

**SUMMARY MINUTES
OF THE**

RADIOLOGICAL DEVICES ADVISORY PANEL

OPEN SESSION

**May 23, 2006
Holiday Inn Gaithersburg
Gaithersburg, Maryland**

Attendees
Radiological Devices Advisory Panel Meeting

Open Session

May 23, 2006

Acting Panel Chair

Elizabeth A. Krupinski, Ph.D.
University of Arizona

Voting Members

John D. Bourland, Ph.D.
Wake Forest University School of Medicine

Bharat B. Mittal, M.D.
Northwestern Memorial Hospital

Xiao-Hua Zhou, Ph.D.
University of Washington

Temporary Voting Members

Judy M. Destouet, M.D.
Advanced Radiology

Scot E. Goldberg, D.O., M.B.A.
Women's Imaging Center

E. James Potchen, M.D., J.D.
Michigan State University

Nonvoting Consumer Representative

Jacquelin Holland, R.N.C., C.R.N.P.
The James Cancer Hospital and Solove Research Institute,
Ohio State University

Nonvoting Industry Representative

Deborah J. Moore, B.S.
Windward Medical, Inc.

FDA Personnel

Nancy Brogdon
Director, Division of Reproductive, Abdominal, and Radiological Devices

Sousan S. Altaie, Ph.D.
Scientific Policy Advisor, Office of In Vitro Diagnostic Device Evaluation and Safety

Thomas P. Gross, M.D., M.P.H.
Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics

Robert J. Jennings, Ph.D.
Office of Science and Engineering Laboratories, Division of Imaging and Applied
Mathematics

Richard Kaczmarek
Office of Communication Education and Radiation Programs, Division of Mammography
Quality and Radiation Programs

Sophie Paquerault
Office of Science and Engineering Laboratories, Office of Device Evaluation

Robert A. Phillips, Ph.D.
Chief, Radiological Devices Branch

Nancy G. Wersto
Panel Executive Secretary

Public Speakers
Colleen Hittle-Densmore
The Anson Group, LLC, for Giotto USA

Andrew Vandergrift
Fujifilm Medical Systems USA, Inc.

Eunice Lin
Konica Minolta Medical Imaging

John M. Sandrik, Ph.D.
GE Healthcare

Sami Tohka, Ph.D.
PLANMED OY

Robin Winsor
Imaging Dynamics

Carol Ryerson
Eastman Kodak

Etta D. Pisano, M.D.
University of North Carolina, Chapel Hill, North Carolina

Margarita Zuley, M.D.
American College of Radiology

John Goble
Sectra

Robert Uzenoff
Fujifilm Medical Systems USA, Inc.

Julian Marshall
R2 Technology

CALL TO ORDER Acting Panel Chair Elizabeth A. Krupinski, Ph.D., called the meeting to order at 10:17

a.m. She noted for the record that the voting members present constituted a quorum and asked the panel members to introduce themselves.

Panel Executive Secretary Nancy G. Wersto read the conflict of interest statement.

A waiver was granted to E. James Potchen, M.D., J.D., in accordance with 18

U.S.C. Section 208(b)(3). She announced that Deborah J. Moore would serve as industry representative. Ms. Wersto then read the appointment of Judy M. Destouet, M.D., Scot

E. Goldberg, D.O., M.B.A., and E. James Potchen, M.D., J.D., to temporary voting status for the duration of the meeting and of Elizabeth A. Krupinski, Ph.D., to acting chair.

Nancy Brogdon, Director, Division of Reproductive, Abdominal and Radiological Devices, acknowledged the work of Dr. Prabhakar Tripuraneni, whose term as a panel member recently ended.

UPDATE ON FDA RADIOLOGY ACTIVITIES

Robert A. Phillips, Ph.D., Chief, Radiological Devices Branch, briefed the panel on interactions with manufacturers since the last panel meeting. There have been very few original PMAs, but FDA has approved changes for various devices.

Guidance on bone sonometers is out for comment. These devices measure bone status using ultrasound as opposed to the more familiar bone densitometry using x-ray. Comments received will likely be used to reclassify bone sonometry from Class 3 to Class 2.

CRITICAL PATH INITIATIVE IN MEDICAL DEVICES

Sousan S. Altaie, Ph.D., Scientific Policy Advisor, Office of In Vitro Diagnostic Device Evaluation and Safety, gave a presentation on FDA's Critical Path Initiative, a serious effort to make product development more predictable and less costly. Critical path tools are used in the assessment of safety to predict whether the product will be harmful; in proof of

efficacy to determine if it will have medical benefits; and in industrialization to ensure the product is manufactured with consistent quality.

For devices, biocompatibility databases are one example of a safety tool; surrogate endpoints and computer simulation modeling are possible effectiveness tools; and practice guidelines and validated training tools are examples of industrialization tools. **CONDITION OF APPROVAL STUDIES: RECENT CHANGES IN CDRH**

Thomas P. Gross, M.D., M.P.H., Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, discussed recent changes in the condition of approval study program. FDA has broad legal authority to require manufacturers to conduct condition of approval studies.

An internal evaluation of the program revealed that there were limited procedures for tracking these studies, IT systems were deficient, high turnover of lead reviewers resulted in a lack of continuity and follow-up, and there was a lack of premarket resources.

In January of 2005 the program was transferred from premarket to postmarket in the Office of Surveillance and Biometrics because resources were available in the office, as was a staff of epidemiologists expert at designing observational studies. In April of 2005 an automated tracking system was established for the program.

Epidemiologists were added to the PMA review team. They are charged with development of a postmarket monitoring plan during the premarket review process, development of postmarket questions, and design of study protocols. To help motivate good studies, there need to be important postmarket questions. Also, CDRH will be posting the status of the studies on the agency's website, and, when necessary, penalties may be issued for failure to conduct condition of approval studies. **FDA PRESENTATIONS**

Robert A. Phillips, Ph.D. began the discussion concerning reclassifying full field digital

mammography (FFDM) systems. New systems are intended to replace screen film mammography (SFM) systems and thus have the same indications for use, screening and diagnosis of breast cancer.

Devices like FFDMs that enter the market after the enactment on May 28, 1976 of the medical device amendments to the Food, Drug, and Cosmetic Act are Class 3 devices, meaning they must be approved through the PMA process unless they can show substantial equivalence to a device already on the market prior to the date of enactment. Since they were on the market prior to that date, SFM systems secure marketing clearance through the 510(k) process.

Following a 1996 panel meeting, several companies submitted 510(k)s for FFDM systems using receiver operating characteristic (ROC) curves to attempt to show substantial equivalence to SFM systems. These attempts were unsuccessful largely due to large intra and inter-reader variability in interpretation.

Four FFDM systems have been approved through the PMA process: the General Electric Senographe 2000D in January of 2000; Fischer Imaging's SenoScan in September of 2001; Hologic's Lorad in March of 2002; and the Siemens Mammomat Novation in August of 2004.

Dr. Phillips discussed what is reviewed during the PMA process for FFDM systems and the problems that have been encountered with marketed FFDMs. He then discussed the reasons why the panel is meeting to consider reclassification of FFDMs to Class 2.

One reason is the preliminary results of the Digital Mammography Imaging Screening Trial (DMIST). Also, there is improved understanding of the technology such that appropriate special controls can be developed to assure adequate safety and effectiveness through the 510(k) or substantial equivalence process.

Dr. Phillips concluded with an explanation of the reclassification process.

Sophie Paquerault, Office of Science and Engineering Laboratories, Office of Device Evaluation, discussed the protocol and conclusions of the DMIST trial. It was funded by the National Cancer Institute through the American College of Radiology Imaging Network (ACRIN) and directed by Dr. Etta Pisano from the University of North Carolina at Chapel Hill.

The trial compared reader performance in detection and characterization of breast cancer screening for FFDM and SFM systems. It involved nearly 5,000 asymptomatic women who presented for screening mammography at certain free clinical sites. Patients underwent both FFDM and SFM mammography.

Five FFDM systems were used, the Fischer SensoScan, Fuji's Computed Radiography System, GE's Senographe 2000D, and Hologic's Digital Mammography System and the Selenia. Reader performance was evaluated using the area under the receiver operating characteristics curve or AUC.

For FFDM, the area under the curve was .78; for SFM it was .74, and the difference was not statistically significant. Performance did not vary significantly according to race, risk of breast cancer, or the type of FFDM system used. In the overall population, there was no significant difference in diagnosis accuracy, but FFDM was more accurate in women under fifty, those with dense breasts, and in pre- or perimenopausal women.

Robert J. Jennings, Ph.D., Office of Science and Engineering Laboratories, Division of Imaging and Applied Mathematics, discussed risks to health and mitigation of those risks in the context of device reclassification. The risks to health with FFDM are essentially the same as for SFM, such as misdiagnosis, image retakes, x-ray exposure, excessive breast compression, electric shock, and infection or irritation due to compression.

The main mitigation of those risks is the 510(k) guidance document, but there are other special controls including voluntary standards with which manufacturers may comply. The guidance document will propose having a device description, physical laboratory data,

comprehensive evaluation of AUC systems, more extensive phantom scoring, reader evaluation of clinical films as in American College of Radiology (ACR) accreditation rather than a large clinical trial, as well as requiring various information on imaging performance. FDA also wants information on the operation of automatic exposure control systems, all available operating modes, and how AUC systems control for signal to noise or contrast to noise ratios as a function of breast thickness.

Preliminary data on patient dose shows that digital systems produce on average 15 percent lower dose than SFM units, but it is still necessary to look at individual systems.

FDA recommends that physical laboratory data be collected according to standards or recommendations, that AUC performance result in patient dose as a function of breast thickness that conforms at least to the European Reference Organization for Quality Assurance in Mammography (EUREF) acceptable level.

For clinical data, FDA would like sets of films covering a range of patient characteristics and machine settings. In the area of labeling, FDA would like a detailed quality assurance program, an explicit summary of the physical device description and laboratory data, and cleaning and disinfection procedures. Although it cannot be mandated, FDA would like the labeling to recommend that facilities maintain an adverse event log.

One voluntary standard for a generic FFDM quality assurance program being developed by ACR and NEMA, once available, could be used to satisfy, by reference, the proposed labeling requirement for quality assurance.

Quality system regulations (QSRs) will ensure that devices continue to be safe and effective once production begins and provide for monitoring of device problems and inspections of manufacturers. The Medical Device Reporting Regulation provides an independent means of obtaining information on adverse events.

Richard Kaczmarek, Office of Communication Education and Radiation Programs, Division of Mammography Quality and Radiation Programs (DMQRP),

discussed the potential effect of reclassifying FFDM on screening mammography. He talked about the Mammography Quality Standards Act (MQSA), which is enforced by DMQRP. The regulations are oriented towards SFM systems, the dominant technology when the regulations were developed. In the PMA process, FDA has required manufacturers to provide information regarding accepted digital imaging metrics. As a result all FFDM systems which have gone through that process meet the requirements of the agency for digital imaging technology. Quality control tests allow facilities to ensure that their equipment operates according to the manufacturers' specifications.

Dr. Zhou asked about variability based on readers and centers in film and digital ROC curves in the DMIST trial. He also noted that for women under fifty FFDM and SFM systems are not equivalent since FFDM performs better in that population. He also asked for clarification of how the equivalency test for the two systems was performed.

Ms. Paquerault said that the data was not controlled by FDA and that it was an overall study and that the average variability was quite small.

Dr. Krupinski asked if there was data on percentage of softcopy versus hardcopy reading in current clinical practice. Dr. Jennings believed the unsubstantiated numbers were around 95 percent softcopy. Dr. Krupinski then asked why softcopy rather than film wasn't used for the control process. Dr. Jennings said that would be desirable but noted the difficulty in properly displaying the images to FDA's readers.

Dr. Bourland asked about the performance standards for both software and digital detectors. Dr. Phillips replied that the software guidance was general guidance to ensure that software is designed in a structured and journeyman-like fashion. Similarly the digital detector

guidance is generic to all solid-state detectors. The standards are included in the guidance document by reference. Dr. Bourland then asked about the potential impact on manufacturers. Dr. Phillips said that one difference would be that under 510(k) manufacturers could make changes with no potential to significantly change the safety or effectiveness without first going to the agency. Another is that for devices brought to market following reclassification, manufacturers would not have to use the PMA process nor conduct extensive clinical studies.

OPEN PUBLIC HEARING

Colleen Hittle-Densmore, The Anson Group, L.L.C., for Giotto USA, spoke in favor of the reclassification and largely reiterated points previously made. She noted there were important differences in data management aspects but stated they were well suited for special controls. In closing she noted that special controls had been used effectively for ultrasound and other diagnostic imaging modalities and agreed they would be appropriate for FFDM.

Andrew Vandergrift, Fujifilm Medical Systems USA, Inc., noted that Fuji produced the first digital radiographic system and that their FFDM system was used in the DMIST trial. He said that both indirect and direct fixed array detectors had been clinically proven as had devices using computed radiography (CR). Mr. Vandergrift further pointed out that there were substantial imaging performance differences among various vendors with significant implications for safety and effectiveness.

He also noted that digital mammography had not been proven below a certain level of DQE and that more clinical investigation would be necessary to establish acceptable levels. Mr. Vandergrift concluded by saying that any regulatory change regarding FFDM must ensure that marketed products demonstrate image quality performance equivalent to or better than devices extensively clinically evaluated.

Eunice Lin, Konica Minolta Medical Imaging, said that her company supports the proposed reclassification and believes that standardized methods could be used to characterize the performance of mammography systems.

Ms. Lin described two of her company's devices, the REGIUS 190 CR computer radiography system and the REGIUS PureView mammography system. Konica believes that clinical trials are not necessary but thinks that DMIST as well as PMA studies validate the system performance data. Ms. Lin described various tests that Konica uses to assess its devices.

John M. Sandrik, Ph.D., GE Healthcare, said that FFDM has shown effectiveness equivalent to SFM for screening and diagnosis of breast cancer in PMA studies, post-marketing studies, and DMIST. Safety and effectiveness have been shown, and there is a special control in the form of a guidance document that can be used following reclassification. MQSA programs serve as a source of data on device performance. NEMA, the National Electrical Manufacturers Association, has developed standard QC templates for manufacturers of displays and printers used with FFDM. The ACR is developing a QC plan for digital mammography.

Dr. Sandrik concluded by stating that GE Healthcare supports the reclassification of FFDM to Class 2.

Sami Tohka, Ph.D, PLANMED, agreed with previous presentations and said that PLANMED supports reclassification as well.

Robin Winsor, Chief Technical Officer, Imaging Dynamics, stated that reclassification would help smaller companies such as her own bring lower cost systems into the market. Reducing costs not only accelerates the time to market for new technologies but also makes technology much more widely available.

Carol Ryerson, Director of Regulatory and Clinical Affairs, Eastman Kodak, said that her company also supports the reclassification.

OPEN COMMITTEE DISCUSSION

No panel members had general questions or points for discussion.

FDA QUESTIONS

1. Do you believe that the risks to health from the device have been identified and that the mitigations for these risks are appropriate?

If not, what additional risks to health are presented by the device? What mitigations for these risks would provide a reasonable assurance of safety and effectiveness?

Panel members agreed that the risks had been identified and appropriately mitigated. One member referred to the fifteen percent reduction in radiation dose. Another panel member felt it would make it more effective and efficient to diagnose breast cancer.

2. Do you believe that the information to be required for 510(k) clearance will be sufficient for determining substantial equivalence between a new device and the predicates?

Panel members generally agreed that the information required for 510(k) would be sufficient to determine substantial equivalence. There were some concerns regarding system and reader variability which the panel hoped to address later in the afternoon.

3. Do you believe the materials presented support reclassification of FFDM devices?

Panel members agreed that the materials presented support reclassification of FFDM devices.

4. If reclassified, are there any concerns that you believe need to be addressed in the labeling (includes direction for use, indications, and contraindications) of these devices?

Panel members generally agreed there were no additional concerns that need to be addressed besides incorporating the guidance document into the reclassification. One member

inquired as to how new detector technologies might be addressed following reclassification.

An FDA representative responded that the agency has broad flexibility in determination of substantial equivalence and that innovative technologies are introduced through that process. He also clarified that the four FFDM systems approved under the PMA process would become the predicate devices for future FFDM systems. Furthermore, he stated that the reclassification included both direct, as are used in digital mammography, and indirect detectors, as are used in computer radiography.

SECOND OPEN PUBLIC HEARING

Etta D. Pisano, M.D., University of North Carolina, Chapel Hill, discussed preliminary data from DMIST. Digital mammography was found to have better diagnostic accuracy in three subgroups, but there was no difference in the entire population.

The AUC difference was quite small over the entire population. For women with fatty breasts the difference was negative, meaning film performed better, but the difference was not significant.

Using the BIRADS scale to look at sensitivities, digital was 27 percent more sensitive in women less than 50. The similarity of the specificities suggests that the reason the areas under the ROC curves were different was that more cancers were found with digital and there was no increase in false positives. Positive predictive values were also similar.

Looking at the numbers of cancers found per machine type, Dr. Pisano noted that there wasn't much power for any individual machine. She discussed the three machines which detected the greatest numbers, Fischer, Fuji, and GE and noted that there was an insignificant difference in area under the ROC curve in favor of film.

Dr. Pisano supported the reclassification and suggested that tomosynthesis should be

changed to the 510(k) process as well.

Dr. Zhou asked about reader variability, and Dr. Pisano responded that it was equivalent for digital and film. Dr. Zhou then asked about variability by center, and Dr. Pisano said that that analysis had not been done yet but would be. Dr. Zhou asked about the gold standard, and Dr. Pisano said it was biopsy proof. Patients with a negative diagnosis were followed for 15 months before the diagnosis was assumed to be correct.

Dr. Goldberg asked whether there was reduced radiation dose regardless of breast composition. Dr. Pisano said she believed that was the case but did not know.

Dr. Mittal asked how radiation dose was measured, and Dr. Pisano said that a TLD chip was imposed on the mammogram for a subset of the patients. Dr. Krupinski said the details had been published in Dr. Yaffe's paper.

Margarita Zuley, M.D., American College of Radiology, stated that the College supports the reclassification based on the studies already discussed as well as other smaller ones. Most radiologists are comfortable with the technology and feel it is safe and effective.

One reason for ACR's support is it will eliminate the need to recruit patients into PMA studies in which they will be double exposed. Also, manufacturers have been slow to innovate because of the challenges of the PMA process.

ACR also recommends that FFDM be broken into two separate devices, acquisition units and processing algorithms. This separation could occur after detector corrections are made from raw data and would allow for better comparison between images from different devices and eliminate the need to try to schedule patients to return to the same units.

With SFM, even with a different acquisition unit similar images can be created if the same screen film combination and chemicals are used. A current problem with digital mammography is that image look will change any time the manufacturer updates its processing

algorithms because radiologists are unable to go back to previous algorithms. If radiologists were able to select processing algorithms, they would not have to constantly adjust for the variability of the technology.

John Goble, Sectra, said that digital mammography can improve patient outcomes, reduce costs, and improve access to quality care in under-served populations and that reclassification of FFDM will serve these interests by expediting innovations into the market.

Sectra also feels that the technology is sufficiently well understood for the development of adequate special controls. Effective quality procedures have already been developed for use in DMIST, and existing QSRs can ensure overall device compliance.

Sectra recommends the use of available standards to expedite the process.

Mr. Goble also hoped the guidance document would separate the technology and make it easier for clinicians to compare to prior exams.

Dr. Potchen expressed his strong support for the comments of Mr. Goble. Dr. Mittal asked Dr. Pisano whether the issues raised by Dr. Zuley regarding processing algorithms had come up in DMIST. Dr. Pisano responded that it was not really an issue in DMIST because most of the vendors were new and repetitive screens were not done. She agreed with the previous speakers that year-to-year image processing changes are problematic in that they make interpretation more difficult and was also concerned about not being able to compare between vendors.

Dr. Krupinski asked whether the digital images were printed or read softcopy in DMIST. Dr. Pisano said it depended on the vendor: GE used all softcopy; Fuji used all hardcopy; Fischer was a combination; Trex Lorad was hardcopy, but when they switched to Hologic it was softcopy but remained the same within vendor.

Dr. Potchen asked whether the guidelines could address the different variations in

vendors from year to year. Dr. Krupinski said that DICOM and IHE addressed that issue and that they could be incorporated into the guidance. Ms. Brogdon confirmed that the language could be incorporated.

Dr. Bourland suggested there may be difficulties in separating the algorithm from the detectors because algorithms may do certain things based on the characteristics of the specific detector. He wondered whether there might be multiple stages of algorithms which could be separated. Dr. Pisano said that data from a study she did comparing different image processing algorithms suggested that it would not be overly burdensome to require vendors to make their algorithms substantially equivalent.

Dr. Zuley clarified that the mammography subgroup of IHE was working to ensure that acquisition units can display all vendors' images correctly and not working on differences in processing.

Robert Uzenoff, Fujifilm Medical Systems USA, Inc., said that the types of image differences Dr. Zuley referred to were also found in SFM. He also noted that some companies have more experience in image processing and that different processing technologies are proprietary. He suggested that this could be an area for ACR recommendations rather than device requirements. Mr. Uzenoff also recommended that individual clinicians be able to make their own determinations regarding what they want images to look like.

Dr. Potchen said that MQSA required very similar images and that most radiologists had accepted a national standard. Dr. Destouet suggested that year-to-year differences were not as dramatic as what Dr. Zuley referred to.

Robin Winsor, Imaging Dynamics, agreed with the comments of Mr. Uzenoff. He referred to the difference between data processing and image processing and suggested that base data that had been data processed but not image processed could be made available if an

institution wanted to utilize a different processing algorithm.

Julian Marshall, R2 Technology, agreed with Dr. Zuley that it is difficult to interpret and compare prior images which a patient may present with and urged that the point at which the acquisition modality is done with detector corrections be identified so that images can be better compared.

CLASSIFICATION QUESTIONNAIRE AND VOTE

Marjorie G. Shulman, Office of Device Evaluation, first led the panel through the General Device Classification Questionnaire.

1. Is the device life-sustaining or life-supporting?

The panel voted no unanimously.

2. Is the device for a use which is of substantial importance in preventing impairment of human health?

The panel voted yes unanimously.

3. Does the device present a potential unreasonable risk of illness or injury?

The panel voted no unanimously.

4. Did you answer “yes” to any of the above questions?

The panel did and thus skips to question 6.

6. Is there sufficient information to establish special controls in addition to general controls to provide reasonable assurance of safety and effectiveness?

The panel voted yes unanimously and thus classified the device as Class 2.

7. If there is sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness, identify the special control(s) needed to provide such reasonable assurance for Class 2.

The panel unanimously identified the guidance document as the necessary special control. Questions 8 and 9 were skipped because they deal only with performance standards. Question 10 was skipped because it applies to Class 3.

11. Identify the needed restriction(s).

Dr. Mittal said that the devices should only be used by those trained to do so, but that restriction is already part of MQSA and therefore the guidance document. The panel agreed the only restriction was the need for a prescription.

Ms. Shulman moved on to the Supplemental Data Sheet. For numbers four and five the panel agreed that the indications for use and health risks were as presented to the panel.

Under number six, the panel recommended the devices be Class 2 and gave the reclassification a high priority.

For number seven, the panel thought that the general and special controls were able to mitigate the risks or that the risk was not unreasonable. For number eight the panel said the information on which the reclassification was based was as presented to the panel. No additional restrictions were identified for number nine. Number ten is applicable only to Class 1 devices.

For number eleven the panel agreed that the devices should not be exempted from the premarket notification of the 510(k) process. For number twelve concerning other existing standards, Dr. Bourland responded that it was as discussed.

Dr. Potchen asked about standardization appropriate to the user. Ms. Shulman said that would be appropriate on the general questionnaire as “Other” in question 7. Dr. Potchen clarified that he wanted standardization so there would be similarity when looking at multiple images from year to year.

Dr. Zuley said that ACR wanted radiologists to have the ability to choose a look that suits them or their practice and pointed out that the screen/film combinations and chemicals

used only had to be the same at the level of the facility. Dr. Bourland noted the difficulty in determining precisely what constitutes the raw image with FFDM.

Dr. Zhou said that software was a part of the system and could not be standardized because some companies are better than others at producing software. Dr. Potchen responded that images can be compared using DICOM standards.

Dr. Krupinski called for a vote on the completed forms and reclassification into Class 2 requiring premarket notification and that the special control be a guidance document. Dr. Potchen made the motion, and Dr. Mittal seconded it. The motion passed unanimously.

Ms. Holland was satisfied the reclassification would meet the needs of the general population.

Ms. Moore seconded Ms. Holland's comment and said the reclassification would allow for innovation, make the technology available to more women, and potentially improve the technology.

Dr. Bourland believed the technology had been shown to be clinically effective and thought the reclassification would help propagate the technology.

Dr. Mittal agreed with the previous comments.

Dr. Destouet hoped the reclassification would help make the technology less expensive and thus more widely available.

Dr. Krupinski agreed and felt that smaller companies would be able to develop FFDM systems and hoped women in rural areas would benefit from direct digital telemammography.

Dr. Zhou thought the evidence demonstrated that the device poses equal or less risk than SFM systems and is still effective.

Dr. Goldberg had nothing to add.

Dr. Potchen said FFDM would improve care in some patients and decrease radiation dose

for all patients. He also highlighted that eliminating the requirement for PMA review would eliminate the need for double exposure of patients undergoing PMA studies of FFDM systems.

ADJOURNMENT

Dr. Krupinski adjourned the meeting at 2:48 p.m.

I certify that I attended this meeting of the Radiological Devices Advisory Panel on May 23, 2006, and that these minutes accurately reflect what transpired.

Nancy G. Wersto
Executive Secretary

I approve the minutes of the May 23, 2006, meeting as recorded in this summary.

Elizabeth A. Krupinski
Chairperson (acting)

Summary prepared by

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