

1 College of Radiology or American College of  
2 Surgeons standards.

3 CHAIRMAN FERGUSON: Yes?

4 MEMBER MONTICCIOLO: Dr. Kurtzman,  
5 maybe you could answer this then. You have  
6 mentioned this has come up a few times in the  
7 presentations about this accreditation for  
8 breast centers. This was hoped, I think,  
9 initially and you can correct me if I'm wrong,  
10 to be a multidisciplinary approach.  
11 Pathologists/radiologists actually, I think,  
12 were involved.

13 And the radiologists have stepped  
14 out of that program because of the concern for  
15 the standards being below those for  
16 radiologists. I believe that is what has  
17 happened. I guess representatives from the  
18 Society of Breast Imaging or ACR might want to  
19 comment. But, you know, the radiology input  
20 in that program has -- I mean, we have been  
21 kind of put out of that program because of the  
22 standards were set lower than expected. Is  
23 that your take on this or I mean, otherwise, I  
24 would like to hear comments at least from the

1 college.

2 DR. KURTZMAN: We could be here all  
3 day, but, in fact, they were not put out of  
4 this. In fact, they decided not to  
5 participate. And Dr. Winchester could  
6 probably speak to this a lot better. He is  
7 the chair of that organization.

8 MEMBER MONTICCIOLO: Dr.  
9 Monticciolo again, a Panel Member. I didn't  
10 mean they were put out. I mean they chose to  
11 not participate after years of being involved  
12 in this, because there were concerns by the  
13 radiology community that the bar was being set  
14 too low.

15 DR. KURTZMAN: Well, we could be  
16 here all day discussing that and I can't speak  
17 for them, but maybe Dr. Winchester could  
18 comment on what happened?

19 CHAIRMAN FERGUSON: Dr. Winchester?

20 DR. WINCHESTER: If I may, Dr.  
21 Winchester, yes. As chairman of the board of  
22 NAPBC, a program which we will see launched  
23 over the next couple of months, I believe, and  
24 we have been working on this for two and a

1 half years is designed to accredit breast  
2 centers in the United States. We have 375  
3 interested centers so far and the number grows  
4 each day.

5 We have set 31 standards, including  
6 breast imaging, and the radiology community we  
7 work with very closely, they had four or five  
8 issues that we tried to address. We solved  
9 four out of those five issues to their  
10 satisfaction, but there never could be  
11 agreement on the part of the radiology  
12 community that they would be in a position to  
13 accept ASBS ultrasound certification for  
14 surgeons.

15 They felt that that was below the  
16 standard of the ACR and, obviously, the ASBS  
17 looked at their process and their  
18 certification compared it to ACR and did not  
19 agree with that. So our board, which is  
20 multidisciplinary with 32 members, agreed that  
21 we should try to continue to encourage the  
22 radiology community to be engaged. They are  
23 not on the board any more, but we have not  
24 changed our standards.

1                   The MQSA, the ACR certification for  
2 breast ultrasound, the ASBS certification for  
3 stereotactic biopsy and ultrasound are in  
4 tact. What has happened, in effect, here is  
5 that a voluntary program that we tried to  
6 launch with the American College of Radiology  
7 on stereotactic core needle biopsy, as you  
8 have seen today, has failed on its voluntary  
9 basis.

10                   We are converting that voluntary  
11 basis to a mandatory basis whereby if you want  
12 to be accredited as a center, radiologists in  
13 that center or a surgeon or other physician in  
14 that center has to meet the certification  
15 requirements of their colleges or their  
16 professional societies in order to grant  
17 accreditation to the program.

18                   That is going to take some time,  
19 because we know right now, for example, that  
20 for breast ultrasound only about 5.5 percent  
21 of radiologists are ACR-certified and for  
22 surgeons it's a little bit lower. And we're  
23 not going to accept that. So we think we're  
24 in a position to raise the bar of care here

1 for individuals practicing within the  
2 accredited centers.

3 MEMBER MONTICCIOLO: It's still in  
4 a voluntary program though. There is no  
5 mandate that you have to be an accredited  
6 breast center in your program, right? Not  
7 like we're mandated for MQSA.

8 DR. WINCHESTER: That is correct,  
9 but the environment that we are practicing in,  
10 as you well know, has been a catalyst for  
11 inclusion in this program with the paper  
12 performance for reporting mechanisms, for  
13 accountability, for transparency, everything  
14 that is happening in the environment out there  
15 is speaking for getting your ticket and being  
16 accredited in order to be able to be  
17 reimbursed, if you will, for that care. It  
18 gets down to that level.

19 CHAIRMAN FERGUSON: Yes, ma'am?

20 MS. LEEK: Thank you.

21 CHAIRMAN FERGUSON: You may finish.

22 MS. LEEK: Angela Leek with the  
23 State of Iowa again. One other question/  
24 comment that I had. Local -- it was stated

1 that the -- this is a local issue and that  
2 each state could handle their own coverage of  
3 this issue. But I wanted to just address how  
4 will surgeons or how do they currently,  
5 because there are states like Iowa and a few  
6 others that have stereotactic regulations, how  
7 do they feel when they have been in one state  
8 or one locale that they do not -- they didn't  
9 have to necessarily do anything to begin doing  
10 stereotactic breast biopsy and they are then  
11 relocated to a state where they need to  
12 requalify or do a lot of initial  
13 qualifications to start doing something they  
14 have done for a long period of time?

15 CHAIRMAN FERGUSON: Yes?

16 DR. KURTZMAN: They would -- if  
17 they --

18 CHAIRMAN FERGUSON: Introduce  
19 yourself.

20 DR. KURTZMAN: I'm sorry, Scott  
21 Kurtzman. If they participated in the  
22 certification process of the ASBS or the ACR  
23 or American College of Surgeons, then they  
24 could transport that from one state to

1 another. And the local hospitals on the  
2 Credentials Committee and the chair of the  
3 departments could sign-off or not sign-off on  
4 their credentials.

5 CHAIRMAN FERGUSON: Other questions  
6 from the Committee? We're going to break for  
7 lunch, so this is your last shot before lunch.  
8 So seeing none, we will now break for lunch.  
9 We will return at 1:00. There is a buffet  
10 outside in the hospital open to everyone.  
11 Exit the room quickly. It will be secured by  
12 the FDA staff during the break. Please, take  
13 any personal belongings you wish to take with  
14 you.

15 Committee Members are advised not  
16 to discuss with other Committee Members any  
17 issues that have come up during this time.  
18 And we will reconvene at 1:00.

19 (Whereupon, the meeting was  
20 recessed at 11:47 a.m. to reconvene at 1:19  
21 p.m. this same day.)

22

23

24

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:19 p.m.

CHAIRMAN FERGUSON: Sorry for the delay. Obviously, the hotel, I read said they were going to have a buffet and, obviously, they didn't. And we had some people who weren't finished eating, so we tried to give an extra 15 minutes and we still don't have everybody, so we're short three people.

MS. WYNNE: Do we have a quorum?

1                   CHAIRMAN FERGUSON:       We have a  
2 quorum.

3                   MS. WYNNE:    Yes.

4                   CHAIRMAN FERGUSON:   Yes, we're only  
5 missing two people.

6                   MS. WYNNE:    Right.

7                   CHAIRMAN FERGUSON:   Yes.   We'll go  
8 ahead and get started with open discussion.  
9 We still have on the list provided at the  
10 beginning Dr. Russell, Dr. Willey and Mr.  
11 David Adams and I think are you all kind of  
12 together?   Are they here?   They're not here.  
13 Okay.

14                   MS. WYNNE:    Mr. Vastagh?

15                   CHAIRMAN FERGUSON:   Mr. Vastagh, do  
16 you want to go ahead?

17                   MR. VASTAGH:    Sure.

18                   CHAIRMAN FERGUSON:       Yes,   Mr.  
19 Vastagh, what you do and all that.

20                   MR. VASTAGH:       Good afternoon,  
21 Chairman,   Dr. Ferguson,   Members of the  
22 Advisory Committee,   Secretary Wynne,   FDA  
23 staff.   My name is Stephen Vastagh.   I am  
24 Industry Director of the Medical Imaging and

1 Technology Alliance, also known formally as  
2 NEMA, National Electrical Manufacturers  
3 Association, and it's mammography group.

4 The members of the mammography  
5 group are manufacturers of mammography-related  
6 products, both equipment, such as systems and  
7 printers, workstations, as well as software,  
8 such as CAD systems. The chair of the group  
9 is Dr. John Sandrik and he is also in the  
10 room, so if you have technical questions, I'll  
11 ask John to help me answer them.

12 I am an employee of the Medical  
13 Imaging and Technology Alliance, which is a  
14 manufacturers trade association.

15 MITA is the collective voice of  
16 medical imaging equipment manufacturers,  
17 innovators and product developers. It  
18 represents companies whose sales comprise more  
19 than 90 percent of the global market for  
20 medical imaging technology, which includes x-  
21 ray, CT scanners, ultrasound, nuclear imaging  
22 and magnetic resonance imaging.

23 The two fundamental questions  
24 raised at this meeting are:

1                   Should       the       FDA       regulate  
2       stereotactic biopsy?

3                   And       should       the       FDA       regulate  
4       interventional       procedures,       other       than  
5       stereotactic biopsy?

6                   MITA's       recommendations,       MITA's  
7       comments include one general comment and a few  
8       specific comments primarily related to the  
9       equipment       under       consideration.       For       the  
10       general       comment,       we       note       that,       to       our  
11       knowledge, no problem has been systematically  
12       demonstrated       or       quantified       requiring  
13       regulation       of       either       intervention       of  
14       procedures in general or stereotactic biopsy  
15       in particular.

16                   As       a       result,       the       possible  
17       beneficial       impact       of       a       new       regulation       can  
18       neither be evaluated nor can the costs of the  
19       regulation be easily estimated.       MITA would  
20       like information on whether there are errors  
21       in       interventional       procedures       as       currently  
22       performed in unregulated environment before  
23       determining whether regulation is necessary.

24                   Similarly,       we       believe       it       is

1 necessary to systematically, rather than  
2 anecdotally, quantify how many procedures are  
3 performed, what percentage of these procedures  
4 are deficient. In other words, define the  
5 clinical need for the regulation.

6 MITA contends that FDA is the  
7 agency best suited as a neutral party to make  
8 such systematic evaluation in support of  
9 continued discussion of the proposed new  
10 regulation. Further, MITA respectfully  
11 suggests that FDA may have the duty to define  
12 and quantify the problem and estimate the cost  
13 and benefits of possible regulation.

14 Now, turning to early equipment.  
15 MITA's primary focus is on the equipment used  
16 for these procedures and MITA doesn't intend  
17 to comment on details of regulation that  
18 relate to training or qualifications of the  
19 personnel or the staffing requirements of  
20 mammography centers.

21 Currently, MQSA standards require  
22 detailed equipment testing, some of which is  
23 proving to be excessive and without benefit,  
24 as technology has improved over the years.

1     However, once part of regulation, such tests,  
2     despite the fact that they may be obsolete,  
3     because of changing nature of technology,  
4     cannot be eliminated, because they are  
5     requirements under MQSA.

6             Due to these experiences under  
7     MQSA, my organization urges the Committee and  
8     FDA to proceed with caution as it considers  
9     new technologies to be added by regulation.

10            Regulation that is excessively  
11     prescriptive for equipment generally has the  
12     effect of suppressing technological  
13     innovation, because it de facto sets  
14     boundaries for equipment operation and  
15     performance. For example, regulations that  
16     seem appropriate for two dimensional images  
17     acquired and viewed on film may unnecessarily  
18     restrict the evolution to images acquired  
19     using digital detectors and viewed in three  
20     dimensions using soft-copy workstations.

21            Should there be additional  
22     regulation, we, the manufacturers, wish to be  
23     involved in the development of the equipment-  
24     related aspects of the regulation. We will

1 support an approach to equipment testing that  
2 is performance related and it is based on  
3 clinical needs for testing, rather than the  
4 regulation being prescriptive in details,  
5 because, as mentioned, such prescriptive  
6 regulation discourages and actually can limit  
7 equipment innovation.

8           Equipment standards that are based  
9 on meeting defined clinical needs do not  
10 become obsolete and that's what we are arguing  
11 for. They don't become obsolete even though  
12 technology may evolve. Rather, they actually  
13 motivate innovation to find new ways to meet  
14 those needs.

15           So to sum it up, the clinical need  
16 that is demonstrated for new regulation and if  
17 there is new regulation, equipment-related  
18 regulation, again should be linked to clinical  
19 needs in terms of testing. Thank you very  
20 much for the opportunity to present our views.

21           CHAIRMAN FERGUSON: Thank you.  
22 Questions from the Committee? Thank you very  
23 much. Dr. Russell Willey and Mr. Adams, are  
24 they here and coordinated and ready to go?

1 DR. WILLEY: We are here,  
2 coordinated and ready to go. Chairman  
3 Ferguson and distinguished Members of the  
4 Committee, I'm Dr. Shawna Willey. I'm the  
5 Director of the Betty Lou Ourisman Breast  
6 Health Center at Georgetown University here in  
7 Washington, D.C.

8 Thank you for allowing me to  
9 present the opinions and the viewpoint of the  
10 American College of Surgeons who represents  
11 73,000 Fellows. We would like to talk about  
12 the possible modification of the regulations  
13 implementing the Mammography Quality Standards  
14 Act to go beyond mammography and to possibly  
15 assert jurisdiction over invasive procedures.

16 We believe that such changes in the  
17 regulation could be detrimental to the  
18 interest of our patients, who are in the need  
19 of breast biopsy, and ultimately could hurt  
20 patient access and possibly patient care.  
21 Specifically, federal regulation of  
22 interventional medical procedures is  
23 unprecedented.

24 The college was founded in 1913 and

1 its mission was to improve the quality of care  
2 for the surgical patient by setting high  
3 standards for surgical education and practice.  
4 And we strongly support efforts to improve  
5 access to high quality and cost efficient  
6 care. However, we believe that the proposed  
7 regulation falls short of meeting some of  
8 those important goals.

9 First, we think it's important to  
10 note that Congress did not ask the FDA to  
11 regulate invasive procedures. In 1992 when  
12 the MQSA was passed, it was really passed to  
13 provide a general framework for ensuring  
14 national quality standards in facilities  
15 performing screening and diagnostic  
16 mammography. The statute refers specifically  
17 to facilities that were involved in screening  
18 and diagnosis.

19 And I kind of want to go through  
20 those definitions just a little bit for  
21 review, even though probably everyone knows  
22 those. But a screening exam is an exam that's  
23 applied to an asymptomatic patient who is at  
24 average risk of developing a disease. And

1 that's certainly the majority of the breast  
2 cancer or breast care patients that we see.

3           When we talk about a diagnostic  
4 imaging, we talk about a mammogram that is  
5 used to determine the nature and cause of  
6 disease or injury and to actually diagnose  
7 that disease.

8           Stereotactic biopsy actually talks  
9 about localization of the process. And we are  
10 using stereotactic biopsy to localize the  
11 problem, so it's not really the mammogram  
12 itself that we are talking about when we talk  
13 about stereotactic biopsy, but we are talking  
14 about a localization process and then a biopsy  
15 to evaluate or to get histology of that area.

16           So we have heard a lot today about  
17 interventional mammography and it's really the  
18 intervention that seems to be under  
19 discussion, not so much the mammography. This  
20 is a procedure and it's a procedure that  
21 surgeons perform. It's a procedure that  
22 radiologists perform, but it's a procedure not  
23 the actual mammogram that's used for screening  
24 and diagnosis.

1                   You have heard many people talk  
2 today about whether or not there is a problem  
3 that has been identified and whether or not  
4 regulating the procedure would solve that  
5 problem, so I won't go into that in any great  
6 detail, except in preparation for this  
7 presentation, we reviewed over 600 articles  
8 about stereotactic breast biopsies that have  
9 been published in the last 10 years.

10                   And when we reviewed those  
11 articles, we really could find no mammography-  
12 related quality issues. In fact, the  
13 conclusion of almost every article is that  
14 stereotactic biopsy is a safe and effective  
15 procedure. And I think that has been  
16 overwhelmingly heard here today that  
17 stereotactic biopsy is valuable. We want it  
18 to be available to all of our patients. We  
19 think it's preferable often times to open  
20 surgical biopsy.

21                   When problems were identified in  
22 those studies, however, often times it was  
23 related more to patient selection, patient  
24 position on the table, selection of biopsy

1 devices, the size of the device, so those are  
2 all characteristics of this procedure that,  
3 from what I have heard today, would not really  
4 fall under this regulation. And yet, those  
5 are the problems that were outlined in the  
6 literature as factors that can impact the end  
7 results after a stereotactic biopsy.

8 One of my biggest concerns is we  
9 heard today that there is 107 members of the  
10 Society of Breast Imaging. We heard that 25  
11 percent of stereotactic breast biopsies are  
12 done by surgeons. I'm worried that if there  
13 is regulation, that we will effectively lower  
14 the number of people who are offering this  
15 modality to patients. And if we lower the  
16 number of providers, then that's going to  
17 become an access problem.

18 We already have problems getting  
19 patients in and diagnosed as quickly as they  
20 want to be. And I work with breast cancer  
21 patients all day long and I can tell you that  
22 they are a highly anxious group of patients  
23 and they don't want to wait for their  
24 biopsies. And there are times that I can

1 envision a woman would choose to have an open  
2 surgical biopsy, rather than wait to have a  
3 stereotactic biopsy or rather than wait to  
4 drive 100 miles to get a stereotactic biopsy.

5           So in closing, the American College  
6 of Surgeons certainly strongly supports the  
7 MQSA and believes that it has improved the  
8 quality of screening and diagnostic  
9 mammograms. However, we do not feel that  
10 federal regulation of stereotactic breast  
11 biopsies will necessarily improve patient  
12 care.

13           We urge the FDA to maintain the  
14 current definition of mammography in its  
15 regulations. I thank you for the time you  
16 have given me and I would like to introduce  
17 the next speaker, who is the Executive  
18 Director of the American College of Surgeons,  
19 Tom Russell.

20           CHAIRMAN FERGUSON: Would you take  
21 a question or two first or do you want to --

22           DR. WILLEY: I can certainly take  
23 questions. We were thinking we would take  
24 them at the end.

1                   CHAIRMAN FERGUSON:       She would  
2 rather hit you now.

3                   MEMBER MONTICCIOLO: I'm on. Well,  
4 I mean, since you are you up there. It's  
5 Debbie Monticciolo, Panel Member. Why do you  
6 think that regulating would lower the number  
7 of providers? I mean, shouldn't good  
8 providers be able to meet the standards?

9                   DR. WILLEY: They should be, but I  
10 think that any regulation is there is just a  
11 certain number of people who may say, you  
12 know, I'm not going to do that. I'm going to  
13 retire instead of practice three more years or  
14 five more years. They may already be meeting  
15 the standards, but they're not going to go  
16 through the process of applying for the  
17 regulation.

18                   And, you know, there may be single  
19 solo practitioners who decide that it's really  
20 not cost-effective for them to go through the  
21 regulatory process and then will just not  
22 offer that.

23                   CHAIRMAN FERGUSON: Are there other  
24 questions? Dr. Russell?

1 DR. RUSSELL: Thank you. Good  
2 afternoon, Mr. Chairman and distinguished  
3 Panel Members. My name is Tom Russell and I'm  
4 the Executive Director of the American College  
5 of Surgeons. So on behalf of our 73,000  
6 Fellows, I'm pleased to appear here today to  
7 present our comments and concerns regarding  
8 the FDA's proposed regulation of stereotactic  
9 breast biopsies.

10 From the very beginning, the  
11 college has always supported access to safe,  
12 high quality care. However, we believe the  
13 unintended consequences of regulating  
14 stereotactic breast biopsies through the MQSA,  
15 which we, obviously, support, would reduce  
16 access to care for exactly the reasons that  
17 Dr. Willey just mentioned.

18 When the MQSA was passed in 1992,  
19 there was a recognized and documented problem  
20 with the quality of screening and diagnostic  
21 mammography. This is not the case as you have  
22 heard repeatedly today of stereotactic breast  
23 biopsy. Recent studies indicate that this  
24 type of biopsy is as effective as open biopsy

1 and has a negative predictive value of 99.95  
2 percent.

3 Perhaps more importantly, the  
4 factors that determine success and quality  
5 include proper patient selection, proper  
6 lesion selection, implementation of standard  
7 surgical practices, proper handling of the  
8 histological specimen and ideal tissue  
9 sampling. The MQSA does not address any of  
10 these issues.

11 We further do not believe that  
12 federal regulation is the proper pathway to  
13 improve the efficacy or outcome of any  
14 surgical procedure, including stereotactic  
15 breast biopsy. This is an incredibly  
16 important point. There are many procedures  
17 that we do today that have nothing to do with  
18 the breast that involve imaging of one kind or  
19 another. Likewise, there are many other  
20 procedures that don't involve imaging at all.

21 But in no case does the Federal  
22 Government regulate who can do or who cannot  
23 do a surgical procedure. Only in the coverage  
24 process where payment decisions are made have

1 we seen anything like this. Is the FDA really  
2 comfortable starting down this road?

3           Furthermore, the notion of placing  
4 restrictions through regulation on the type of  
5 physician who can provide services and  
6 procedures that involve imaging flies in the  
7 face of the future of medicine and surgery, in  
8 which we believe physicians and surgeons will  
9 be working collaboratively and organized  
10 around cycles of care and disease management.  
11 And competency will depend on the ability to  
12 perform imaging procedures, not from what  
13 specialty you happen to come from.

14           Without access to this technology,  
15 it simply will not be possible to manipulate  
16 the tissues in the manner that will be common  
17 place in the future. Technology is driving  
18 all of us together and we can no longer take  
19 the position that only one specialty is  
20 competent or qualified to utilize a certain  
21 imaging technique.

22           Finally, image-guided surgery is an  
23 ever-changing field. While once stereotactic  
24 imaging was limited to one or two methods of

1 biopsies, today's surgeons across the country  
2 are using stereotactic imaging for laser  
3 ablation, placement of needle localization  
4 wires and placement of brachytherapy catheters  
5 for treatment of breast cancer after surgery.

6 We strongly believe these examples  
7 only hint at what the future will bring. And  
8 we believe greater use of image guidance will  
9 lead to better outcomes, less invasive  
10 procedures and higher patient satisfaction.  
11 We are concerned that regulation of  
12 stereotactic breast biopsy under the MQSA will  
13 have a chilling effect on these advances,  
14 which are almost always discovered by  
15 inquisitive surgeons who are in search of new  
16 methods to improve old techniques.

17 Further, we note that x-rays are  
18 only a small aspect of the field of image-  
19 guided surgery, which includes ultrasound,  
20 MRIs and other imaging techniques. Limiting  
21 use of one type of imaging modality through  
22 regulation is not only illogical, but  
23 threatens to hamper advancements in other  
24 areas of image-guided surgery.

1                   In closing, the American College of  
2 Surgeons is deeply committed to providing the  
3 best possible care to patients in need of  
4 breast biopsy. Our goal is to provide the  
5 most accurate and appropriate type of biopsy  
6 required in the most expeditious manner  
7 possible.

8                   Not only do we believe regulating  
9 stereotactic breast biopsies will not help  
10 achieve this goal, we maintain that it will  
11 hurt patient access and patient care. Federal  
12 regulation of interventional medical  
13 procedures is unwarranted and inappropriate  
14 under the MQSA in the absence of a finding  
15 that there is a clinically significant  
16 mammography-related problem and an MQSA  
17 standard that can address the problem.

18                   No such problem or associated  
19 standards have been presented to the Agency.  
20 This federal intervention would moreover be  
21 detrimental to the interest of our patients.  
22 It would reduce the number of available  
23 providers and in many communities lead to  
24 delays in diagnosis or increased reliance on

1 more invasive open biopsies or less clinically  
2 affected ultrasound procedures for certain  
3 types of lesions.

4           As a representative of the  
5 physicians who primarily treat breast disease  
6 in this country, the college strongly supports  
7 the MQSA and believes it has improved the  
8 quality of screening and diagnostic  
9 mammograms. We will continue to support all  
10 efforts to improve the quality of care for the  
11 surgical patient by setting high standards for  
12 surgical education and practice as well as  
13 support efforts to improve access to high  
14 quality and cost efficient care.

15           And we will continue to support and  
16 develop programs to improve the quality of  
17 care surgeons provide to patients with breast  
18 disease. However, we believe the attempted  
19 regulation at hand falls far short of  
20 achieving these goals.

21           Thank you again, Mr. Chairman, for  
22 this opportunity to offer the American College  
23 of Surgeons' comments and views. Dr. Willey  
24 and myself would be pleased to answer any

1 questions that might be forthcoming. Thank  
2 you.

3 CHAIRMAN FERGUSON: Thank you.  
4 Questions of the Committee for either? Seeing  
5 none, thank you very much.

6 DR. RUSSELL: Yes..

7 CHAIRMAN FERGUSON: David Adams is  
8 a part.

9 MR. ADAMS: Hello, my name is David  
10 Adams. I'm here speaking on behalf of the  
11 American Society for Breast Surgeons. I am a  
12 paid consultant. My background is as an  
13 attorney and as a former policy official with  
14 the Food and Drug Administration. And I'm  
15 really here to sort of give you my assessment  
16 of putting all this information together and  
17 making what amounts to a policy decision.

18 And the policy decision here today  
19 is whether FDA is going to embark on a new  
20 type of regulatory initiative, a rather  
21 significant one, going beyond what we have  
22 traditionally regulated under MQSA, which is  
23 traditional practice of mammography.

24 This is a regulatory initiative

1 that would extend the Federal Government's  
2 reach into medical procedures, surgical  
3 procedures, based on the notion or the fact  
4 that within those procedures there is some  
5 breast imaging that helps in localization.  
6 And in deciding whether to have a rather  
7 significant federal regulatory initiative, I  
8 think there are several things we need to  
9 think about.

10 And Dr. Finder phrased, I think,  
11 the question correctly, the best way it could  
12 be phrased, and it's really two questions.  
13 Not just should we regulate stereotactic  
14 biopsy or invasive procedures, but why? And  
15 in looking at that question, I think just  
16 quickly one of the things to consider at the  
17 outset isn't what the law says and there is  
18 some debate over ambiguity in the statute as  
19 to whether FDA has authority to regulate  
20 invasive procedures as opposed to traditional  
21 mammography and that's not really a question  
22 for you.

23 But I think it's worth considering  
24 that this is not something Congress looked at

1 or talked about when that legislation was  
2 passed. I just don't see it. There was a  
3 major national problem that Congress addressed  
4 related to screening and diagnostic  
5 mammography. There were hearings. There is a  
6 long record on that and the problem has been  
7 addressed, you know, with some fair degree of  
8 success.

9 We don't see Congress having  
10 mentioned or talked about this issue at all.  
11 And with that as a starting point, you know,  
12 the first question has to be that we would  
13 have always asked, back when I was at FDA in  
14 the Office of Policy, well, what is the public  
15 health concern that warrants a new significant  
16 regulatory initiative?

17 And I mean, you always want to be  
18 starting out having some identified public  
19 health concern, because regulatory initiatives  
20 always come at a price and there is FDA's  
21 scarce resources for one thing, but regulation  
22 itself, I mean, if it's going to have an  
23 impact, and you shouldn't be doing it unless  
24 it's going to have an impact, there's going to

1 be a cost.

2 I mean, if you really are going to  
3 be changing people's behavior and making  
4 things happen differently or changing practice  
5 or criteria, there is going to be a cost. And  
6 the third thing to think about in saying well,  
7 we need to start out figuring out what the  
8 public health issue is that if you're going to  
9 regulate, you've got to come up with the right  
10 standards and how can you come up with the  
11 right standards if you haven't figured out  
12 what the problem is that you are trying to  
13 address with those standards?

14 So we need to be asking at the  
15 outset what's the problem we're addressing?  
16 And more specifically, what's the mammography-  
17 related problem we're addressing? There have  
18 been people proposing regulation suggesting  
19 that there is a problem and that well, we have  
20 to ask what's the evidence of that? How do we  
21 know there is a problem?

22 Well, one of the great things about  
23 FDA, I think, that I always admired is that  
24 the Agency is a very data-driven agency and

1 it's different from other federal agencies.  
2 Most of these other agencies are run by  
3 lawyers and economist people like me. And FDA  
4 isn't. It's run by scientists and health care  
5 professionals and its decisions are data-  
6 driven and for a good reason.

7 I mean, you need to know what you  
8 know. You need to know what you know. It's  
9 basic to the scientific method. And that's  
10 the way we need to go at or you need to go at  
11 answering Dr. Finder's questions.

12 And in terms of the why, what's the  
13 problem? This is the second meeting of this  
14 Advisory Committee where this has been the  
15 subject to discussion and I haven't seen the  
16 evidence of the problem in either of these two  
17 meetings. Certainly, no evidence of a  
18 specific mammography-related problem that  
19 we're dealing with here.

20 We have seen the evidence,  
21 information, data on ACR failure rates, 30  
22 percent that may be related to imaging, but  
23 that isn't evidence of a problem. I mean,  
24 that's -- one can define any standard and have

1 any sort of failure rate. The question is  
2 what does that mean clinically if the failure  
3 rate starts out at 30 percent and then goes to  
4 a lower rate after some education, does that  
5 mean that there is a clinical outcome that's  
6 changed or does it just mean people have  
7 studied hard to meet the specific criteria for  
8 accreditation? We don't know.

9 I mean, if we look at things like  
10 the false negative rate and look at  
11 discordance, we see a really, really low rate  
12 out of the published literature. It doesn't  
13 seem to have any bearing to the notion of 30  
14 percent of the people coming in to apply  
15 failing and failing to meet these particular  
16 standards.

17 We have heard a few anecdotal cases  
18 cited of failure to make the diagnosis. In  
19 one case a surgeon's failure to make a  
20 diagnosis and it was a very sincere and  
21 passionate presentation with the punch line  
22 being it was obvious that the surgeon didn't  
23 have the appropriate training and experience  
24 and accreditation, that was why that happened.

1                   Well, we really don't know that's  
2 why it happened at all. We know there is  
3 always going to be, you know, a failure rate.  
4 Diagnoses are going to be missed. You have  
5 the best top experts in the country here in  
6 terms of doing stereotactic biopsy. They will  
7 all tell you people have misses. The best  
8 people have misses. It doesn't mean that  
9 there was a mammography problem or, you know,  
10 any particular problem you might even be able  
11 to identify.

12                   There are going to be misses. And  
13 a few anecdotal cases of misses doesn't tell  
14 us anything. I mean, that's just not evidence  
15 upon which we can or you can make a decision  
16 and go forward. Variable standards that you  
17 see, different standards in the community,  
18 that's not a problem, that's not, you know, a  
19 bad clinical outcome. One might argue that  
20 well, if we could find a problem, maybe that's  
21 the reason for the problem, but that in and of  
22 itself isn't a problem.

23                   So we -- I mean, we just haven't  
24 seen this. And there has been a course of

1 discussion of discordance rates as something  
2 to look at. And I mean, if you want to look  
3 at it and look at what you're seeing in the  
4 published literature, it's extraordinarily  
5 low. And it is getting lower.

6 In our written submission, we  
7 looked at the literature and looked at a  
8 number of published studies and we provided  
9 those to you, which you can have a look at. I  
10 mean, we see, you know, the more current  
11 discordance rates getting down to, you know,  
12 0.8 to 1.7 percent. And this really isn't --  
13 doesn't seem to be a function of improving  
14 mammography. I mean, it seems to be a  
15 function of the biopsy method itself when  
16 you're using larger needles and vacuum  
17 assisted biopsy.

18 And if you look -- and this is also  
19 in the materials we provided in our statement.  
20 If you look at what the literature shows as to  
21 why there is this discordance, I mean, there  
22 are a number of reasons. One of the main one  
23 is being biopsy method, the number of lesions.  
24 Sometimes there is mistargeting, but what's

1 the mistargeting the result of? Sometimes  
2 it's patient movement. Sometimes it's tissue  
3 movement, what they call the snowplow effect.

4 The -- what is the mammography  
5 standard that's going to address those issues,  
6 even if you think those are clinically  
7 significant issues? And I mean, of this  
8 little tiny percentage, I mean, what part of  
9 that do we even assume could be related to  
10 mammography? We really don't know. And we  
11 don't know what the standard is that would  
12 make -- that would give us a significantly  
13 different clinical outcome.

14 When Dr. Barr was asking earlier  
15 presenters well, what, I mean, is our measure  
16 of success? One has to assume the measure of  
17 success is not just coming up with uniform  
18 federal standards. The measure of success is  
19 having different clinical outcomes.  
20 Otherwise, you are just regulating for the  
21 sake of regulating and that doesn't make a  
22 whole lot of sense and I don't think that's  
23 what FDA is suggesting that they want to do or  
24 this Advisory Committee would want to do.

1                   Of course, Dr. Finder and FDA, they  
2                   speak for themselves, obviously. I mean, the  
3                   thing that -- the reason surgeons are here  
4                   isn't really to argue over we don't like  
5                   regulation or you are regulating for the sake  
6                   of regulating. There is a real concern.  
7                   Stereotactic biopsy is a good thing. We want  
8                   surgeons to do it. We want more surgeons to  
9                   do it. We want surgeons to be doing this sort  
10                  of procedure, rather than surgical biopsy  
11                  where that can be done.

12                  But we also know that surgeons are  
13                  having a hard time doing these procedures.  
14                  They are having a hard time gaining access.  
15                  And this isn't an issue that we are asking you  
16                  to address. I mean, you know, they are issues  
17                  between -- out in the professional community,  
18                  but it's just a fact of life that surgeons are  
19                  dealing with.

20                  And we know -- I think it's hard to  
21                  reasonably, even without evidence, assume that  
22                  if you impose federal regulations, a federal  
23                  regulatory regime on invasive procedures, it's  
24                  not going to get easier. I mean, the surgeons

1 are having a hard time gaining access as it is  
2 and this isn't going to make it easier. It's  
3 almost certain to make it more difficult.

4           And what -- I mean, you know, we're  
5 going to end up -- we know deep down at the  
6 bottom of our hearts that we're going to see  
7 situations where women have gotten frightening  
8 mammograms and, you know, should have gotten -  
9 - it would have been better for them to have a  
10 stereotactic biopsy, but some women are going  
11 to be getting surgical biopsies when we would  
12 really like to see them get stereotactic  
13 biopsies.

14           This seems almost inevitable and  
15 the question is why? I mean, if we're looking  
16 at this record, you know, we just don't see  
17 the evidence in the record that tells us there  
18 is a problem or what it is or how a  
19 mammography standard is going to deal with it.

20           Surgeons have come here today in  
21 good faith really. They are quite sincere  
22 about their concerns about the patients, about  
23 their patients and about making this procedure  
24 available for their patients. And they are

1 quite sincere in offering to work with you and  
2 develop data on what the heck is going on out  
3 in the community.

4 I mean, not just looking at  
5 reported rates in the literature, but what's  
6 really happening. Everybody should be looking  
7 at this. This is important. We don't want  
8 to, you know, ignore a potential problem if  
9 there is some problem out there. And so what  
10 we really ask at the end is that you accept  
11 and appreciate our sincere concerns and our  
12 desire to work with you to help figure these  
13 things out.

14 CHAIRMAN FERGUSON: Thank you.  
15 Questions of the Committee? Yes?

16 MEMBER RINELLA: Diane Rinella,  
17 mammography consultant on the Committee. Is  
18 it possible that if the regulation were passed  
19 and the surgeons did meet the requirements for  
20 the regulation that it would increase their  
21 access to stereotactic breast biopsy?

22 MR. ADAMS: That's a good question.  
23 I mean, the -- one might, you know,  
24 hypothesize that this might be a way of maybe

1 pushing the door open wider or, you know, for  
2 surgeons, you know, make it more difficult for  
3 people to deny a surgeon's access. I mean, I  
4 can't say. I mean, that would be a good  
5 objective. I can't say that wouldn't happen,  
6 but I'm just not certain that we would see  
7 that, but we would like to see it.

8 CHAIRMAN FERGUSON: Others? Yes,  
9 thank you, Mr. Walters. Dr. Israel?

10 DR. ISRAEL: Thank you, Mr.  
11 Chairman and Committee Members. My name is  
12 Philip Israel. I am a surgeon and I am a  
13 Member of this Committee, but because of some  
14 relationships with industry with biopsy  
15 devices that are used on stereotactic tables,  
16 we thought it would probably be better if I  
17 did not vote on this issue today.

18 But I would like to just make a few  
19 comments. And I know the day is growing long  
20 and the Committee Members are getting weary.  
21 I may want to paint the picture that we are  
22 presenting to you with a different brush than  
23 has been painted to this point. I've been  
24 involved with stereotactic work for a long

1 time, since 1989.

2 And I'm in Atlanta, Georgia. I  
3 have a breast center. We have done in the  
4 neighborhood of 20,000 stereotactic breast  
5 biopsies. Our patients are very happy in the  
6 City of Atlanta and I have good knowledge of  
7 what is happening at all of the hospitals, who  
8 is doing the biopsies, who is causing a  
9 problem and are the patients happy?

10 And the radiologists and the  
11 surgeons in Atlanta, Georgia on a community  
12 level are working very well together. One  
13 group is not accusing another group of  
14 dragging down the standards. Everybody does  
15 the best they can. We help one another. And  
16 it is working quite well.

17 Now, I've been involved in teaching  
18 this technology to radiologists and to  
19 surgeons. I have had the good foresight of  
20 being able to, over the last 15 years since  
21 1991, sit back and see it develop across the  
22 country. I have traveled a lot and I've  
23 talked to a lot of people and to patients.  
24 And I think that patients are very satisfied

1 with what's being done now.

2                   And instead of criticizing the  
3 radiology community or the surgical community  
4 and focusing on the poor quality, what I would  
5 do is congratulate the surgical community and  
6 the radiology community for they have taken  
7 the technology, they have introduced it  
8 clinically in a very nice way and a very  
9 responsible way and it has benefitted  
10 thousands and thousands of patients. And this  
11 wasn't easy.

12                   That took a lot of effort by the  
13 leadership in both the surgical and the  
14 radiology community. I dubbed stereotactic  
15 breast biopsy as a homeless technology when it  
16 first came out and I first learned about it  
17 and tried to integrate it in clinical  
18 practice. And I felt like it was homeless  
19 because it really didn't fit into any  
20 category.

21                   For example, it didn't fit into  
22 radiology very well, because up until that  
23 time, not a single radiologist in this country  
24 had done -- had made an incision in a breast

1 to do a breast biopsy. So that was an issue  
2 and they -- radiology did not embrace this  
3 technology very rapidly. It has taken years  
4 and years and years of training and  
5 encouragement.

6 On the other hand, it was a  
7 homeless technology in the surgical community,  
8 because surgeons didn't have the imaging skill  
9 that needed to be paired with this. But this  
10 is a new day in this country, I think, in  
11 terms of specialization for radiologists and  
12 surgeons. There are surgeons now -- I have  
13 done breast only for 20 years. And there are  
14 many other surgeons who are specializing or  
15 promoting breast in their practice. These  
16 surgeons can do stereotactic breast biopsy  
17 very well.

18 In the radiology community, there  
19 are those that take fellowships, they focus  
20 and they do it very well. There are  
21 individuals in the radiology community and in  
22 the surgical community who could stand some  
23 improvement and I think we will see this  
24 improvement as time goes on.

1                   And I will say that as a last  
2     comment, I really don't see regulation as the  
3     answer to the problem. I think improved  
4     outcomes are the result of education, teaching  
5     and physician specialization. If a  
6     radiologist focuses on breast work, if a  
7     surgeon focuses on breast work, that's where  
8     you see your very best result and that's where  
9     you raise the standard.

10                   And I'm sorry, I don't see it  
11    through regulation. We all believe in  
12    elevating the standard of care. Our patient  
13    is of primary interest. And I think we can  
14    all work towards that goal without any kind of  
15    controlled mechanisms that we're talking about  
16    here today. Thank you.

17                   CHAIRMAN FERGUSON: Thank you, Dr.  
18    Israel.

19                   DR. ISRAEL: Any questions?

20                   CHAIRMAN FERGUSON: Questions?  
21    Thank you.

22                   DR. ISRAEL: Thank you.

23                   CHAIRMAN FERGUSON: She wants to  
24    make a comment.

1                   MEMBER MONTICCIOLO:     Oh, yes, I  
2     didn't have a question for you, so but I just  
3     wanted to -- this is Debbie Monticciolo, a  
4     Panel Member. I just wanted to say that was a  
5     beautiful presentation. I think it was a very  
6     accurate depiction, at least in Atlanta. I  
7     have been in Atlanta. I was actually invited  
8     by Dr. Israel to the site and that's one of  
9     the reasons I was surprised to think -- I  
10    wouldn't want to think, as a radiologist, that  
11    this regulation would have the intention of  
12    excluding anyone.

13                   It was a joy to work with you. I  
14    have also had the pleasure of working with Dr.  
15    Dowlat and so I think it's very well-said.  
16    It's, you know, what we would like to see. I  
17    would like to see people who are interested in  
18    doing this working together to make it as good  
19    as possible.

20                   CHAIRMAN FERGUSON:    Yes?

21                   MEMBER TIMINS:     I also want to say  
22    that I don't view this as an issue of  
23    specialty, but an issue of quality and how to  
24    assure quality. And it shouldn't be one

1 specialty versus another. So I agree that Dr.  
2 Israel was very well-spoken.

3 CHAIRMAN FERGUSON: Thank you.  
4 Okay. The stated accrediting bodies, the  
5 beautiful ladies I had lunch with said they  
6 would like to address, since I don't have  
7 anyone else listed. So they can come forward.

8 MS. DAVIDSON: Dr. Ferguson has to  
9 recognize me, because I inspect his facility  
10 for mammography. My name is Sherry Davidson  
11 and I am from the State of Arkansas and any  
12 financial interest I have is just to the State  
13 Health Department. I am an MQSA Inspector.  
14 I'm also part of the State of Arkansas  
15 Accreditation Body.

16 And what I wanted to do was  
17 probably state the obvious, but maybe for  
18 those who are not involved in the day-to-day  
19 implementation of the Mammography Quality  
20 Standards Act, it may not be obvious. So my  
21 observation is that the Act, MQSA, does not  
22 mandate that mammography facilities be  
23 accredited by the ACR.

24 It mandates that mammography

1 facilities be accredited by an FDA-approved  
2 accrediting body. So there are three states  
3 who still have accreditation programs and  
4 we're very proud of those and we do meet the  
5 same standards.

6 But my question that goes along  
7 with that is probably for Dr. Barr or Dr.  
8 Finder is does it follow then that if this is  
9 adopted into whatever the next genesis of MQSA  
10 becomes for interventional, would it follow  
11 then that any professional society or state  
12 who would be willing to write procedures that  
13 would be acceptable to the FDA could also  
14 accredit stereotactic? That's my question.

15 DR. FINDER: This is Dr. Finder.  
16 In terms of accreditation bodies, I wouldn't  
17 envision any change in the overall approach to  
18 accreditation, so that we could allow national  
19 organizations, we could allow states just as  
20 we do for the MQSA Program as it currently  
21 exists.

22 CHAIRMAN FERGUSON: And that would  
23 by itself allow the American College of  
24 Surgeons, the American College of Radiology,

1 the states, anybody to participate in that?  
2 Is that correct?

3 DR. FINDER: Under the current  
4 standard under MQSA, I believe that the only  
5 requirement is that they be a nonprofit, so,  
6 yes, we could have American College of  
7 Surgeons, any organization that would meet the  
8 requirements as established in our regulations  
9 could become an accreditation body under that  
10 scenario.

11 CHAIRMAN FERGUSON: Thank you.

12 MS. TERRY: My turn?

13 CHAIRMAN FERGUSON: Yes.

14 MS. TERRY: I'm Kay Goss Terry.  
15 I'm with the State of Texas Mammography  
16 Accreditation Program. And I have no  
17 financial reimbursement. I paid my way here.  
18 We, as the State of Texas, currently have  
19 regulations in place where we regulate breast  
20 biopsy and needle localization units. We have  
21 requirements that facilities have to apply to  
22 the state.

23 They submit credentials. Their  
24 physicists report, they have to have an annual

1 physicist report. We do dose. We do phantom  
2 images. And they have to have current  
3 licensure in order to operate that breast  
4 biopsy unit.

5 And as a State Radiation Program,  
6 we have been mandated by our state legislature  
7 to ensure that these facilities meet our  
8 current regulations. We inspect them every  
9 three years. Part of what I have been hearing  
10 this morning is everybody wants us to accredit  
11 or to regulate breast biopsy units. And our  
12 problem would be once you go beyond the  
13 imaging part and you place that needle to the  
14 procedure, it becomes a practice of medicine.

15 And we, as a radiation program, are  
16 no longer allowed to regulate a practice of  
17 medicine. We have a whole separate board in  
18 our state that does that. It's the Board of  
19 Medical Examiners. So we would not be able to  
20 help with that. So I have two questions.

21 One, does the FDA have the same  
22 kind of mandate? And two, how many other  
23 states have already preexisting breast biopsy  
24 regulations in place? Thank you. Any

1 questions?

2 CHAIRMAN FERGUSON: Thank you.  
3 Comments, questions? Dr. Barr?

4 DR. BARR: Helen Barr, FDA. Kay,  
5 I'm sorry, I don't understand your question,  
6 does FDA have a mandate to --

7 MS. TERRY: I'm sorry. Kay Terry.  
8 Medical practice, once the procedure becomes  
9 part of a practice of medicine, are you  
10 allowed to regulate or go in and do that? And  
11 one of the other speakers was just talking  
12 about that also.

13 DR. BARR: Helen Barr, FDA. Some  
14 would say MQSA went into that realm. There is  
15 no specific mandate or policy at FDA.  
16 Traditionally, it has not stepped into the  
17 regulation of practice of medicine, but some  
18 would say MQSA stepped in that area, but we  
19 have nothing specific on the books. And I'm  
20 sorry, you had a second?

21 MS. TERRY: Oh, just Kay Goss Terry  
22 again. It's just to see how many states  
23 actually already have preexisting breast  
24 biopsy regulations in place. Because I know

1 there are several that do.

2 CHAIRMAN FERGUSON: Dr. Timins?

3 MEMBER TIMINS: I know that the  
4 State of New Jersey -- Julie Timins, a Panel  
5 Member. I know the state of New Jersey does  
6 inspect stereotactic biopsy units. And there  
7 are two sets of criteria, one for the separate  
8 standing stereotactic units that do not  
9 perform mammography and then another standard  
10 for the ones, obviously, that do perform  
11 mammography.

12 I could not get statistics from  
13 them, because of illness in their department,  
14 but they are not regulating the medical  
15 practice. They are regulating the equipment.

16 CHAIRMAN FERGUSON: Other questions  
17 or comments? Yes?

18 MEMBER PASSETTI: Bill Passetti  
19 from Florida. I just had one question. Are  
20 you seeing any specific problems with these  
21 units that stand out to you?

22 MS. TERRY: Kay Goss Terry.  
23 Actually, no, they are all passing  
24 accreditation. Sorry, certification

1 inspections.

2 CHAIRMAN FERGUSON: Other questions  
3 or comments? Any of the other accrediting  
4 body ladies wish to speak? Anyone else? You  
5 know, one of the criticisms, I think, that we  
6 faced last time is that we weren't open  
7 enough, so anybody who wants to get up there  
8 and grab that microphone, and if you don't  
9 then we are going to start the Committee  
10 discussion part, as soon as she finishes.

11 We are going to poll the Members of  
12 the Committee to see do they think  
13 stereotactic biopsy should be regulated? Why  
14 or why not? And I spoke to Dr. Finder at  
15 lunch and asked him are we going to do like a  
16 show of hands, a vote? He said it would be  
17 more important to address each of you  
18 individually to give your idea why or why not,  
19 because what FDA is looking for is more of a  
20 thought process in our thinking on this issue,  
21 than a mere show of hands, it was this many  
22 for, this many against. Is that correct, Dr.  
23 Finder?

24 DR. FINDER: Yes, that is. One

1 caveat to that, that discussion will take  
2 place after your internal discussion --

3 CHAIRMAN FERGUSON: Right.

4 DR. FINDER: -- about the matter.  
5 So those questions will come up at the end of  
6 the discussion.

7 CHAIRMAN FERGUSON: And I know that  
8 Diane has to go at 2:45, so we're going to let  
9 her go first when we get to that part.

10 MS. WAGNER: Judy Wagner, breast  
11 cancer patient advocate. I have one question  
12 and I as a woman and as an advocate, I think,  
13 I'm hearing, and this is my perception, that  
14 surgeons are saying we can't do these  
15 procedures, because we are not reviewing  
16 enough mammograms, etcetera. So if that's the  
17 case, then we will just take our patient and  
18 do an open breast biopsy.

19 The State of California requires  
20 that every woman be given information about  
21 the possible ways to get an answer to their  
22 breast issues. And I think that as women, I  
23 think women are going -- if they are not -- if  
24 they are given facts that they can assimilate

1 without any bias, they are going to look for  
2 the person or the place where they are going  
3 to get that, either the type of procedure that  
4 they want.

5                   So to say that it's my ball, it's  
6 my patient, I'm in charge of the patient and  
7 I'm going to just tell that patient I can't  
8 get in to do a needle guided biopsy and you  
9 want an answer yesterday, you are going to  
10 take that patient and do an open. I think  
11 it's ludicrous. I am sorry. As a woman, I  
12 think it's ludicrous.

13                   And one other thing. I think I was  
14 referred to in a statement and I never used  
15 the word surgeon. Thank you.

16                   CHAIRMAN FERGUSON: Thank you. Dr.  
17 Israel, yes?

18                   DR. ISRAEL: Well, I would like to  
19 respond to that issue and I appreciate it  
20 being brought up. I think there is a little  
21 misunderstanding. The surgeons don't have any  
22 problems, the ones that do breast work, don't  
23 have any problem looking at 480 mammograms  
24 every two years. I'll probably look at 480

1 mammograms once a month. So that's not the  
2 issue.

3           And if surgeons are doing  
4 stereotactic breast biopsy in conjunction with  
5 radiologists, which many of them do, then they  
6 are not required to have any regulation  
7 regarding the number of mammograms they look  
8 at, because they are doing it with an MQSA  
9 radiologist.

10           And the other issue about surgeons  
11 recommending open biopsy, I have spent the  
12 last 12 to 15 years of my professional career,  
13 as have many of these surgeons, going around  
14 and telling surgeons stop doing open biopsy.  
15 Let's get a diagnosis with image-guided,  
16 minimally invasive biopsy, then if we have a  
17 cancer or a premalignant lesion, we go to  
18 surgery.

19           Surgeons do not advocate taking  
20 patients to the operating room as the initial  
21 procedure.

22           CHAIRMAN FERGUSON: Thank you. Dr.  
23 Lee?

24           DR. LEE: Carol Lee from the SBI.

1 I gave my disclosures previously. I just  
2 thought it was important that I reemphasize,  
3 because we spoke, Dr. Dershaw and I spoke,  
4 first thing that I emphasize that we are in  
5 complete agreement with the comments of Dr.  
6 Israel that we're here because we're concerned  
7 about quality of delivery of care and whether  
8 MQSA legally covers interventional procedures,  
9 I think, is beside the point.

10 As I said in my presentation, there  
11 are no headline news stories about the  
12 problems with stereotactic breast biopsy does  
13 not mean that there is not variability in the  
14 quality of the delivery of this procedure.  
15 And I think the fact that the NAPBC, the  
16 American Society of Breast Surgeons is  
17 developing certification and accreditation  
18 attests to the goal of improving quality.

19 But we also know that these  
20 voluntary programs are just that. They are  
21 voluntary. And 20 percent of facilities are  
22 now accredited and I do think that inclusion  
23 under MQSA and as somebody who has lived with  
24 MQSA under its inception, I have to say I'm

1 not a huge fan of regulation either.

2 But when it results in improved  
3 quality, which I believe it will, not only a  
4 decrease in false negatives, which is probably  
5 the bottom line, but also in the performance  
6 and the management of these patients. I think  
7 it's a worthwhile tradeoff. Thank you.

8 CHAIRMAN FERGUSON: Thank you. Mr.  
9 Adams?

10 MR. ADAMS: I introduced myself a  
11 few minutes ago. David Adams, Society for  
12 Breast Surgeons. In terms of variability and  
13 Dr. Lee had a slide earlier indicating  
14 different false negative rates, I believe,  
15 from one center to another and it might be a  
16 few percentage points in difference that one  
17 might see looking at different centers, what I  
18 recall Dr. Dershaw this morning suggesting  
19 that in terms of looking at performance, you  
20 can't really gauge it very well by comparing  
21 one center to another center.

22 I thought his point was that you--  
23 because of variability and patient  
24 populations, I know the circumstance is it

1 would be not necessarily -- it wouldn't  
2 necessarily give you a reliable answer to  
3 compare one center to another, that it might  
4 be more useful to compare different outcomes  
5 from different doctors within the same center.

6 That's my recollection. I don't  
7 have a scientific background, but that's what  
8 I recall he said.

9 CHAIRMAN FERGUSON: Thank you. Dr.  
10 Lee?

11 DR. LEE: Dr. Dershaw had to leave  
12 early and I want to clarify, and again, I'm  
13 interpreting his comments, but I believe what  
14 Dr. Dershaw was referring to is differing  
15 positive predictive values of the biopsy. We  
16 clearly don't believe and that is definitely  
17 true that your positive predictive value will  
18 be dependent on your prior probability and on  
19 your patient population.

20 But the delayed false negative rate  
21 should have no bearing whatsoever on your  
22 patient population. That is an absolute  
23 number aside from positive predictive value.  
24 And we definitely need to strive for as low a

1 positive predictive value as possible.

2 I also wanted to emphasize that the  
3 Society of Breast Imaging and the American  
4 College of Radiology absolutely do not support  
5 any sort of regulation that would exclude any  
6 specialty from the performance of this  
7 procedure. Thanks.

8 CHAIRMAN FERGUSON: Thank you.  
9 That's an awful lot of Ps. Anyone else  
10 comments, questions and then -- oh, Dr.  
11 Wagner?

12 DR. WAGNER: Richard Wagner,  
13 general radiologist. I just have a question  
14 regarding the published literature that has  
15 been quoted regarding the failure rates. I'm  
16 just wondering if that reflects what happens  
17 in everyday practice, like the small groups  
18 that maybe do 10 or 20 stereotactics a year.  
19 What is their failure rate? I don't think  
20 there is any way of knowing that.

21 And they talk about the negative  
22 opinion about anecdotal studies, but that's  
23 the only thing we have now. And there are a  
24 lot of them out there that show bad things are

1 happening out in the public and that's why I  
2 think regulation is needed.

3 CHAIRMAN FERGUSON: Thank you.  
4 Anyone else or shouldn't I ask? Go ahead.

5 DR. LERNER: Hi, Arthur Lerner from  
6 the American Society of Breast Surgeons. I  
7 just want to address the question that was  
8 just raised. We're going to hopefully provide  
9 that kind of data through our study, if you  
10 just give us a chance to get this together.  
11 We should be able to give you the kind of data  
12 we're all talking about and we all need by the  
13 end of this calendar year, for at least 200  
14 patients that were done in the community, not  
15 in the meccas and academic centers. So we  
16 will have that for you. Hopefully we'll be  
17 able to share that with you soon.

18 CHAIRMAN FERGUSON: Thank you very  
19 much. Seeing no one else at the microphone,  
20 we are going to have a discussion between the  
21 Committee and you may want to question one of  
22 these other people or throw out what you are  
23 thinking and then we're going to go and let  
24 you explain yes or no, why or why not. So any

1 questions that the Committee has of any of our  
2 presenters or of any of our other Panel  
3 Members. Yes?

4 DR. BYNG: Jeff Byng, Panel Member  
5 representing industry. There has been quite a  
6 discussion today about quality and a number of  
7 very detailed positions put out, but I'm  
8 reflecting on two things that I would perhaps  
9 like some additional clarification on. The  
10 American College of Surgeons and their  
11 colleagues have said they reviewed 600  
12 articles or so on this particular topic  
13 without a documentation of problems with the  
14 procedure, other than as they mentioned with  
15 respect to positioning or targeting, but not a  
16 quality problem per se.

17 That contrasted with, I think, the  
18 ACR presentation from Dr. Dershaw this morning  
19 that showed a pie chart with some breakdown of  
20 the nature of the problems that are reported.  
21 So I would like to make sure that I'm at least  
22 seeing all the data that's available on this  
23 particular topic. Whether FDA has any  
24 additional information or clarification on the

1 existence of a quality problem here or whether  
2 the ACR can elaborate on the nature of some of  
3 the data that they have, for example, with  
4 respect to the phantom and the reasons for the  
5 failure and its association, perhaps, with the  
6 quality that would be to a performance  
7 improvement metric.

8 CHAIRMAN FERGUSON: ACR, I suppose.  
9 Who do we want to answer that?

10 MS. BUTLER: Penny Butler, ACR.  
11 I'm actually not prepared to provide a  
12 breakdown other than what Dr. Dershaw had  
13 presented. And just to repeat, they were 3  
14 percent dose failures. These were all,  
15 obviously, high dose failures. A lot of them  
16 were related to technique problems or  
17 inappropriately high techniques were set up  
18 and these were mostly digital units.

19 The clinical problems were  
20 primarily as a result of not necessarily image  
21 quality, but targeting issues and the phantom  
22 failures were primarily due to poor image  
23 quality. And this is, essentially, following  
24 the same criteria as we follow for

1 mammography. It was the inability to see the  
2 five respects of masses.

3 DR. BYNG: And as a follow-up to  
4 that, is there an association between the  
5 corrected performance and the improvement in  
6 the outcome then as those quality issues have  
7 been addressed? In other words, is that  
8 phantom the appropriate phantom for this  
9 particular test and in terms of evaluating the  
10 quality of the image?

11 MS. BUTLER: We think the phantom  
12 is the appropriate phantom. It's,  
13 essentially, the same phantom as the  
14 mammography accreditation and that's because  
15 it's an x-ray imaging technique. In terms of  
16 the performance, it's very difficult to -- the  
17 phantom doesn't address targeting issues. The  
18 phantom addresses whether you can see it.

19 The targeting issues is based on a  
20 clinical evaluation of the breast images, the  
21 actual procedure. Did that answer your  
22 question? This is Penny Butler, ACR, again.

23 CHAIRMAN FERGUSON: I have a  
24 follow-up on the image, failing the image.

1 When these facilities resubmitted, was there a  
2 corrective action that was taken? Was the  
3 equipment replaced? Was a tube replaced?  
4 What corrective action did you see take place  
5 from that failure of the phantom?

6 MS. BUTLER: This is Penny Butler,  
7 ACR. It depends on the type of corrective  
8 action that were -- and whether we are aware  
9 of the corrective action depends on where they  
10 are in the accreditation process. This  
11 accreditation is set up similar to mammography  
12 where upon a first failure, the facility takes  
13 their own corrective action. They don't  
14 inform us what the corrective action is.  
15 There is no oversight.

16 After a second failure, they have  
17 to submit to us a corrective action plan  
18 before they resubmit the images. This is  
19 where we know what the corrective action was  
20 that took place. And it could be training of  
21 the individuals performing the examinations.  
22 It could be replacement of equipment. It  
23 could be medical physicists paying a visit to  
24 evaluate the equipment and help improve the

1 quality of the equipment. It really varies on  
2 what the reasons are.

3 CHAIRMAN FERGUSON: We'll start  
4 right there.

5 MEMBER WILLIAMS: This is Mark  
6 Williams on the Panel. Just a quick question  
7 for Penny before she gets away. One of the  
8 test QC procedures, is this correct, is to  
9 note the offset between the system reported  
10 location of the lesion and the location of the  
11 needle, as it is finally deployed.

12 Are those data and the rate -- and  
13 this is one part of a big picture that we are  
14 looking at here, but one question, of course,  
15 is ability of the system to, in fact,  
16 correctly localize. Are those data available  
17 by way of the accreditation process?

18 MS. BUTLER: Penny Butler, ACR. We  
19 do not have the data from the specific QC test  
20 available to us during accreditation. What we  
21 ask is are the required tests performed? And  
22 we ask the professional at the site, that is  
23 the medical physicist, to evaluate the  
24 technologist's performance of those tests as

1 an oversight and then we want to make sure  
2 when we see the physicist's report that they  
3 did do the evaluation and provide feedback as  
4 necessary, changes as necessary and they  
5 report back to us that the test was performed  
6 correctly. But we do not collect that  
7 specific data.

8 MEMBER WILLIAMS: Okay. So we  
9 really don't know. Thanks.

10 MR. UZENOFF: Bob Uzenoff,  
11 Committee Member. I have a question for FDA  
12 about the reason for calling this meeting  
13 today really. And I note that although the  
14 word has been used that the FDA is proposing  
15 regulation, I don't hear that. I think it's a  
16 rather open invitation to comment and discuss  
17 should FDA be regulating stereotactic or non-  
18 stereotactic imaging.

19 And I'm kind of surmising that one  
20 of the motives -- I think if the FDA had a  
21 clear idea this should be done, you would  
22 probably be proposing something, but I'm  
23 guessing maybe the motivation for this might  
24 come from the Institute of Medicine report

1 from 2005 "Improving Breast Imaging Quality  
2 Standards."

3 And the regulation for stereotactic  
4 imaging was one of the recommendations in  
5 that. And I'm wondering if you could comment  
6 on that for motivation? And then also, I've  
7 been through the report and I might have  
8 missed it, but I don't see in there a problem  
9 that needs to be addressed either. And I was  
10 kind of surprised by that. I see a  
11 recommendation, but I really didn't see  
12 justification for the regulation behind it.  
13 So could you comment on that?

14 DR. BARR: This is Helen Barr, FDA.  
15 Before the Institute of Medicine report, we  
16 had been talking for a number of years,  
17 probably since the inception of MQSA, about  
18 whether or not stereotactic biopsy or  
19 interventional breast procedures that use  
20 imaging should be part of MQSA.

21 You saw that some -- I'm sorry, I  
22 can't remember the speaker. Someone had a  
23 quote from the early days of, I think it was  
24 put as, the reason it was excluded, but I

1 would like to say as one of the reasons that  
2 FDA excluded regulation of stereo, at that  
3 time.

4           So we have been talking about it  
5 over the years. Under my watch in the past  
6 eight years, I have continually posed the  
7 question that I would like to see what the  
8 public health issue is that, you know,  
9 supposedly needs regulation. I've been asking  
10 people over the years to define the public  
11 health issue for me and if an issue can be  
12 defined, is federal regulation the way to  
13 attack it?

14           So you are right. Under my watch,  
15 I have not seen that to date. The Institute  
16 of Medicine did give us a recommendation and  
17 we are required to respond to Congress, who  
18 requested that report, about how we're going  
19 to institute the recommendations. That  
20 doesn't necessarily mean we have to, but you  
21 are correct, I would say, for transparency  
22 purposes, for me to say that some of the  
23 current motivation to have a meeting where we  
24 again hear all these topics is the

1 recommendation in that report.

2 And we had had some criticism in  
3 the past that not everyone was aware of  
4 meetings. Not everyone had the chance to talk  
5 about, you know, what they see as the pros and  
6 cons of this issue. And, you know, I  
7 certainly myself want to keep abreast of any  
8 changes that would cause the FDA to think any  
9 differently.

10 And several people have said the  
11 FDA's proposed regulation if stereo, we have  
12 not proposed any regulations, at this point in  
13 time. So I think that is a little bit of  
14 mischaracterization. Thank you.

15 CHAIRMAN FERGUSON: Ms. Mount, our  
16 waiver lady.

17 MEMBER MOUNT: Carol Mount, Panel  
18 Member. I have a question, I guess, to any of  
19 the surgeons that have stereotactic breast  
20 biopsy units in your practice that you are  
21 using. Do you do any image quality checks or  
22 targeting checks on a daily basis? What do  
23 you do to assure that you are targeting and  
24 that you do have a good picture?

1 DR. ISRAEL: We do calibration on a  
2 daily basis before we do any procedure. And,  
3 of course, we have -- we follow all the rules  
4 and regulations of the state in terms of the  
5 medical physicist checking dose and our  
6 equipment to make sure that it is safe for the  
7 patient and operational standards. Is that  
8 what you wanted to know?

9 MEMBER MOUNT: Carol Mount, Panel  
10 Member. Yes. Basically, I was just wondering  
11 if you do the same things every day that we do  
12 before we do any patients on our machines.

13 DR. ISRAEL: I think we do, yes.  
14 Mr. Chairman, could I make a comment not  
15 necessarily relating to that?

16 CHAIRMAN FERGUSON: I'm going to  
17 give you some leeway.

18 DR. ISRAEL: Yes, 30 seconds.  
19 Philip Israel, breast surgeon. I think we're  
20 throwing around numbers here. The question  
21 that was just asked about perspective of the  
22 numbers showing problems with stereotactic  
23 breast biopsy that Dr. Dershaw presented,  
24 there are probably close to a million breast

1 biopsies done in this country every year.

2 I suspect close to 80 percent of  
3 those are done with image guidance. That's a  
4 huge number. The number that Dr. Dershaw is  
5 throwing out, I don't remember him being able  
6 to address this, it's a relatively tiny  
7 number. And these were people who failed an  
8 accreditation test.

9 And I don't think that we can base  
10 assumptions and evaluation on that small  
11 number compared to the huge numbers of  
12 biopsies that are done and are done apparently  
13 successfully.

14 CHAIRMAN FERGUSON: Thank you.  
15 Committee Members, other questions, comments,  
16 discussion, anybody want to pick at a little  
17 bit? Yes, Dr. Timins?

18 MEMBER TIMINS: I noted that Dr.  
19 Wagner expressed concern about the statistics  
20 that are presented in terms of false  
21 negatives. That what you see in the  
22 literature is the best practice that is  
23 available. And what happens in the community,  
24 there is a very strong chance, even a

1 probability, that it is different than what  
2 you see published in peer-reviewed journals.

3           So what is the best practice that  
4 is published in the literature is going to be  
5 different in different parts of the United  
6 States. Also, that only one-fifth of the  
7 stereotactic units out there have voluntarily  
8 submitted for any kind of accreditation  
9 implies that you can't extrapolate from that  
10 20 percent and say everybody is meeting the  
11 same standards, because the other 80 percent  
12 probably are not. They are self-selected and  
13 they are not going to be as good. And that is  
14 my concern.

15           CHAIRMAN FERGUSON: One more.

16           MEMBER ROSEN: Eric Rosen.

17           CHAIRMAN FERGUSON: One more.

18           MEMBER ROSEN: Eric Rosen, Panel  
19 Member. I just want to reiterate, I agree  
20 with your statement and I also feel like Dr.  
21 Dershaw was pointing out that of these 20  
22 percent who voluntarily sought accreditation,  
23 we still found substantial problems in,  
24 approximately, a quarter of them that resulted

1 in failure.

2 So the concern, I think, is that  
3 there is a problem, even among organizations  
4 that voluntarily seek accreditation. There is  
5 concern that there would be an even greater  
6 problem among facilities that don't seek  
7 voluntary accreditation.

8 CHAIRMAN FERGUSON: And that's  
9 radiologists, surgeons, everybody that's in  
10 the business.

11 MEMBER ROSEN: Anybody who performs  
12 a procedure.

13 CHAIRMAN FERGUSON: Dr. Barr?

14 DR. BARR: Helen Barr, FDA. I  
15 would just like to -- when we say failures,  
16 yes, there are accreditation failures, but  
17 that accreditation process is non-outcome  
18 based. And I think that that should be  
19 stressed.

20 MEMBER ROSEN: Yes, Eric Rosen.  
21 And I think that's an excellent point. We  
22 need to separate that measure, metric failure  
23 of accreditation, from a true false negative  
24 problem. I don't think anyone has really

1 well-addressed the issue of what is the real  
2 false negative rate from stereotactic biopsy  
3 in this country and what is the variability.  
4 It simply hasn't been reported well in the  
5 literature.

6 DR. BARR: This is Helen Barr, FDA.  
7 I think you make an excellent point and it's  
8 one of the problems in public health that  
9 we're faced with, is, you now, where is the  
10 evidence? Where are the data? Are we too  
11 premature? Do we even know what we are doing  
12 yet?

13 MEMBER ROSEN: Eric Rosen. I agree  
14 with that and my concern is somewhat different  
15 than the arguments I've heard presented here.  
16 It's not that we haven't heard of a problem,  
17 so there must not be one. My concern is that  
18 just because we haven't heard of a problem,  
19 doesn't mean it doesn't exist. But I do  
20 believe that we should gather evidence to  
21 determine whether there truly is a problem or  
22 not. But without some sort of process to do  
23 that, I don't see how it can happen. It  
24 certainly isn't happening by itself.

1                   CHAIRMAN FERGUSON: Carol?

2                   MEMBER MOUNT: Carol Mount, Panel  
3 Member. I just had one comment. In all the  
4 presentations today, nobody mentioned the fact  
5 whether or not they were using a technologist  
6 to position. Now, I know the word  
7 localization came out several times. And all  
8 technologists in the room know that probably  
9 the hardest thing we do in mammography is spot  
10 compression views with a very tiny paddle to  
11 localize that very specific lesion.

12                   So I'm just wondering, I know that  
13 in most radiology offices, a technologist who  
14 does positioning every day, day in and day  
15 out, does position this patient and finds the  
16 very tiny calcifications. Then the  
17 radiologist does perform the biopsy. What  
18 happens when the surgeon is doing this?

19                   DR. LERNER: Arthur Lerner from the  
20 American Society of Breast Surgeons. While  
21 the technologist does put the patient on the  
22 table in our center, she puts the patient on  
23 the table after we discuss the approach we  
24 want to take. And we take in a number of

1 factors in how we want to approach the lesion.  
2 Shortest distance from skin to lesion, view  
3 that it is best seen in.

4 With an eye towards the fact that  
5 everybody who is having a stereotactic biopsy  
6 potentially will be in the operating room next  
7 week either for an excision, because of a  
8 tippy or some other lesion that needs to be  
9 excised or for therapy.

10 So we have a discussion. The  
11 position on the table, which is done by the  
12 technologist, has to be approved by the  
13 doctor. When I sit in front of that screen  
14 and say okay, this is what I'm looking at and  
15 this is what I want to biopsy, that is not the  
16 technologist's role. Although, I ask my  
17 technologist all the time for help, the  
18 ultimate responsibility for the adequacy of  
19 that biopsy is mine. And so I take that  
20 responsibility in every case.

21 And in our practical examination  
22 that we're giving to our surgical colleagues  
23 to certify them, they have to take that  
24 responsibility also.

1                   MEMBER MOUNT:    Carol Mount, Panel  
2 Member.    I would say that's probably pretty  
3 similar to the way it is done in the radiology  
4 office, too.    It is the radiologist that  
5 directs the technologist.    However, do you  
6 feel all centers use technologists?

7                   DR. LERNER:    Do I?    I'm sorry?

8                   MEMBER MOUNT:    Or are you -- do you  
9 feel all surgeons use technologists or do you  
10 feel you are an exception?

11                  DR. LERNER:    No, I -- in all my  
12 travels, in all my teaching, in all my  
13 discussions with people, I have yet to find a  
14 surgeon dumb enough to try and do this without  
15 a technologist.    I will confess to you right  
16 now that after the patient, the next most  
17 important person in that room is the  
18 technologist.    It's not the surgeon and it's  
19 not the radiologist.

20                  CHAIRMAN FERGUSON:    Dr. Timins?

21                  MEMBER MOUNT:    Thank you.

22                  MEMBER TIMINS:        I would like,  
23 Julie Timins, Panel Member, to address Carol  
24 Mount's question with a reply that I know of

1 visiting stereotactic units that are brought  
2 around by a nurse. And the surgeon and the  
3 nurse are involved. And the surgeon, I guess,  
4 is the technical person in that regard,  
5 because the nurse is not allowed to be -- to  
6 function as a radiologic technologist. So not  
7 everybody is using a registered radiologic  
8 technologist.

9 MEMBER MOUNT: Carol Mount. On the  
10 same topic, the reason I asked the question is  
11 because one of our nearby facilities has a  
12 stereotactic breast biopsy table. They had a  
13 breast surgeon and the breast surgeon would  
14 perform her own stereotactic breast biopsies  
15 without a technologist in the room, even  
16 though the table was located in the Radiology  
17 Department.

18 When they finally got an  
19 experienced breast radiologist on staff, they  
20 started doing the stereotactic breast biopsies  
21 and they noted the difference in the number of  
22 images that were required for the surgeon to  
23 take his or, I should say, her prep for her  
24 study versus the number of images that were

1 required when the technologist was involved.

2 So after some consultation and  
3 physicists doing a little dose calculation for  
4 them, the surgeon did then allow a  
5 technologist in the room to position the  
6 patient and that's why I brought this up.

7 CHAIRMAN FERGUSON: Thank you.  
8 Diane?

9 MEMBER RINELLA: If I can just add,  
10 Diane Rinella, Committee Member, I do know of  
11 stereotactic mobile units in the State of  
12 California where the technologist positions  
13 the patient, targets the patient and  
14 oftentimes inserts the needle and it is due to  
15 the fact that, in my opinion, it's because  
16 it's not regulated. And they feel like they  
17 are not going to get caught. The technologist  
18 doesn't want to lose their job, so nothing is  
19 said.

20 And in seeing these things and  
21 hearing these things, I feel like that's why  
22 we don't know really what's going on out  
23 there. No one wants to get caught. No one  
24 wants to lose their job. And no one wants to

1 say anything. So it's kept hush-hush, in my  
2 opinion.

3 DR. BARR: Helen Barr, FDA. There  
4 are many -- if there are issues, such as you  
5 say, another question is who is best to  
6 address them? Is the state the best one to  
7 address that, you know, only qualified  
8 radiologic technologists should perform  
9 procedures involving imaging? So what I'm  
10 looking for is not only identification of a  
11 problem, but if problems exist, is federal  
12 regulation the best way to tackle those  
13 problems?

14 DR. LERNER: Arthur Lerner,  
15 American Society of Breast Surgeons. In  
16 California, there is an impediment to surgeons  
17 doing stereotactic biopsies. They have to get  
18 a special certificate before they are allowed  
19 to do that. So very few of my colleagues in  
20 California, the surgeons, are actually doing  
21 that right now.

22 I would just like to make a plea.  
23 Anecdotes are great. They are interesting to  
24 listen to, but they don't make science. They

1 really don't. I could stand before you and  
2 give you anecdote after anecdote from my  
3 personal experience, but that's not science.  
4 And once again, I urge the Committee in its  
5 wisdom to wait to see some data.

6 CHAIRMAN FERGUSON: Thank you.

7 MEMBER ROSEN: Eric Rosen, Panel  
8 Member. I agree that we need evidence-based  
9 data to make a decision, but I also think that  
10 you can't use the plea for evidence-based data  
11 when it helps you and use anecdote when that's  
12 helpful, too. I think that we have to use one  
13 standard to make a decision and hold everyone  
14 to that same standard.

15 And I think that there have been  
16 some inflammatory statements made today  
17 regarding the possible loss of access to  
18 stereotactic biopsy if we were to consider  
19 regulation of the procedure. And I don't  
20 think there is any evidence to support that.  
21 So I think we have to be very careful that we  
22 use evidence-based data for everything when we  
23 are basing our recommendations and decisions.

24 MEMBER TIMINS: Julie Timins, Panel

1 Member. A physician within the license to  
2 practice medicine is allowed to take  
3 radiographs and to use radiography to assist  
4 in procedures. And there is no requirement  
5 that a physician needs to have a radiologic  
6 technologist.

7 So I don't see whether or not there  
8 is a radiologic technologist involved as a  
9 specific issue. Also, I work at institutions  
10 where surgeons and radiologists have worked  
11 side-by-side with stereotactic biopsies. And  
12 it's a combination that's a good combination.  
13 Here the issue should be one of quality, not  
14 of turf.

15 MS. SEGELKEN: Jane Baker Segelken,  
16 Panel Member. I understand your comments  
17 about anecdotes, but anecdotes inform and very  
18 often they are the impetus for further  
19 research. And I think they are important to  
20 hear.

21 CHAIRMAN FERGUSON: Any other  
22 comments from the Panel? Yes?

23 MS. FINKEN: Nancy Finken, consumer  
24 advocate and my profession is as a teacher. I

1 just throw this out for thought. Teachers are  
2 all certified across the country in their  
3 individual states. And there are very high  
4 standards in some states. However, it doesn't  
5 guarantee the best of education, as we all  
6 know. It's up to the person practicing and  
7 carrying out what they know is the best  
8 educational practices.

9 So I tend to look to that as  
10 something to compare in the medical field.  
11 You do need to have standards and those are  
12 more -- they are achieved more by the  
13 individuals reaching for the best treatment  
14 and the best quality care than being all  
15 consumed over whether we're meeting the  
16 regulations of a standard that has been  
17 superimposed on the profession. Thank you.

18 CHAIRMAN FERGUSON: Okay. Seeing  
19 no hands, I know Diane has a flight to catch  
20 and I wanted to have her comments. And we are  
21 going to poll everyone as to should we  
22 regulate stereotactic biopsy? Why or why not?  
23 We'll start with you.

24 MEMBER RINELLA: Diane Rinella.

1 DR. FINDER: Before you get started

2 --

3 MEMBER RINELLA: Yes.

4 DR. FINDER: This is Dr. Finder.

5 Most of the discussion today has been focused  
6 on stereotactic breast biopsy. But we  
7 actually had two questions that we're asking,  
8 because the regulation as currently written  
9 deals with interventional mammography. So  
10 there actually are two questions.

11 One is the issue of stereotactic.  
12 The other is all the other procedures that  
13 would fall under interventional. And we  
14 didn't have a lot of discussion on that,  
15 needle localization, things like that. So I  
16 would kind of bring up the point that it's  
17 more than just stereotactic, even though  
18 that's what you have been focusing on.

19 So when you do the discussion, we  
20 actually have two questions. One is should we  
21 regulate interventional procedures, other than  
22 stereotactic? And again, giving your reasons  
23 why or why not. And then the second question  
24 would be about stereotactic biopsy

1 specifically and whether we should regulate  
2 that and why or why not. So those are the two  
3 questions.

4 CHAIRMAN FERGUSON: When you say  
5 those procedures, you mean that are  
6 mammographically imaged, not breast  
7 ultrasound? Correct?

8 DR. FINDER: Correct. We're  
9 talking about mammographically imaged other  
10 procedures and the main ones that we think  
11 about would be needle localization and, again,  
12 there wasn't a lot of discussion. There is no  
13 accreditation process at the present time for  
14 that. There are other interventional  
15 mammographically, intents and procedures,  
16 including galactograms, which they are not  
17 done very often, but those could fall under  
18 interventional.

19 So there are two separate questions  
20 and I would very much like to hear what the  
21 Committee has to think about both of them.

22 MEMBER RINELLA: Diane Rinella,  
23 Committee Member. Well, with regards to  
24 stereotactic breast biopsy, first, I would

1 like to say that I appreciate and I understand  
2 where the surgeons are coming from. They are  
3 not used to being regulated like we are in  
4 mammography and it would be a major change.

5 But in my 20-plus years in doing  
6 breast imaging and being involved hands-on  
7 with patients during interventional  
8 procedures, stereotactic breast biopsy,  
9 localization, tachography and breast  
10 ultrasound, I'm of the opinion that regulation  
11 of these could only increase the quality of  
12 care for patients. And I feel like that's the  
13 bottom line. That's why we're here.

14 CHAIRMAN FERGUSON: Thank you. And  
15 unless someone else has a time constraint, so  
16 I don't get everyone confused, I'll just start  
17 at the end of the table and we'll come this  
18 way or you want me to start at the other end?  
19 Yes, okay. Well, let's --

20 MS. WYNNE: How about like a 5 or  
21 10 minute break?

22 CHAIRMAN FERGUSON: Are people  
23 wiggling? Do they need a break? I think  
24 let's take a 5 minute, 10 minute at the very

1 longest and reconvene and then we're going to  
2 get out of here.

3 (Whereupon, the above-entitled matter went off  
4 the record at 2:51 p.m.  
5 and resumed at 2:59 p.m.)

6 CHAIRMAN FERGUSON: We are going to  
7 start. Diane left, so we will start and now  
8 we can talk about her, but we will start and  
9 we hopefully will conclude in an hour, about  
10 4:00. If you're making transportation  
11 arrangements, that's our target.

12 So Nancy is not here. We can't do  
13 anything without Nancy. So I will reread the  
14 question and when Nancy gets back, we'll start  
15 with Dr. Winchester.

16 Should FDA regulate stereotactic  
17 biopsy and the reasons to regulate or not?

18 And No. 2, should we regulate  
19 interventional procedures other than  
20 stereotactic and the reasons to regulate or  
21 not? And those would be the questions. And  
22 again, we're more interested in the thought  
23 process and the thought analysis, than the,  
24 you know, there is one here and one there.

1 DR. FINDER: This is Dr. Finder. I  
2 want to emphasize that last statement. We are  
3 really looking for the reasons not just I want  
4 to do this or I don't want to do this and we  
5 don't know the thought process behind it.  
6 We're not looking for totals. We're looking  
7 for reasons more so than anything else.

8 CHAIRMAN FERGUSON: But I have got  
9 a little list here. I'm making numbers. Dr.  
10 Winchester.

11 DR. WINCHESTER: Dr. Winchester.  
12 Well, as for the question about interventional  
13 mammography with respect to needle  
14 localization biopsy and galactography and  
15 other procedures, we have really heard nothing  
16 about that today. And I have heard no  
17 discussion about that, so I would recommend  
18 that that not be -- in my thought process, I  
19 don't have any thoughts, because I didn't hear  
20 anything today about that.

21 So I think it should focus on  
22 stereotactic or needle biopsy regulation. I  
23 was encouraged as the day went on, as a  
24 surgeon, to observe the discussion about

1 inclusiveness of and not pitting one  
2 specialist against another, but looking at  
3 qualifications, experience, outcomes and doing  
4 the right thing for the patient. And I think  
5 that's a very healthy discussion.

6 If this procedure were to become  
7 regulated, I do not know, however, how the  
8 regulations would be written and I have no  
9 assurances that the same spirit of discussion  
10 which occurred today would be translated into  
11 the regulations, if this were to be a  
12 regulated procedure.

13 Secondly, FDA has been described as  
14 a data-driven organization. I think that's  
15 laudable. And we have heard some data today.  
16 We have heard some anecdotes today. And we  
17 have heard some incomplete, but planned data  
18 coming from ASBS. So it would be my  
19 observation that we, based on 600 articles of  
20 literature indicating very small differences  
21 and false negatives, but other studies that  
22 have shown some differences, that we need  
23 further information, further data, before we  
24 can focus on that in making a decision or

1 recommendation about regulation.

2 I know we don't want to talk about  
3 legal issues, but I was taken by Dr. Finder's  
4 comment that this Panel ought to move forward  
5 with your thought process and not worry about  
6 the details of whether MQSA technically is  
7 going to be interpreted by the lawyers as  
8 including interventional mammography or what  
9 Congress is going to do.

10 Well, nobody knows what Congress is  
11 going to do and never have known, so that's  
12 all speculation. And as far as attorneys go,  
13 with all due respect to attorneys, you never  
14 know what's going to happen there either. So  
15 for this Panel to talk about thinking along  
16 the lines of one path of regulation or not,  
17 not even knowing whether it is going to be  
18 possible, I think, is inappropriate.

19 So the access issue, I agree with  
20 Eric and others that that falls along the  
21 lines of speculation, as well. We don't have  
22 good data that regulation or lack of  
23 regulation is going to affect access to the  
24 patients. That's it for me.

1                   CHAIRMAN FERGUSON: Thank you.

2                   MR. UZENOFF: Bob Uzenoff. I'm  
3 gratified by the presentations that we have  
4 had at this meeting, because I came to the  
5 meeting wanting to be informed to address  
6 these two questions, but not aware of the  
7 problem that the regulation proposed or the  
8 regulations would have addressed.

9                   And a very distinguished group of  
10 presenters here, representing all sides. And  
11 on both questions of stereotactic and non-  
12 stereotactic interventional procedures, you  
13 know, these are important questions to ask, as  
14 Dr. Barr pointed out. I was glad to hear that  
15 it has always been in FDA's mind to consider  
16 regulation in this. And the question is asked  
17 periodically and it is being asked again  
18 possibly to some extent by the 2005 Institute  
19 of Medicine report.

20                   And speaking for my constituency,  
21 which is industry in this area, I'm not  
22 finding a problem to be solved for -- that  
23 would be solved by regulation. Which is not  
24 to say that there aren't problems. I respect

1 and agree with Dr. Rosen's question, you know,  
2 just because we're not hearing about problems,  
3 doesn't mean that there aren't problems out  
4 there.

5 So there may be problems. I don't  
6 think we know which -- what problems there  
7 are. And so I cannot speak. There aren't --  
8 it's not regulated now and I can't find it  
9 appropriate to speak in favor of regulation of  
10 either of those from the equipment or the  
11 industry side of that, which is not to say  
12 that we shouldn't think about this issue or  
13 maybe think about ways to have data.

14 And we heard today about data that  
15 is being collected and there will be data in  
16 the future. But my answer would be no, on  
17 both questions, because there isn't a  
18 compelling supporting justification for it,  
19 which is not to say that the subject doesn't  
20 deserve continued watching.

21 CHAIRMAN FERGUSON: Thank you.

22 MEMBER PASSETTI: Bill Passetti. I  
23 think my comments go to both questions. As a  
24 regulator that also works for a public health

1 agency, I'm all for regulation when I think  
2 there is a clear need that a regulatory  
3 approach will have some benefit to it.

4           However, unfortunately, I have seen  
5 many times regulations being written when they  
6 thought they may help or they may be needed  
7 and it usually has a bad outcome when you  
8 approach it that way. So at this point, I'm  
9 like several of the others. I think I'm not  
10 convinced, at this point, that regulation is  
11 the way to go forward, at this point. Thank  
12 you.

13           MS. SEGELKEN: This is Jane Baker  
14 Segelken. I am in favor of having the FDA  
15 regulate stereotactic biopsy. I did have a  
16 stereotactic procedure done in 2004 and it was  
17 to my good fortune that I was able to go out  
18 of town, out of my very small rural community,  
19 to a large medical center to have this done.

20           The people in my community do very  
21 few of these and their experience is not  
22 great. And there is, from what I understand,  
23 anecdotal information, very little oversight.  
24 The -- as a volunteer, a breast cancer patient

1 advocate, I talk to women all the time in my  
2 community who their surgeons and their  
3 radiologists actually say to them that they  
4 shouldn't have this procedure done, if they  
5 can't leave the community.

6 So I think that, you know, a lack  
7 of standards does put women at greater risk  
8 than they already are. So I think that it is  
9 -- it behooves us to take a closer look at  
10 this and to consider regulating the procedure.

11 DR. FINDER: This is Dr. Finder.  
12 You addressed stereotactic. What about other  
13 interventional?

14 MS. SEGELKEN: Well, I guess I  
15 could say that the same reasons do -- well, I  
16 would say that for the same reasons that I  
17 gave for stereotactic, I would give for the  
18 others, although I didn't hear any information  
19 today on that, so it's hard for me to really  
20 address it, other than strictly anecdotally.

21 MEMBER MOUNT: Carol Mount. I,  
22 too, thought that the discussion today was  
23 awesome. I thought both sides were  
24 represented very well. My stand on the

1 situation is I think there should be some type  
2 of regulation in place. I don't necessarily  
3 know if the current one that we have is the  
4 perfect one, but I do think at a very minimum  
5 the equipment should be tested and maintained  
6 in the very same way across the board.

7 Just because I know we have found  
8 issues on our own equipment when we're done  
9 our weekly testing where our physicist or our  
10 service engineer has been able to come in and  
11 correct them and had we not done those and put  
12 a patient on the table, we might not have  
13 known it.

14 So I do think that at a minimum,  
15 equipment should be regulated and I feel that  
16 with the other procedures listed, because the  
17 equipment generally is already being used for  
18 screening or diagnostic mammograms, I think  
19 the equipment issue is addressed. So I do  
20 think there needs to be some type of  
21 regulation, very minimum, with the equipment  
22 testing that we currently have.

23 MEMBER WILLIAMS: Mark Williams.  
24 Just to go down a couple of the issues. I

1 haven't been persuaded that MQSA is  
2 inappropriate because of its definition or  
3 because of constraints on it for the purpose  
4 of regulating stereotactic biopsy. In fact,  
5 you might make an argument, I think, from a  
6 practical standpoint that if there was a part  
7 of the federal regulations that would be the  
8 least cumbersome to do it, it would probably  
9 be MQSA.

10 I have also been unconvinced that  
11 regulation would be exclusive to any  
12 particular specialties or disciplines. I  
13 share the opinions of the many who have said  
14 that more data would be nice. The ACR have  
15 provided data that has been very helpful,  
16 although we have seen that that represents a  
17 relatively small slice of what is out there.

18 And, of course, the monster in the  
19 attic is what those others are doing. And I  
20 don't know of a great -- one of the --  
21 actually, one intriguing possibility was  
22 raised by NEMA, which I think suggested that--  
23 or asked the question is the FDA the right  
24 mechanism, and I would assume, in

1 collaboration with the association of  
2 societies here today and maybe others to get  
3 more data and analyze it in a collective way.

4 But common sense says that this  
5 standard of performance of those invisible  
6 folks in the attic is probably below the ones  
7 that we have seen. And it may be that in the  
8 lack of any mechanism for getting good  
9 reliable data on those folks, it may be that  
10 the only way to get into the attic is to make  
11 folks, you know, answer to regulatory  
12 mandates.

13 So having said that, then if we  
14 can't come up with other alternative non-  
15 regulatory strategies, then, at this point, I  
16 would be in favor as far as stereotactic  
17 biopsy goes.

18 As far as other procedures like  
19 wire-localization, I'm not a radiologist or a  
20 surgeon, but my sense is that those -- that  
21 the objectives of those, for example, wire-  
22 localization are very different than for a  
23 stereotactic biopsy. And so I think that  
24 maybe the -- some of the relevant issues that

1 we have talked about today for stereotactic  
2 biopsy may not apply to those.

3           There is a secondary, I guess, sort  
4 of practically driven question, which is if  
5 you are going to do that, then where are the  
6 recommendations going to come from for how to  
7 do that? And I think we are probably, from a  
8 practical standpoint, a lot closer to being  
9 able to do that for stereotactic biopsy than  
10 we are maybe for those other procedures.

11           So I'm not very strongly in favor  
12 of -- to, you know, pull the switch today of  
13 the latter. So I'm split on those two.

14           CHAIRMAN FERGUSON: Okay.

15           MEMBER TIMINS: Julie Timins. I  
16 think in deciding whether or not to regulate  
17 the stereotactic breast biopsy, there are two  
18 issues to consider and one is that of quality  
19 and the other of radiation to the public. And  
20 with quality, there is a concern with image  
21 quality, the actual imaging itself and then  
22 there is the concern with the quality of the  
23 procedure, which includes training of the  
24 physician operator.

1                   We -- it's very interesting that  
2     the American College of Breast Surgeons has  
3     this survey on stereotactic breast biopsy and  
4     I look forward to the results, but if this is  
5     a voluntary reporting, the data can be  
6     selective and it's not necessarily  
7     representative of what's going on. I'm just  
8     concerned that we are not getting the complete  
9     report on the quality of the procedure and how  
10    effective it is and what the false negative  
11    rate is.

12                   Since there is radiation to the  
13    breast, I think that it's for stereotactic  
14    breast biopsy to be regulated under MQSA.  
15    There are a small percentage of units out  
16    there that are giving too high a dose. We are  
17    very concerned with radiation to the breast,  
18    since it does induce cancer in excessive  
19    amounts.

20                   I don't think once again that this  
21    is an issue of who performs the stereotactic  
22    procedure. I think it is a question of  
23    quality. I think it is appropriate for this  
24    to be regulated. I know that there are

1 stereotactic units out there that don't pass  
2 inspection. So I don't have statistics on  
3 that, but I know it does happen. So I am in  
4 favor of regulation of stereotactic breast  
5 biopsy.

6 Needle localization and  
7 galactography, they are both procedures that  
8 use mammographic imaging and I think they fall  
9 under the same purview. Image quality is  
10 important, the radiation dose is important and  
11 there are certainly well-established  
12 guidelines for needle localization. I have to  
13 presume that there are guidelines for  
14 galactography as well.

15 It's not as if the wheel needs to  
16 be reinvented. I would be in favor of  
17 including mammographically guided  
18 intervention, such as needle localization and  
19 galactography under MQSA.

20 MEMBER MONTICCIOLO: Debbie  
21 Monticciolo, Panel Member. I would say that I  
22 thought the discussions were very useful  
23 today. And I heard a lot of the discussions  
24 from my surgical colleagues here, concerns

1 about exclusion, and I wouldn't want to see  
2 that be the case.

3 I came into this thinking that the  
4 regulations would be based on similar programs  
5 that we have developed jointly, so I just want  
6 to go on the record as saying I like the idea  
7 of an inclusive policy that would respect  
8 anyone who has a clear interest and willing to  
9 meet quality standards.

10 So I would say I am in overall  
11 favor of regulation of stereotactic biopsy and  
12 under that circumstance I am opposed to -- you  
13 asked for our comments on needle localization  
14 and galactography. I think those are already  
15 adequately covered under the current  
16 regulations, because the people who perform  
17 those are already regulated, have to be  
18 certified under MQSA as interpreters.

19 I mean, by and large, the people  
20 who do wire-locs and do galactography are  
21 already in the -- the equipment that is used  
22 is already fairly well-covered. And then we  
23 had this discussion at the last Committee  
24 meeting that there are cases of places that

1 maybe have a unit that's only used for wire-  
2 loc and not for diagnosis and screening that  
3 might fall outside the purview of MQSA  
4 currently, but I think if you're not using the  
5 machine for diagnosis, then it's really a very  
6 limited use and would be adequate, I think, to  
7 serve its purpose.

8           So I would not favor separate  
9 regulations for those areas. On a personal  
10 note, I think galactography, I'm actually kind  
11 of hoping I'll never have to do another one as  
12 long as I live, but it's just a bias, it's not  
13 an exam I enjoy doing and we don't do very  
14 many of them, so it's a pretty minor addition.

15           DR. BYNG: And Jeff Byng, Panel  
16 Member representing industry. I'm going to  
17 address both questions simultaneously, because  
18 I think that my thought process applies to  
19 both equally. I believe in the comments that  
20 were expressed by many of my colleagues and  
21 many of the folks here that we need to be  
22 data-driven relative to addressing any  
23 potential issues or problems, quality problems  
24 in this case.

1                   With the origins of MQSA, I think  
2                   there were a substantial number of articles  
3                   and issues in the public domain that  
4                   represented a quality problem that needed to  
5                   be addressed and regulation was effective in  
6                   dealing with that.

7                   Based on what we have heard today  
8                   and the data that has been discussed and  
9                   presented, I don't think that there is the  
10                  same level of information that describes the  
11                  quality problem that exists in this  
12                  environment.        It seems there are some  
13                  initiatives to try to collect and consolidate  
14                  that data and I believe that we need to  
15                  continue to pursue those in order to be in a  
16                  better position to try to address quality  
17                  problems, so if one does indeed exist.

18                  So I do not believe that  
19                  regulation, at this point, is the current  
20                  approach that could potentially address the  
21                  situation.    If there were to be regulation  
22                  though and referring back to, according to the  
23                  through process, MITA's statement from  
24                  industry that a performance-based metric would

1 be one that I believe would be most  
2 appropriate.

3 In addition, I think that the  
4 question was about, what was -- whether there  
5 were better ways to address a potential issue  
6 than regulation, because I believe regulation  
7 is probably the most severe way to try to  
8 drive behavior. And perhaps more effort can  
9 be dedicated towards some other consideration,  
10 such as education or the linkage with  
11 reimbursement or other procedures, mechanisms  
12 to drive behavior.

13 MS. HOLLAND: Jackie Holland. I  
14 would like to begin by saying it's always kind  
15 of difficult for me to be in a room with  
16 everybody who believes and is practicing  
17 quality care. The folks who are not are not  
18 here and never will be. So as a consumer  
19 advocate, it's difficult. We all believe in  
20 the same thing and want to make sure that  
21 quality care is being delivered.

22 In the case of both topics, I would  
23 be in favor of regulation and that comes from  
24 many years experience working in the

1 community, talking with patients not only in  
2 my own community, but I do speak at  
3 engagements all over the country. And so I'm  
4 one of those people who is actually hearing  
5 about the problems. The surgeons aren't  
6 hearing about it. The radiologists aren't  
7 hearing about it. But little old me out there  
8 in the community, we're hearing and then we  
9 investigate and find out sure enough there are  
10 problems that exist.

11 So I think it's very important that  
12 because we have the trust of the public in our  
13 country to consider that and also with  
14 evidence base. I know in nursing it's a very,  
15 very big topic, evidence-based data. It's  
16 important that we continue to do it, but it's  
17 also important that when we look at evidence-  
18 based material, that it includes everybody  
19 that we possibly can include, people in rural  
20 areas, people in urban areas, poor people rich  
21 people, you name it.

22 And, unfortunately, some of the  
23 evidence-based materials do not really include  
24 a broad, broad picture of the population.

1 Thank you.

2 MEMBER ROSEN: Eric Rosen. And I  
3 would favor regulation of stereotactic biopsy  
4 by MQSA. And also, I think it's very  
5 important that it should be an inclusive for  
6 all medical specialties to be able to perform  
7 the procedure. It should not be exclusionary  
8 to any medical specialty. I think that's  
9 critical. But I do think that it's equally  
10 critical that we're all held to the same set  
11 of standards.

12 I think that I would love to have  
13 more data to make my decision, but I'm making  
14 the decision based on the data that I have  
15 available for making the decision. And I  
16 think, in the absence of strong evidence in  
17 favor of a problem, we have a lot of indirect  
18 measures that there are problems.

19 The first to me is that both the  
20 surgical and radiologic colleges decided to  
21 develop an accreditation program in the first  
22 place, which to me implies the need for  
23 accreditation. And interestingly the fact  
24 that only a very small percentage of

1 facilities have applied for what is a  
2 voluntary accreditation program. And that  
3 further, of those voluntarily applying for  
4 accreditation, a substantial number have  
5 failed to meet the standards.

6 I also am troubled that there is a  
7 large variability in the false negative rates  
8 that have been reported and I'm pretty  
9 confident that this topic has been very under-  
10 reported or under-addressed by the literature.  
11 I don't think that voluntary data is  
12 forthcoming and although I am reluctant to  
13 advocate for regulation, I think that that's  
14 the only way that we will be able to ensure  
15 that there is quality in the procedure.

16 And I think that's ultimately what  
17 MQSA is about, is ensuring the quality and  
18 access for women to quality procedure, rather  
19 than trying to correct a program that is rife  
20 with problems. So that's my perspective.

21 As far as regulating other  
22 procedures, I haven't really thought about  
23 that a lot specifically for wire-localizations  
24 and galactography, so I'm going to have to

1 pass on that, making that decision right now.

2 MS. FINKEN: Thank you. Nancy  
3 Finken, consumer advocate. Again, I commend  
4 everyone for your excellent presentations and  
5 giving me an opportunity to see both sides of  
6 a very critical issue. As far as the question  
7 goes, number one, what I think needs to be  
8 guaranteed to all women or all people is that  
9 the equipment has met standards, has been  
10 tested, has met the NMQSA Standards for dose,  
11 for quality of the films, for quality of the  
12 equipment, that women and men are guaranteed  
13 that there will not be excessive doses of  
14 radiation due to faulty equipment.

15 I just think that's a no-brainer  
16 and I think our standards right now pretty  
17 much direct in that way. As far as should we  
18 or should we not regulate the field, which I  
19 see as a different issue, we do need more data  
20 from the many resources that are out there  
21 searching for data.

22 We need to know more about the  
23 long-term accuracy rate and that is really key  
24 here. Centers of excellence have been set up

1 and I think that's wonderful. The idea there  
2 is that we're teaming the specialists and it  
3 sets an example, I'm sure, for other parts of  
4 the medical field across the country.

5           However, there are so few of these  
6 centers of excellence and I worry about the  
7 women and men who are living away from these  
8 centers of excellence by even 25 miles. And I  
9 think we need to be aware of the kind of  
10 medical treatment that is out into the rural  
11 areas where poor people, immigrants, all the  
12 many people who are making up this country are  
13 having a struggle to get good quality medical  
14 care, no matter what it is.

15           Access to quality care to me is a  
16 key issue in our whole medical approach. So  
17 do I think it needs to be regulated? I don't  
18 think that gives us quality. As I had  
19 referred before to teachers and our  
20 credentialing, it doesn't make for the best  
21 teacher. You also need the dedication and  
22 determination of the people who really want to  
23 serve the public.

24           Again, if regulation could be done,

1 number one, on equipment, that's separate.  
2 But as to the medical professions or  
3 specialties, I think if we can regulate  
4 without designating the specialty, that if a  
5 surgeon wants to pursue how to do this  
6 procedure and can follow a program set up by  
7 their society or joint societies, that they  
8 should be allowed to do that without  
9 regulation from the Federal Government,  
10 unless, as has been suggested, it gets out of  
11 hand and the regulations are so flaunted.

12 I don't think that would happen,  
13 but I see regulation as the last step in any  
14 kind of situation of quality.

15 Should we regulate interventional  
16 procedures? Again, the equipment, I strongly  
17 back the idea of having standards there, but  
18 we didn't address any of the other procedures  
19 and I wouldn't want to comment on whether they  
20 should have standards of procedure for the  
21 doctors. The equipment, yes, but the medical  
22 specialists, you hand out the people-to-people  
23 part of it, we don't have any information to  
24 make that decision.

1                   So I think on that, I rest my case.

2                   CHAIRMAN FERGUSON:    I guess that  
3 leaves me.   And I think it has been a great  
4 discussion.   I have learned a lot this week in  
5 talking to different people.   I have learned a  
6 lot at this meeting.   And I side with high  
7 quality.   The same reason we did with MQSA.   I  
8 am very sensitive to the American College of  
9 Surgeons and our colleagues that they have to  
10 be assured that they are not in any way going  
11 to be excluded from the process.

12                   I hate that they feel that way.   I  
13 hear them say, I think Dr. Israel said, you  
14 know, the reason we are here, the reason we  
15 are here and they all, everyone of them, said  
16 we're for higher quality.   We support MQSA.  
17 We want the very best for our patients.   We  
18 want the very best outcomes.

19                   So I really believe that we all  
20 want the same things, but there is a concern,  
21 I think is the best way it was put, that some  
22 how one group of providers will be favored  
23 over the other.   I was very glad to hear Dr.  
24 Barr say no, that's not what is going to

1 happen on my watch. And I think it is on her  
2 watch that we will see what comes forth, if  
3 anything.

4 I think I wrote down some numbers.  
5 There is 800,000 stereotactic biopsies being  
6 done; that's a lot of women. Those women,  
7 just like she said, want to walk in and know  
8 that they are getting the same high level of  
9 care just like they do with the screening  
10 mammogram today. Today they know they are  
11 getting the same baseline. It's not a  
12 variable standard of care.

13 I also agree that it doesn't need  
14 to be -- there needs to be some performance  
15 standards. I liked what the surgeons said  
16 about pathology and not just because the gun  
17 is in the picture. We need that data. We  
18 need the data to know that we have good  
19 pathology correlation.

20 The scariest thing to me about not  
21 doing this is what has been said many times  
22 that 20 percent of our facilities are  
23 voluntarily participating. I promise you it's  
24 that -- they are the very best. They are the

1 ones, just like you said, that we need people  
2 dedicated to doing these procedures. We need  
3 people dedicated to breast disease and  
4 diagnosis.

5           And those people who have  
6 voluntarily gone through the process are the  
7 very best. It's that 80 percent out there  
8 that we need to bring along. And if there  
9 were a way to do it other than regulation, if  
10 there was -- I don't think education will  
11 bring them along. I think some people have  
12 just got to be whipped. And I'm one of them.  
13 I'm one of them.

14           But I think that that will raise  
15 the quality, that will assure women. I've  
16 looked around the table. Every woman on this  
17 Panel spoke in favor, because they are the  
18 ones that are facing it. They are the ones  
19 that are going to walk in the door and want to  
20 know that they are going to have high quality  
21 no matter where they are.

22           And even though I come that way, I  
23 want the surgeons to know that I personally  
24 will do whatever I can to give them, if this

1 proceeds, whatever level of comfort can be  
2 given, because I think they deserve that,  
3 because I think they want to get there. They  
4 want their concerns eased and I want to help  
5 do that in any way.

6 But I am for regulation of both.  
7 And, yes, Ms. Wynne?

8 MS. WYNNE: We're ending really  
9 early today. I would just like to say a few  
10 things before we close the meeting today. Dr.  
11 Barr commented earlier that we're losing quite  
12 a few of our Panel Members. I would like to  
13 thank Dr. Timins, Dr. Williams, Dr. Ferguson,  
14 Dr. Byng and Carol Mount for being on the  
15 Panel for the last four years. They have been  
16 great people to work with. And I know that  
17 you and I, we all appreciate their volunteer  
18 work to be on this Committee.

19 I would like to also tell you the  
20 summary minutes from the last meeting are up  
21 on FDA's dockets. There is a paper out front  
22 that, if you needed to pick that up and get  
23 the website, I can't flip back in here and  
24 give it to you right now, but it's at the

1 fda.gov/dockets.

2 All the slides, all the  
3 presentations from today's meeting will also  
4 be on docket shortly and, not so shortly, the  
5 transcript from this meeting will be up on  
6 docket.

7 Our next meeting is going to be  
8 sometime in the fall of 2008. Now, unless  
9 someone else has something to say, hit it.

10 CHAIRMAN FERGUSON: We're  
11 adjourned.

12 MS. WYNNE: Thank you.

13 (Whereupon, the above-entitled  
14 matter was concluded at 3:35 p.m.)

15

16

17

18

19

20

21

22

23

24

1

2

3

4

5

6

7

8

9

10

11