women who went from 7 to 36 months with their cancers unrecognized.

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Next slide. Another example of how -- and this is stuff that Dr. Dershaw talked about of variability and quality. I want to -- 60 percent of the failures were due to targeting issues, clinical images, but 30 percent was due to the phantom. The phantom failed to pass, so the image quality was poor. And in order to perform this procedure properly, you have to be able to see the finding. And so I think that that is also a very important point.

Next slide. The other reason for not including stereotactic biopsy under MQSA that has been stated that voluntary accreditation programs already exist, so why do we need to regulate this? And again, Dr. Dershaw covered this in his presentation.

Next slide. Out of the, approximately, 2,300 stereotactic units in operation in this country, only about 20 percent of them are accredited under the ACR and the American College of Surgeons Program as of November 1st.

Next slide. So in response to these reasons for not including stereotactic biopsy -- next -- as far

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as being burdensome, for those facilities that are already operating under high quality standards, the actual additional documentation, the actual burden of regulation, is not particularly high, and I speak from experience, you know, as a member of a facility that is accredited.

The additional paperwork is minimal over and above what we already are doing, and what we would do regardless of whether or not there was an accreditation program in place.

As far as no documented need -- next slide -- we -- I have shown that there is variable performance. It's documented in the literature that there is a variation in the delayed false negative rate, and the voluntary accreditation failure rates among highly motivated facilities, I think, shows that there is variability in the performance of these procedures.

And in terms of the voluntary accreditation programs that already exist, we have already said that a small proportion of facilities are accredited. And, Dr. Barr, if I may address, you know, your question of -- I

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don't know where -- of can education replace mandatory regulation, it certainly could if facilities, if practitioners, would all take the time and trouble to become educated. But as we can see that, when it's a voluntary program, that doesn't necessarily happen.

Next slide. So in addition, the Institute of Medicine in their report in 2005 on improving breast imaging quality standards also called for the inclusion of stereotactic biopsy under MQSA.

Next. So in conclusion, we know that the number of breast biopsies is increasing in this country, and we know that the accuracy of image-guided procedures requires care and expertise. It's not an automated system where the machine does the work and you push some buttons.

We know, from published literature, and from our accreditation program failure rates, that quality is variable. There is also anecdotal evidence that this is the case. And the Society of Breast Imaging feels that, when a woman goes to a facility to have a breast biopsy, an image-guided breast biopsy, she should be able to be

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certain that the equipment is functioning properly, that the people who are operating the equipment are -- have the required training and expertise, and that management recommendations, appropriate management recommendations, will be made to the best of the physician's ability. Thank you. I'll be happy to answer any questions.

CHAIRMAN FERGUSON: Questions?

DR. WINCHESTER: You cited the -- with respect to documented need for regulation of variability studies to citations in the literature. One was eight years old, and one was seven years old.

DR. LEE: That's right.

DR. WINCHESTER: Do you think anything has happened since those published reports were --

DR. LEE: I think --

DR. WINCHESTER: Do you have any more recent literature that --

DR. LEE: I think, Dr. Winchester, that more recent reports with more -- with different technology, with different devices, has shown that the false negative rate has decreased, at least the concordance

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rate has improved. But in terms of the long term false negative rate, there are very few papers that have addressed that. I do believe it has decreased, but in terms of the variability, I don't know of any literature, more recent literature, that has addressed that.

Yes, Dr. Barr?

DR. BARR: Helen Barr, FDA. Hi, Dr. Lee. Thank you. What, with MQSA, with any regulation, one thing when you propose a regulation that people want to know, that Congress wants to know, is what measure you're going to use to say whether this has helped public health. What measure would you see us using? For MQSA, we tend to use the decrease in breast cancer morbidity and mortality.

The recent published results show that stereo is fairly close to open biopsy in its success rate. What would you see us using as the measure? Concordance with open biopsy, the accreditation failure rate, can you give me some thoughts on that? Thank you.

DR. LEE: I think both of -- I think the

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bottom line will be the delayed false negative rate. And there is published data that suggests that it is very low. Is it as low as it can be? We don't know that. And I think that would be one measure that we could look towards. I think positive predictive value.

I know that it's very variable depending on the population, but that is another -- something that we could look toward long-term follow-up of these patients, I think, is another measure that we could look at. Those are all things.

DR. BARR: Thank you.

DR. LEE: Yes. Thank you.

CHAIRMAN FERGUSON: Other questions of the Committee? You want to have another speaker, or you want to take a break now, or take a break after the speaker? Take a break? Okay. We'll take a 10 minute break, and then we'll return promptly.

(Whereupon, at 10:07 a.m. a recess until 10:22 a.m.)

CHAIRMAN FERGUSON: Are we all back or close? Yes, I think they are over there getting coffee. Yes, I

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see all three. So the next speaker then has a pre-loaded program, whoever wants to jump up there.

MS. WYNNE: I think I had mentioned to Dr. and Mrs. Wagner, if they are in the room, because they are already pre-loaded into the computer. Thank you.

DR. WAGNER: I don't have a slide show. I also do not have any financial interests in my trip. I financed this trip in the interest of providing quality breast care for women in the future on my own.

Thank you for this opportunity to present my statement to the National Mammography Quality Assurance Advisory Committee. My name is Richard Wagner. I have been a general diagnostic radiologist for 28 years and have now directed my career to a practice dedicated totally to breast care.

In my process of searching for a position as a clinical breast radiologist, it has become increasingly apparent that the standards of breast care vary considerably. I have worked in several different medical facilities, both hospitals and clinics, and it has been quite disturbing to observe the variation and

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the quality of breast care offered to women, especially for diagnostic imaging examinations and procedures.

In the majority of the facilities that I have worked, many radiologists and most non-radiologists performing breast procedures did not practice at the level required by the American College of Radiology Accreditation for these studies.

Missed cancers and misleading information can lead not only to anxiety, but also unfortunate outcomes for the women we serve in our communities. Stereotactic-guided interventional procedures require the ability to accurately target the lesion of concern and correlate this finding with the prior screening and diagnostic mammography examinations, which is why a strong working knowledge of breast imaging is so vital when performing this procedure.

The American College of Radiology has established the highest standards of accreditation for stereotactic breast biopsies, which physicians must achieve to become ACR-accredited. We need one high standard for all outcomes -- for all physicians who

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perform stereotactic biopsies in order to achieve continuity and quality outcomes.

I have seen technicians localizing lesions for physicians who are inexperienced in this procedure and suspicious lesions were missed on biopsy with no subsequent review of the initial imaging findings in the pathology report for concordance of the final results. This level of practice, unfortunately, leads to missed and/or delayed diagnosis of breast cancer for the patient.

Ultrasound is also an integral part of the diagnostic breast care adding another valuable component to the diagnostic process, but is extremely operator-dependent. The ACR Committee on breast ultrasound accreditation has updated the program requirements for ACR breast ultrasound accreditation.

The ACR Breast Ultrasound Accreditation Program, including ultrasound-guided breast biopsies have the highest standards for accreditation and should apply to any physician of any specialty who desires to perform breast ultrasound, including image-guided

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breast biopsies.

But several organizations have developed a certification program for physicians with standards that are less rigorous than the ACR Ultrasound Accreditation Program. This is why it is so important to have one set of high standards that all physicians performing these procedures must achieve.

I have also had the opportunity to present to the Institute of Medicine Advisory Committee prior to the publication of the report improving breast imaging quality standards. I strongly believe that the Mammography Quality Standards Act or MQSA needs to be changed to Breast Imaging Quality Standards Act or BIQSA with the 2007 reauthorization, so that all diagnostic procedures that involve breast care can be regulated to achieve the highest standards of breast -- of practice and the physicians performing them will be required to meet these standards.

This would, indeed, help assure that women receive uniform level of care regardless of the medical facility or physician performing the examinations. I

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realize that no one likes to be regulated, but mandating one high standard that all physicians must achieve would create a framework for quality that could be duplicated and monitored and as has been the case for screening mammography.

To have various certifications for breast procedures with varying degrees of standards, not only is difficult to monitor, but quality is not equal. Mammography has evolved since the early quality standards of 1992 and these standards have seen several reauthorizations to improve quality and breast cancer detection. Yet, there is only one standard set for mammography. So why should there be varying standards for breast diagnostic procedures, such as breast stereotactic and ultrasound image-guided procedures?

Breast MRI is moving forward as another adjunct for diagnosis and yet, we do not even have one standard for this procedure. We move forward without having uniform standards in place for what is already routinely practiced.

The initial key component in breast

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diagnostic process is imaging and the standards of the ACR are the highest. For over three-quarters of a century, the ACR has devoted its resources to making imaging safe, effective and accessible to those who need it.

The American College of Radiology is a professional society whose purpose is to improve the health of patients in society by maximizing the value of radiology and radiologists by advancing the science of radiology, improving radiologic service to the patient, studying the socioeconomic aspects of the practice of radiology and encouraging improving or improved and continued education for radiologists and allied professional fields.

It would seem to me that all women would benefit if physicians delivering breast care and performing breast interventional procedures met one high set of standards. The women would be assured that their breast diagnostic procedures had the same high uniform standards required of their mammographic screening examinations.

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Women do not know the difference between credentialing certifications and accreditation. Women want to trust the medical system and once they are aware of a suspicious finding, based upon screening mammography or physical examination, they want an accurate answer providing quick -- provided quickly through appropriate diagnostic examinations.

Regulation will provide the assurance that the diagnostic imaging portion of their breast care will be of high quality and equal, no matter which physician is performing the procedure. Will the National Mammography Quality Assurance Advisory Committee be willing to advocate and support multiple certification and accreditation programs at various levels of performance for screening mammography?

I strongly recommend that the National Mammography Quality Assurance Advisory Committee consider mandating stereotactic breast biopsy procedure accreditation and recommend that MQSA be changed to BIQSA, so that other imaging modalities, especially ultrasound, can be regulated appropriately as well.

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Breast care is evolving and standards need to be in place so all physicians practice with the same objectives and requirements at the highest level in order to provide the best care for our patients. Thank you. Are there any questions?

CHAIRMAN FERGUSON: Questions?

DR. WINCHESTER: A question for the Chair. Are we considering ultrasound today?

CHAIRMAN FERGUSON: No.

DR. BARR: I actually -- Dr. Barr, FDA. I actually don't have a question, but I got several questions during the break and Dr. Wagner's talk reminded me that I should give you an update on MQSA reauthorization. MQSA expired on September 30, 2007 and is due to be reauthorized. It has not been to date. The authority of FDA to certify and inspect facilities does not sunset with the expiration, so we continue our usual business, business as usual for us.

The reauthorization is actually a reauthorization to allow Congress, to allow itself to appropriate funds for MQSA. So it generally does not

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affect our day-to-day business and it can be -- we have gone a year or more without reauthorization in the past times when it has been up for reauthorization. Does anyone have any questions on that? I'm sorry. I probably should have said that at the beginning, because I have gotten some questions on that.

CHAIRMAN FERGUSON: Any anticipation of when reauthorization will occur?

DR. BARR: No, I don't know. Thank you.

CHAIRMAN FERGUSON: Other questions? Yes? Sorry to keep asking all the questions. I wish somebody else would ask a question.

DR. WINCHESTER: To Dr. Wagner or any other members of the radiologic community. I don't have the facts and figures, but it appears as though the number of breast imaging specialists in the United States is going to be a problem for the future in terms of numbers being able to meet public demand.

The first question is, is that the case or not? Do you expect that there are going to be adequate manpower to address the needs?

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And secondly, what affect do you think regulation of this procedure might have on the numbers?

DR. WAGNER: Well, I think there are a relatively small number of so-called clinical breast radiologists, but there are a lot of, or I shouldn't say a lot, but a fair number of radiologists that are interested in breast care and these people are not, as far as I know, challenged by any sort of regulation. In fact, I think they welcome it.

It's one of the problems with breast care now that the general radiologist is concerned about is lawsuits and I think lawsuits are brought about by physicians, radiologists and non-radiologists that don't deal with the patients properly. They don't communicate with the patients regarding their breast care issues. And there are numbers and I don't have references to that, but there are numbers that indicate that clinical breast radiologists are sued at a very, very low rate.

So I think if there were more physicians that were encouraged to go on to breast care and shown that they wouldn't be involved with lawsuits, because they

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provide better quality care, I think that might affect a lot of the physicians. Another has to do with clinical breast radiologist daily work in environments that are extremely efficient. They do high volume screening and diagnostic procedures.

And I think there is new models out there that are coming into being that do high volume and I think they possibly could meet the needs of the screening and diagnostic patient population in the future.

CHAIRMAN FERGUSON: Yes?

MR. UZENOFF: Dr. Wagner, Bob Uzenoff, Committee Member. You mentioned the evolving nature of breast biopsy in these types of exams.

DR. WAGNER: I'm sorry, I didn't catch that. What?

MR. UZENOFF: You mentioned the evolving nature.

DR. WAGNER: Yes.

MR. UZENOFF: Of the equipment and the procedures in biopsy. And this question is for you or

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perhaps someone from the ACR, the ACR Accreditation Program. One of my concerns would be that in regulation that the regulations would be appropriate to some clinical outcome and be reflective of changing technologies.

Now, since, I think, 1999 is the date of the QC manual for the ACR Program, has -- are you aware, has that program changed to reflect changes in technology?

DR. WAGNER: I think maybe Dr. Dershaw or Dr. Lee might be able to answer that.

MS. BUTLER: Could I be recognized?

CHAIRMAN FERGUSON: Please.

MS. WYNNE: I would also like to remind all of the Panel Members when you ask a question, please, state your name before you ask the question.

MS. BUTLER: Penny Butler, ACR. The manual itself has not changed. However, there has been aspects of the manual that have the -- the technology has changed, so we have been addressing some of those items in our frequently asked questions that is available on the website. We are -- have been talking about updating

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the manual, but a lot of this is going to depend on actually the outcome of these discussions and FDA's deliberations, because as with MQSA and mammography, when the regulations came out, we had to modify the manual to make it consistent with the regulations.

CHAIRMAN FERGUSON: Yes?

MEMBER TIMINS: Julie Timins, on the Panel. One of the Panel Members had asked a question regarding concern with access to care and how regulations might interfere with that. And I note that in the State of New Jersey that there are -- there has been roughly a 10 to 15 percent drop in the number of facilities performing screening mammography and an increase in delay of availability of screening mammography, because of fewer facilities and perhaps fewer radiologists interpreting.

However, there has not been a delay in access to diagnostic mammography and there is no evidence that there has been a delay in access to biopsy and surgery.

DR. WAGNER: I might add one other thing. With the advance of digital mammography, I think the

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number of patients that are being able to -- are being able to be encompassed on each machine has increased considerably, sometimes doubling or sometimes tripling and these images can be sent to other facilities where they can be interpreted.

CHAIRMAN FERGUSON: Thank you. And she made a very good point. I forgot, I'm Dr. Ferguson. You have to say that so for the transcript, they will know who is asking the question or who is speaking when they do a transcript of this. So when you ask a question, as Dr. Timins did, please, say it's Dr. Timins. Go forward, you know, I'm Dr. Timins.

MS. WYNNE: Would the next speaker come forward, please?

MS. WAGNER: I am Judy Wagner and I thank you for the privilege of speaking before the National Mammography Quality Assurance Advisory Committee as a nurse, breast cancer patient advocate and breast cancer survivor.

I have been continuing to be a devoted advocate for the advancing of the quality of breast

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care, especially advancing the implementation of physician standards for diagnostic imaging examinations and image-guided procedures. The implementation of appropriate practice and accreditation standards as has occurred with the mammography quality standards set for mammography will help assure women that standards are met for diagnostic breast mammography, breast ultrasound, breast MRI, ultrasound-guided biopsy, stereotactic-guided biopsy, MRI biopsy, image-guided pre-operative needle position and specimen radiography.

In addition to improved quality of care for these imaging examinations and image-guided procedures, we can also expect improved patient outcomes with reduction of medical costs. If appropriate standards are not put in place, we can expect continued use of medical equipment by physicians without appropriate levels of training and experience and more unnecessary examinations and biopsies resulting in unnecessary anxiety for the patient.

I have firsthand experience as to what can occur when a physician does not have appropriate

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training and experience in breast diagnostic imaging and image-guided biopsy. In 2002, after my screening mammography and an additional diagnostic mammography examination showed suspicious microcalcifications in my left breast, I needed a stereotactic needle-guided biopsy to determine a diagnosis.

I was referred to a physician to perform this biopsy. Despite his best efforts, this physician was unable to perform the stereotactic breast biopsy. I was then informed that I would need to undergo an open breast biopsy in order to sample my suspicious microcalcifications.

I chose to seek out another physician who was MQSA-certified possessing appropriate training and experience as well as accreditation for this procedure. He was able without any difficulty to perform the image-guided biopsy. I learned the following day that I had breast cancer. In retrospect, it became clear that the reason the first physician could not perform the biopsy was because he had neither the appropriate training nor experience in mammography or stereotactic-guided needle

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biopsy.

Members of this Advisory Committee, please, understand that the purchase of a piece of medical imaging equipment does not qualify a physician to perform imaging examinations or image-guided procedures any more than the purchase of a set of golf clubs qualifies a person for the Masters.

It is imperative that appropriate training and experience standards be implemented as part of MQSA for diagnostic imaging examinations and image-guided procedures as recommended in the Institute of Medicine's report on improving breast imaging quality standards.

Before it is assumed that my experience is an isolated incident, please, be informed that as a patient advocate, I often hear of experiences from women with many similar issues. Unfortunately, for women instead of the advancement of universal practice and accreditation standards, over the last four years we have seen various diagnostic breast imaging examinations and image-guided procedure standards promoted by multiple groups, which are not equal in terms of

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physician training and experience.

Why would any group provide physician training practice and accreditations that are less than those previously established as the standard of care by the American College of Radiology? The American College of Radiology has established the highest practice and accreditation standards for medical imaging and image-guided procedures. Whom does it benefit when lower standards are advocated and advanced?

Instituting mandatory breast imaging practice and accreditation standards is needed and should be addressed in the upcoming reauthorization of the Mammography Quality Standards Act. Adoption of the current voluntary practice and accreditation standards established by the American College of Radiology would help assure women, regardless of their location, that these high accreditation standards are being met by their physicians and medical centers.

The Mammography Quality Standards Act has been a landmark legislation accomplishment and although federal regulations are often fraught with objection,

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regulation of mammography has improved breast care. At the 2005 National Mammography Quality Assurance Advisory Committee meeting it was stated that mandating qualifications has improved quality compared with voluntary programs.

Mammography accreditation rates increased steadily after MQSA went into effect. I applaud the American College of Radiology's new accreditation program entitled "Breast Imaging Center of Excellence," which provides this designation only for physicians and centers that have acquired accreditation in mammography, diagnostic breast ultrasound, ultrasound-guided biopsy and stereotactic biopsy.

Standards are a measuring tool and our framework for achieving and sustaining quality. The Institute of Medicine's definition of quality, as provided in the 2001 report "Crossing the Quality Chasm," a new health care system of the 21st Century is the following: The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with

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current professional knowledge.

That is why I strongly advocate universal mandated standards for breast diagnostic imaging examinations and image-guided procedures, so that any physician performing these procedures will have the same set of standards under which breast care will be delivered and thus increase the likelihood of desired health outcomes in breast care.

These examination procedures include, but are not limited to, diagnostic mammography, breast ultrasound, breast MRI, ultrasound-guided biopsy, stereotactic-guided biopsy, MRI-guided biopsy, image-guided preoperative needle position and surgical specimen imaging.

But due to the fact that many of these imaging modalities use other systems beyond x-ray to attain the required image, it may be necessary for Congress to consider changing the Mammography Quality Standards Act to the Breast Imaging Quality Standards Act, as suggested in the IOM report, "Improving Best Imaging Quality Standards," to include these additional

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imaging modalities.

The American College of Radiology is the organization established for the advancement of medical imaging and their standards for voluntary accreditation of diagnostic imaging modalities were established with this focus and thus should be required standard for all physicians performing these breast imaging examinations and procedures.

Since the core of image-guided procedures is the imaging component, it would seem best to implement appropriate standards. This would help assure all women of the same practice standards just as the mammography practice standards required within MQSA. Breast care issues continue to cause women a great deal of fear and anxiety for which I have firsthand experience.

Women of all ages, socioeconomic status and even those in the medical field become paralyzed with fear at the mere implication that there might be a questionable finding on their mammogram suggesting breast cancer. That is why women deserve the highest standards at all steps of the process of breast care

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from screening, through diagnostic imaging and image-guided procedures.

Breast care delivered with one high standard for all imaging would help provide the competency and trust that women deserve and expect from their physicians. I speak for the women for whom I advocate and I ask that this Committee recommend mandating universal practice and accreditation standards for breast imaging examinations and image-guided procedures as established by the American College of Radiology.

I also recommend that this Committee support the Institute of Medicine's recommendation for changing the Mammography Quality Standards Act to the Breast Imaging Quality Standards Act. Accreditation standards, which all physicians should achieve, are needed to help assure that all women receive the highest level of care. Thank you.

CHAIRMAN FERGUSON: Thank you. Questions of Ms. Wagner? Thank you very much.

MS. WAGNER: Thank you.

CHAIRMAN FERGUSON: Oh, there is a question.

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MS. FINKEN: From what I hear, it appears that you are -- pardon?

CHAIRMAN FERGUSON: Identify yourself.

MS. FINKEN: Oh, I'm sorry. I'm Nancy Finken, consumer advocate. From what I hear, you sound to me like you are from a large urban area.

MS. WAGNER: Yes, I am.

MS. FINKEN: And my question is what happens to the women out farther from the urban area? Will these facilities and qualifications extend to, I don't know pick a name like, Keokuk, Iowa?

MS. WAGNER: I do a lot of presentations to women's groups, church groups and I always ask this question. If you had to receive quality breast care 100 miles away, would you go? And the answer uniformly is absolutely. There are big centers in Wisconsin, where I come from, that are up in the upper areas that serve 100 mile radiuses and many of them are using the digital system at outlying satellite clinics to transport the images.

I believe as a woman and as an advocate that

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if you found out on your screening mammogram that you had a suspicious lesion that was highly suspicious and needed a diagnostic workup, you would go to China if you needed to get there. It is amazing, I get a lot of calls from women who are in systems that are questioning their systems and I recommend another facility.

And I have a sister who lives in Missouri. She says where can I find my accredited breast center and I said well, just look it up on acr.org and we found out. You know, so women want to know. This is a new generation. My granddaughters can tell you to get your mammogram. I mean, we are educating each other and we are wanting these high standards.

And so I believe that women would go as far as it would be necessary to get the diagnostic workup that would be necessary. And I hear women all the time when I'm walking in the dog park, I talk to women in grocery lines, wherever I see a woman and I get the same feedback. Oh, I do go to that good breast center, that accredited breast center. My physician told me to go there.

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So it is happening, but not fast enough, as far as I'm concerned, since I was somebody who, thank gosh, I went in a different direction.

CHAIRMAN FERGUSON: Thank you. Other questions?

MS. WAGNER: Any other? Thank you.

CHAIRMAN FERGUSON: Thank you. Dr. Russell, I believe you have something preloaded. Are you ready?

DR. FINDER: He's not here yet.

CHAIRMAN FERGUSON: Well, the next people that have got something preloaded then.

DR. LERNER: Good morning. My name is Arthur Lerner. I'm a breast surgeon in White Plains, New York and I am here to represent the American Society of Breast Surgeons. The society has or will be reimbursing me for my travel expenses. I'm proud to say I'm a past president of the society and currently co-chair of their Committee on Imaging Technology.

By way of other disclosure, I would like the Committee to know that until recently I was on the board of directors of Hologic, a manufacturer of stereotactic

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equipment, and serve on the Scientific Advisory Board of a number of device companies, breast biopsy device companies and have participated in the development of some of the breast biopsy devices that are now currently in use.

I want to thank the Committee for this opportunity, the Chair and all Members, for this opportunity to address you this morning. Our society was founded about 12 years ago and very briefly has over 2,500 members, mainly from the United States, but representing 35 countries. It is a society that was formed to encourage the study of breast surgery, to promote research and development and advocate for both the surgeon and the patient as well.

Next slide, please, next, please. We have taught for a number of years that there has been a paradigm shift in breast care and that is that the needle has replaced the knife for almost all diagnostic breast biopsy procedures.

Next, please, and the next one also. Through our courses both at our annual meeting, the courses

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sponsored throughout the country, throughout the years and in conjunction with the American College of Surgeons, that paradigm shift has been incorporated into our teaching of stereotactic procedures as well as other image-guided breast biopsy procedures.

It should be rare today that any woman or man, for that matter, needs to see an operating room environment to make a diagnosis of a breast problem.

Next, please. The key points we would like to make is that stereotactic procedures are, in fact, not mammography. Yes, they are images of the breast, but not mammography as we all understand mammography to be.

Next, please. There is no scientific evidence-based justification for the Federal Government to become involved in regulation of an effective safe medical procedure. We need to make our decisions based on science. Training and certification of physicians and stereotactic breast biopsies we feel are best done by the representative colleges and the societies and we would argue that credentialing of these procedures

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should and must remain a local process.

Next, please. The regulation of stereotactic biopsy procedures possibly, and I'll address this in a moment, possibly may restrict access of certain physician groups to these technologies and therefore limit the access of these technologies to their patient population.

Next slide, please. The physician doing a procedure, a stereotactic procedure does not interpret the mammogram.

Next. The diagnosis is based on the biopsy, rather than solely on the interpretation of the images.

Next, please. The imaging, as you all know, is used exclusively for localization of the target lesion during a stereotactic procedure. Next slide. And regulation of these procedures, in my judgment and in the judgment of others, will lead the Federal Government into regulating therapeutic procedures in the not too distant future.

Clearly, there are clinical trials underway right now in this country and elsewhere that are using

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image-guidance to treat small breast cancers non-surgically. We will use stereotactics, ultrasound or MRI to guide some tool into the breast to either ablate or extract in tact a small breast cancer, thereby saving women surgical procedures.

When the clinical trials are finished, these technologies will be available. And do we really think that the Federal Government should be regulating the treatment of breast cancer in the near future?

Next, please. In the literature, as I said earlier, there is no evidence that this technology suffers from inadequate sampling, high discordant rates or unacceptable false negative rates.

Next. I would like to address just for a moment discordance, because as you review the literature, there is confusion and different definitions of discordance. I believe that a discordant biopsy is one where there is an unexpected pathologic result that differs from the expected result based on the interpretation of the mammographic images.

Next. The reported rate of discordance in

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the literature is around 2 percent.

Next. Discordance in and of itself is not a problem as long as it is recognized that there has been a discordant biopsy and appropriate action is taken.

Next slide, please. What we think is most important and it was addressed earlier are the false negatives. This is the important measure of diagnostic value.

Next. How many cancers become evident at the site of a prior image-guided biopsy, or in this case, stereotactic biopsy with an initial biopsy showing a benign diagnosis?

Next. The reported rate in the literature, and we saw some numbers earlier, are from zero to 4 percent and, next, this parallels the reported rate for open surgical hook-wire localization diagnostic biopsies.

Next. Concerns about restricting access to stereotactic procedures. There are areas in this country where surgeons, in fact, and we need to acknowledge this, do face restrictions on access that

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make it difficult for them to offer stereotactic biopsies as an alternative to surgical biopsies.

Next. Regulation may, may make it more difficult for surgeons, appropriately trained, to offer these procedures.

Next, please, next slide, next bullet. Recently, the American Society of Breast Surgeons conducted a survey of its membership.

Next. 46 percent of the respondents, and there were 577 who filled out the survey, 251 were doing stereotactic biopsies.

Next. However, 54 percent of the respondents who did not perform these procedures, not an insignificant number, reported they were blocked from accessing the technology by radiologists in their community. Now, I don't mean to say that this is a widespread practice, but we have to recognize that these turf battles do go on and they serve no useful purpose, either to the physician community or more important to the patient population that we serve.

Next, please. The society's current concerns

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over federal regulation is that we all agree, I hope, that stereotactic breast biopsy is superior to open surgical biopsy in the appropriate clinical setting.

Next, please. Federal regulation may exacerbate difficulties that surgeons are currently having offering these procedures to their patients.

Next, please. Regulation will not benefit patients, in our judgment, by improving false negative rates and will likely mean that more patients will be subjected to surgical biopsies if regulation is written and becomes a fact in a way that allows for exclusion of any group of properly trained physicians.

Next, please. Stereotactic breast biopsy, in our judgment, will not improve. It is already an excellent procedure. Potentially, it will only perhaps become more difficult to offer.

Next, please. We had a meeting this past August with Dr. Schultz and Dr. Barr and Dr. Finder and other members of the FDA and they invited us to come to Washington to talk to them about these problems. And Dr. Schultz offered the surgical community and the

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surgical community for purposes of that day consisted of representatives of our society, myself included, members of the American College of Surgeons, of the Society of Surgical Oncologists and the American Society of General Surgeons. And Dr. Schultz offered these challenges to us.

Next, please. Certify surgeons, next, accredit surgical facilities, next, and provide data that shows that the stereotactic procedures being done in the community parallel the results of the published literature. Our response to that have been, next, next, we have an active certification program for surgeons. I think it's important to understand that we believe there is a distinction between certification and accreditation.

Certification should be a process for the individual to demonstrate his or her training, ability, competence and understanding of the technology and how to apply it in a clinical setting. Accreditation is for a facility, for the technology. Most of us in the surgical community who have been doing these procedures

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work in facilities that are not ours. We are not involved in the accreditation process.

Therefore, we need a certification process for ourselves. For those few surgeons who do have this technology in their practices, we have offered them a facility accreditation program that will stand the test of the American College of Radiologies Program, I do believe. As part of that accreditation program for their technology, they must first become certified.

The certification program that we are offering is a complex and difficult process. There is a minimum amount of, and it's not minimum, experience that is necessary as well as appropriate training through CME education hands-on courses that are required. You have to submit cases with images, but we differ here in that we do not separate out imaging from the procedure.

In order to pass that part of the exam, you not only have to have adequate imaging, but you have to show the pathology and the treatment plan, how this biopsy is going to affect the patient going down the road. So our certification program, the part of it that

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requires imaging also requires the knowledge of breast pathophysiology and clinical breast management.

There is a written examination that has a fairly substantial section on radiation safety and unique to all certification programs as far as I know is there is a practical examination where the candidate must come and be examined on the technology and demonstrate their knowledge of and ability to use the technology without depending upon a radiation -- a radiology technologist to do the procedure while they stand by and watch.

We offered this certification just recently. At a recent meeting in New Orleans, we examined our first 20 surgeons on that practical exam. It was a great learning experience for everyone. It is not an easy exam to pass.

Next. As I said, we have developed a facility accreditation program which we have for you and we will distribute to you. And, next, we have responded to Dr. Schultz' request for collecting data.

Next slide, please. We have developed a

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database which we began only in August after Dr. Schultz asked us to do this. We picked a point in time so that we could have follow-up over time and we requested surgeons practicing in the community to give us a minimum of 10 and hopefully 20 consecutive cases of stereotactic biopsies from that point forward with images, with pathology, with indications, mammography reports, etcetera.

We are beginning to put together that data. So far we have amassed 120 cases and we're aiming for 200 cases by the end of this calendar year to put into our database. As I said, because Dr. Schultz wanted data from the community, these surgeons come from a wide geographic distribution by design. They are from private or group practices. They perform these procedures in a variety of clinical settings and facilities.

You can see under Bullet 3 there the types of information that we are looking for and we will be pleased when the database is complete with 200 cases to provide you with this data to help you make your

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decisions about moving forward with or without regulation of these procedures. The database won't close, however, at 200 cases. Part of the certification process and part of the accreditation process will be participation ongoing in these databases.

Next, please. So our existing programs that we have available for our surgical colleagues include a performance and practice guideline for stereotactic breast biopsies. We have one for ultrasound as well, although we're not discussing ultrasound you said, stereotactic certification, facility accreditation. We are also developing a proctoring program that will allow surgeons who wish to begin to develop their skills in this field to have someone visit them in their clinic, in their center and help them do cases. Someone who has been trained as and is skilled as a stereotactic proctor.

Next, please. So in summary, stereotactic biopsies, breast biopsies are not mammography in our judgment and therefore do not fall under the regulatory authority of the Federal Government.

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Next bullet. To justify Government regulation, if regulation is to come about, there must be scientifically documented problems that regulation will address and hopefully will resolve.

Next, please. If stereotactic biopsies are regulated, in the near future then we must acknowledge the fact that we will then be regulating treatment of small breast cancers for a number of patients.

Next. Regulation cannot allow one organization to dominate and decide the training, background, certification and accreditation of another organization of well-trained physicians. There must be parallel programs. The outcomes, the standards, the outcomes of care must be the same. The same high quality must be achieved. But there are different pathways because of different training and background.

There are different pathways in these processes that are appropriate for surgeons, in my judgment, and I don't mean to tell any radiologist what they should be doing, but there are different pathways to get to the high quality of care that would include a

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background and basic knowledge of breast pathology, of breast pathophysiology and of breast care going forward from a breast biopsy.

Next, please. Professional organizations like our society, the American College of Surgeons and the American College of Radiology are best positioned to educate and certify physicians to ensure the quality of care.

Next. We request the Advisory Committee allow us to get the data that Dr. Schultz asked us to. We need data over time, so that we can address the true false negative rate, not at the time of biopsy and not necessarily at six months, but at least at a year out from the biopsy and hopefully going forward, even over a longer term than one year. We would like to provide you with the data when it is available and we will ask you to use that data in your deliberations about regulation.

Thank you very much for your attention.

CHAIRMAN FERGUSON: Thank you. Questions from the Committee? Yes?

MEMBER MONTICCIOLO: Debbie Monticciolo,

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Committee Member. That was a very nice presentation. I'm concerned about the suggestion that if regulated, this will favor one group over another, since the regulations, if enacted, will apply to both surgeons and radiologists and any other physician equally. And I think the programs that are designed now include both groups at least and don't exclude one group or another.

The other thing is that, you know, I address in the same question is, you have several accreditation programs, so I'm assuming the surgeons that have gotten accredited would feel comfortable. So what is their concern about making it mandatory? It seems that if they can meet your qualifications now, they shouldn't really be terribly bothered by meeting high quality standards.

DR. LERNER: Two different questions I'll try and address for you. The first part of the question, if regulation comes about, absolutely would support what you just said about there being standards for the different specialties, high standards that have to be met and there not be written into regulation any method

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for any one group to dominate over any other group. And we would support that if regulation has to come about. I'm not saying that --

MEMBER MONTICCIOLO: Well, is there a suggestion that that's what was going to happen? Because my understanding is these are for quality issues and not specific --

DR. LERNER: There is not a suggestion. There was a concern. I think there is a difference and --

MEMBER MONTICCIOLO: Yes, I would like to make sure that we note that there is a difference, because as a radiologist, that never entered my mind that this is supposed to close somebody off. I mean, the programs that are enacted, even by the American College of Radiology, recognized the fact that surgeons and other practitioners do these procedures. It's just a matter of quality.

DR. LERNER: I don't disagree at all. I totally agree with you. And your second question, remind me, please.

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MEMBER MONTICCIOLO: Well, you have several accreditation programs in place. And the question is, I mean, do these not come up to the standard that is being proposed? Is that the concern? Because it seems like if you have those programs and surgeons back them and are aware of them, that they would welcome them being established as required.

DR. LERNER: Again, we come back to what is regulation going to do? Are we regulating because we can or are we regulating because there is a demonstrated problem? If there is a demonstrated problem through evidence-based medicine, we will be at the head of the list supporting what you are doing.

But until that time, we question the need for regulation, respectfully request that the surgical societies and the subspecialty -- the surgical colleges and the subspecialty societies are in the best position to determine quality of care and the pathways to achieve quality of care.

CHAIRMAN FERGUSON: Yes, Dr. Timins?

MEMBER TIMINS: Julie Timins on the Panel.

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At first I was surprised when Dr. Dershaw put up his slides of facilities that were accredited between 2004 and 2006, only four underwent accreditation by the American Society of Breast Surgeons. I think you partially answered that in stating that few of the surgeons have stereotactic biopsy equipment within their private practices and that explains the small number.

How would you respond to the statement that of the American College of Radiology Accreditation Program for stereotactic biopsy that 25 percent of the facilities do not pass initially? What is your response to that?

DR. LERNER: I think there is a difference in the way you determine pass or fail. If you -- for instance, the cited example was that the target lesion is covered by the biopsy device on what we would call our post-fire or presampling stereotactic pair. Well, in fact, that happens every day. That's exactly what often happens during a stereotactic procedure.

Recognizing that the lesion is there underneath the biopsy device and using directional

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capability of today's devices to decide which quadrant to focus your sampling on, to us, demonstrates the background in knowledge of applying this technology in a clinical setting.

So that we have been told that a number of the failures have been because the images did not show the lesion, they were covered by the device. Well, that's the real world. That's what happens and overcoming that and the demonstration of being able to overcome that is the pathology, that you've got the lesion, expected lesion you were after. You understood the technology. You understood how to maximize the technology and its directional capabilities and got the right tissue and that, I think, is the difference between the way we look at it.

MEMBER TIMINS: You also -- was this the certification program where you had just started a program where you examined 20 physicians/surgeons in their actual performance of the technique? I thought that was a very interesting approach in quality assurance.

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DR. LERNER: Thank you.

CHAIRMAN FERGUSON: Yes?

MEMBER WILLIAMS: Yes, this is Mark Williams, a Panel Member. One comment and one question. The comment first. I applaud the fact that more data are being obtained and I would encourage the analysis of those data to occur in as broad a fashion as possible, since there are, obviously, different details in the way that the ACR and other organizations might analyze them, so that we can come up with some sort of a global consensus.

The question I have, I guess is really more for the FDA, and maybe Dr. Finder or Dr. Barr can handle this. In several talks so far, we have had some discussion of the definition of MQSA, the definition of mammography, the screening aspect and the diagnostic aspect and where that stops and starts.

With the upcoming update of MQSA, is that something that we should be focusing on or is that something that can be, if appropriate, if it's decided that MQSA or whatever you want to call it, whatever it

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is called in this next iteration is appropriate for this, are those real issues for us to be thinking about?

DR. FINDER: It's Dr. Finder. The answer in short to your question is no, because many of the issues that were brought up deal with the Act, the statute itself, which FDA does not have control over. It's a Congressional matter. They can look at the statute and the reauthorization and decide to make changes if they feel appropriate.

But the definitions that we are working under are established in the statute. We have to work with those as they are. And I would say to the Committee, at this point, to -- because there is some question that has been raised about whether there is authority under that statute to regulate interventional mammography.

I would go with the assumption that we do have the authority, at this point, that is a question that is being looked at by our lawyers in addition to the fact that the Congress may look at it in the statute. But I think for the purposes of this discussion you have to make an assumption that the

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authority does exist and your discussions here are more to focus on if we do have that authority, are there reasons to regulate these procedures? Does that answer your question?

MEMBER WILLIAMS: Yes.

DR. FINDER: Okay.

CHAIRMAN FERGUSON: Other questions?

DR. BYNG: Yes, Jeff Byng, a Panel Member representing industry. In the study and the data that you are collecting, you indicated a number of things that you would be recording in addition to the equipment. Is there any metrics or measures that you are tracking to ensure that the equipment is performing or functioning properly?

DR. LERNER: In that particular study, we are relying upon state licensure of the equipment and the regulatory authorities within each state that the physician is practicing to ensure the safety of the equipment. As we move into accreditation, then we will become more involved with that. I hope that answers your question.

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DR. BYNG: A follow-up, if I may. When you say as you move into accreditation, you are referring to the accreditation program that you described earlier for the surgeons?

DR. LERNER: Right. For the technology as opposed to the certification program and now the data program. This data program that you have seen and the data we're going to provide will be rolled into both of those programs.

DR. BYNG: Thank you.

MS. FINKEN: Nancy Finken, consumer advocate and a survivor. My concern again the women out there, is there a way in which this can be brought on mobile units to areas which do not have medical centers? And traveling 100 miles as Mrs. Wagner pointed out can be a burden on women with young children or elderly parents, etcetera, that prevents them from seeking the care they really should have.

DR. LERNER: Clearly, that issue is much greater than just getting biopsies, in terms of radiation after breast preserving procedures and

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distances and everybody is working hard to overcome those issues. Yes, there are mobile companies, but, as most things today, it becomes a matter of finance. You have to have the volume to pay the mobile company to make that trip to bring the technology to the community.

There are some very good mobile companies with very good technologists and very good technology available, but it becomes a matter of numbers and the ability to afford to do this work. We're all in peril with the proposed reductions in reimbursement for stereo. We may be all out of that business in five years when Medicare's reimbursement rate goes below your costs.

MS. FINKEN: Does that mean with the mobile units that the doctors would have to be radiologists in order to interpret or you are suggesting that the surgeons, the breast surgeons could be certified to use that mobile equipment adequately?

DR. LERNER: Yes, we're suggesting that people who are doing these procedures whether on fixed units --

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MS. FINKEN: Okay.

DR. LERNER: -- prone tables or upright units or in mobile units be appropriately trained and certified. That should apply to everybody.

MS. FINKEN: Thank you very much.

DR. LERNER: That is our goal.

MS. FINKEN: Okay.

CHAIRMAN FERGUSON: Yes?

DR. WINCHESTER: In previous comments by many of the radiologists there is the statement about them being -- and I acknowledge the history here of their taking the leadership and setting standards. They have done tremendous things. Do you think the surgeons' efforts in this area of standard setting are equivalent to that or are we talking about two levels of standards? Are we talking about comparable standards?

DR. LERNER: We're talking about in terms of outcome and quality comparable standards. We're talking about slightly different pathways through that standard procedure, through those procedures, based on background and training. But the end point that we are all after

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is the exquisite care offered to our patients with quality, low complication rate and a very low false negative rate.

CHAIRMAN FERGUSON: I have a question. This is Dr. Ferguson. And mine is along the same lines. I think I hear you saying that we're working towards the same thing? We want high quality. We want access. We want the wonderful things that have been accomplished through MQSA. But what I hear in other conversations and from you is that there is a concern that through regulation, surgeons may somehow be excluded from this process.

And that's not what I want to see happen. I don't think that's what anybody wants to see happen. So I would like to know what concern there is and how could that be alleviated?

DR. LERNER: Well, first, I'm overwhelmingly pleased to hear your statements about equality of access going forward, whether there is or isn't regulation, there must be equality of access. We react to the experience of our colleagues out in the field who have

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had trouble accessing the technology.

You might be interested to know that the American Society of Breast Surgery was formed and founded with a grant from Lorad, one of the makers of the prone tables, back in the early 1990s to help combat the efforts of the American College of Radiology and to block surgeons from doing these procedures. That's the way the society began.

Hopefully those days are over. I went for stereotactic training in 1991 and was asked to leave the center, because I was a surgeon. So we have a background of concern. I don't mean to imply at all that anybody in this room or at the FDA would ever think about making regulation that would be exclusionary, but I'm just offering the concern that if regulation does come about, as it is written, that we all pay attention to the way it is written so that by accident, not by design, it doesn't become exclusionary.

CHAIRMAN FERGUSON: Thank you. Dr. Barr, did you --

DR. BARR: Thank you. This is Helen Barr,

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FDA. I just wanted to clarify Ms. Finken's question and your answer, because I heard you mention the word interpret with these mobile vans. And you answered about interpretation. So I think that maybe there needs some clarification there.

DR. LERNER: That's absolutely a fair question. I misused the word.

DR. BARR: Well, Mr. Byng asked about interpretation.

DR. LERNER: I understand, but I think I also used the word. And mammograms are interpreted not by us, but by our colleagues in radiology, that's where the interpretation comes. The technology for biopsying under stereo is a localization technology.

We in the sense interpret the position of the biopsy tool to the targeted lesion. Yes, that's an interpretation, but it's not a reading of a mammogram. It's not a signing of BIRADS classification to something we're seeing that has already been done for us by our colleagues in radiology.

CHAIRMAN FERGUSON: Yes, Dr. Timins?

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MEMBER TIMINS: Now -- Julie Timins, Member of the Panel. There is no requirement that you need to be a radiologist to interpret mammography. You need a certain amount of training and numbers in order to qualify as an interpreter. And MQSA works on that assumption. In fact, the vast majority of people who interpret mammograms are radiologists by training.

MEMBER RINELLA: Diane Rinella, Committee Member. You had mentioned being blocked from doing stereo. Could you give me an example of how you are blocked?

DR. LERNER: If you go back and look at the program that was put together jointly between the American College of Surgeons and the American College of Radiology a number of years ago, in there there are suggestions for training for surgeons and radiologists and the training differs whether there is a cooperative program where surgeons and radiologists work together or work independently.

In the independent setting it says for the surgeon that you should review 480 mammograms every two

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years. It doesn't say you should interpret 480 mammograms. It said you should look at 480 mammograms interpreted by a radiologist qualified to do that. We have scores and scores and scores of our colleagues who write to us in the society that they are blocked from doing it, because they don't read 480 mammograms. That's a misuse of those standards.

Now, again, these are -- granted, they are not widespread. They are isolated incidents, but we have to protect against those becoming widespread.

CHAIRMAN FERGUSON: Thank you very much. Mr. David Adams, is he here? You all tag team? However you like.

DR. KURTZMAN: Thank you, Mr. Chairman and Members of the Panel. My name is Scott Kurtzman. I'm the Executive Council for the Society of Surgical Oncology. I also Chair the Training Committee and was responsible for the training of surgical oncology fellows and breast fellows for many years.

I also am a board member of the Executive Council of the NAPBC, the National Accreditation Program

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for Breast Centers. The Society of Surgical Oncology is reimbursing me for my expenses for this visit, otherwise I have no other financial interest. I am the Director of Surgery and Program Director at Waterbury Hospital in Connecticut. By the way, Connecticut has the highest rate of breast conservation. I've got a very busy breast practice and I'm also a Professor of Surgery at the university.

Also with your permission, I would like to split my time since much of what I'm going to say is redundant, has been already said, with Dr. Dowlat, who is also another breast surgeon.

Next slide, please. I'm going to give some information supporting the ASBS position. I'll tell you a little bit about the Society of Surgical Oncology, the history of surgeons performing stereotactic biopsies and training of breast specialists.

Next slide, please. The Executive Council of the SSO agrees that there is no evidence of unfavorable patient outcomes related to the performance of stereotactic biopsy. MQSA expressly refers to screening

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of diagnostic mammography and with no disrespect for Dr. Dershaw, who is one of my instructors many years ago, this is not mammography. Three stereotactic biopsies are not the same as screening or diagnostic mammograms.

Next slide, please. Surgical oncologists and breast surgeons are trained in the performance of image-guided biopsy, regulation of the procedure is unprecedented and as you have heard before, there is no problem that will be fixed via regulation. The Society of Surgical Oncology has, approximately, 2,000 members from many countries. In a survey, about half specialist in breast diseases, three-quarters of our members use ultrasound in their practice and 83 percent use biopsy instruments of one kind or another.

Next slide. In the training programs for surgical oncology fellows and breast fellows, we rotate through rotations including, but not exclusive to, surgery, radiology and pathology. So we have a well spread out experience in all these areas and are experienced in all aspects of those -- that kind of care.

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Next slide, please. With respect to stereotactic biopsies, Dr. Dowlat is going to go into this a little bit more. The first stereotactic biopsies used devices such as ABBI, which were basically a surgical procedure and surgeons were involved in the beginning. The biopsies were done in collaboration with radiologists in many cases.

Next slide. So what are the issues? Surgeons are not asking to perform or interpret screening or diagnostic mammography. We have made that point quite clear. The skills needed to line up with the target lesion identified by radiologists are well within the capability of surgeons. Surgeons are well-equipped to correlate the pathologic findings with the patient's history, risk factors, physical examination and imaging.

Next slide, please. Training and certification mechanisms are well-worked out. Credentialing is a local issue to be left to hospitals and the states. We don't necessarily need federal credentialing of procedures. With respect to

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discrepancy and data and outcomes, there is no data that false negative rates of stereotactic biopsies is a problem and anecdotes are certainly not helpful.

Next slide. Surgeons are the consultants on patients with breast diseases, surgeons utilize the patient's history and examination to guide the patient through the decision regarding the assess -- for mechanism of biopsy and patients rely on their surgeons and want that person involved in their care throughout their diagnosis and treatment.

Next slide. Restricting surgeons ability to perform the biopsy will interfere with the prompt and personal care of the patients. And in those areas of the country where there are no trained radiologists, patients will undergo surgical rather than image-guided biopsies if regulations are put in place that exclude surgeons.

Next slide. So in summary, there is no reason and the FDA does not have the jurisdiction to regulate the procedure of stereotactic biopsies under MQSA. Surgeons are trained in all aspects of the care

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they are involved in in stereotactic biopsies. The Society of Surgical Oncology and its Executive Council and membership will strongly oppose any regulation to restrict our ability to perform these biopsies.

Next slide. And in conclusion, the SSO supports quality improvement and regulation where needed. We will not support unneeded regulation that significantly advantages one group over another while effectively excluding someone else. And I know that has come up before and that's the end of my presentation.

CHAIRMAN FERGUSON: Do you want to take questions or have him do the other half?

DR. KURTZMAN: Your call.

CHAIRMAN FERGUSON: The Committee want to ask him questions or hear the rest of the presentation?

DR. KURTZMAN: Maybe it would be--

CHAIRMAN FERGUSON: Let him go.

DR. KURTZMAN: Yes.

DR. DOWLAT: Good morning. I'm a surgeon at Rush Presbyterian or Rush University in Chicago. I have been involved with the development or introduction of

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the stereotactic biopsy from day one. I thought I could give you just an outside or a perspective of what has been happening over the past several years.

Next slide, please. In 1980s, I recall that the widespread screening mammography resulted in detection of shadows in the breast which were not always cancer. In fact, 1 out of 5 turn out to be cancer. This prompted me, next, please, to search for a better answer and needle -- stereotactic needle biopsy was developed at the Karolinska Institute in Sweden was "my attention" and I went and learned about it and then later on introduced it into the United States.

Next. Ever since I would say over the past decade, over 2000 surgeons have been trained for performance of stereotactic biopsy. The program started by the American College of Surgeons and subsequently by American Society of Breast Surgeon and a lot of other groups as well.

Please, next. The society certification and accreditation concepts established this year. Next, please. Certification for the individual surgeons,

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accreditation for the surgeons' facility, application requires submission of cases from the individual surgeons. We have had rigorous written exam. The passing score is high and that is just the latest number, 21 out of 24, four applicants passed.

Next, please. Rigorous practical exam is also in place. The numbers are a little bit higher than Dr. Lerner's only because the examiners were also examined as well.

Next, please. Currently, we are also collecting, as Dr. Lerner mentioned, data from practice surgeons, from all parts of the country in order to establish data as requested by Dr. Schultz. If we look at the complication rates of the procedure, cancer miss rate, patient satisfaction and so on, data tracking required for recertification in the future dates.

Next, please, next, please. I briefly want to talk to you about the treatment, because previous speakers have touched upon the diagnosis. I have also been involved in the development of the treatment of these small cancers using stereotactic technology.

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Next, please. Typical cancer, do you detect it by mammography as shown in that image. Please, stereotactic table, same for biopsy is it can be used for treatment.

Next, please. The one treatment that I mentioned is the laser treatment, also cryoradiofrequency can be also guided through the stereotactic technique into the tumor. This is inside to treatment without the need for surgical removal, which I think is the way of the future.

Next. Just to confirm that the lower needle shows the laser needle in the center of the tumor and the needle monitors the temperature.

Next. An example of a patient that I treated in '02. The first image on the left a month later and a year later far right showing that the tumor has been converted into necrotic as well as fluid, which can be aspirated.

Next, please. So my question to surgeons as a surgeon is that if neurosurgeons have been practicing stereotactic needle biopsy for brain surgery, why can't

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surgeons, general surgeons be regulated for breast biopsy and therapy as is our focus? Thank you for your attention.

CHAIRMAN FERGUSON: Thank you. Questions of either speaker from the Committee? Seeing none -- oh, there is a question.

DR. KURTZMAN: Can I? You asked a question before, why is it that surgeons are concerned that they might be excluded from this? And I think that we have been prohibited from doing it at some of our hospitals and there has been -- if you look at the regulation in other areas, they are written in such a way to make it quite difficult for surgeons to participate in image-guided biopsy and I don't know if it's appropriate to speak about the NAPBC here, but there certainly have been issues regarding the ability of surgeons to perform biopsies.

MEMBER MONTICCIOLO: Well, my understanding is the regulations that were the guidelines right now that are the manual that the ACR put out, these were agreed upon guidelines which include inputs from the

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surgeons. And so that's why I asked the question, those guidelines do not prevent surgeons at all from doing this procedure. So this focus that it's somehow designed to hurt surgeons is, in my mind, a false one.

I don't understand when you look at these regulations, they are for quality that would apply to everyone equally.

CHAIRMAN FERGUSON: Yes?

DR. WINCHESTER: Dr. Winchester. Having been involved with the genesis of that document bilateral college agreement with Dr. Bassett and many others back -- way back, the intent was, obviously, to not exclude any physician who had the requisite training experience documentation. ACR was responsible for accrediting the facility's equipment, radiologic technicians and physicists and so forth.

That is a bilateral agreement which has been renewed and is in effect now, I believe, until either 2008 or 2009. And that's why I asked Dr. Dershaw the question early on during this day in his presentation, he cited that agreement and my question to him was are

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we going to maintain that agreement with respect to who does what and what the qualifications are.

That has to be agreed upon by the American College of Radiology and the American College of Surgeons, but there's no guarantee that that's going to happen, but those are the politics.

CHAIRMAN FERGUSON: Dr. Barr, yes?

DR. BARR: Helen Barr, FDA. I would just like to say for the record, I don't know if some of the concern comes from the fact that Dr. Finder and I are radiologists, but I would like to say for the record that if we were to regulate this procedure, unless Congress put mandates in the statute that I had to follow, under my watch there would not be a program in place that would exclude any one group and whatever qualifications there were would apply equally and not be exclusive.

As I said though, that's, you know, up to -- if Congress could change that, but under my watch at the FDA, I would have no plans to exclude any group if we were to regulate the procedure. Thank you.

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CHAIRMAN FERGUSON: Yes?

MS. FINKEN: I just have a comment and I thought I would make it while the gentlemen were available for response. You know, I noticed that these accreditation programs, the one that Dr. Dowlat just mentioned starting in 2007 and some of the database, you know, it supports the idea that if you have the prospect of regulation, it prompts people to action.

And, you know, that's the issue. These things weren't done independent of the concern for being regulated. And I -- you know, our issue, I think, is prompting people to respond to quality issues, so I wondered if you had any comments about that?

DR. KURTZMAN: Well, I think that certainly is true, but, in fact, there is not a quality issue. In fact, the false negative rate is quite low. And the fact that people failed the test that the ACR gave them doesn't necessarily follow, in fact, the patients were harmed where diagnoses were not made. So, yes, what you are saying is people will step up when they need to be accredited or certified, but, in fact, there is not a

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problem that needs fixing.

CHAIRMAN FERGUSON: Other comments?

MS. LEEK: Mr. Ferguson?

CHAIRMAN FERGUSON: Yes, ma'am, please, come identify yourself.

MS. LEEK: My name is Angela Leek and I'm with the State of Iowa Certifying Program and Accreditation Program. Currently, in the State of Iowa, we have stereotactic biopsy rules in place. And there were just a couple of things that I wanted to comment on and just ask a few questions.

It seems what I'm hearing is all the parties are in favor of high quality standards for stereotactic breast biopsy procedures. But what I'm also hearing is that both programs currently are voluntary. And so I guess my concern is that the people that do not want to be -- they want to fly under the

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