MS. BROGDON: That's right.

DR. CASTELLINO: Tab 1, page 1.

DR. IBBOTT: And this is being presented also in the sponsor's presentation. Are there comments about this? From a physicist's point of view it seems straightforward but perhaps that's not the appropriate -- I'm not the appropriate reader for this. It's the person who would be using the system.

DR. SOLOMON: This may be a good place to include the always and never thing that we've been talking about. I don't know if this is the appropriate place.

DR. KRUPINSKI: This is also why it would be interesting that we could have seen the difference between the classic and the not classic. Here you're talking more about classic nodules and performance based strictly on those to see if this truly is appropriate.

MR. MILLER: Just to clarify quickly, the primary analysis is based on all unanimous nodules. It was one of the sensitivity analyses that --

DR. KRUPINSKI: Right, but not all of
those were classic.

MR. MILLER: That's correct.

DR. SOLOMON: The only other thing, I guess, is to possibly emphasize the fact that somebody doesn't realize that ground glass nodules would not be included in this. If I just read it kind of casually, it's a solid pulmonary nodule, I might think all nodules would be included, whereas you might want to distinguish the fact that the system is not meant for ground glass nodules or other things.

DR. KRUPINSKI: You mentioned satisfaction of search here and I'm just wondering if there is a reverse. You are going through -- there's all these other abnormalities. You note, yeah, there's atelectasis back here. Then you go and you bring up the nodules. Has anybody looked at the possibility that you are going to get a reverse SOS and now you're all concentrated on the nodules and you forget to report the initial findings. Has anybody looked at that?

I mean, if you're not going to give your report, you know, if you're not going to sit there and
dictate before you look at the CAD, there's the possibility that now you're all wrapped up in the CAD and all of a sudden the other stuff goes out of your mind. Clinically do you see that happening?

MR. MacMAHON: Well, I haven't actually used this system so I'm just speaking from general experience. Of course, in reading CT scans, as I think Dr. Castellino described, we go through it multiple times already.

We go through the mediastinum and personally I make notes, or my resident makes notes as we go through because it's really hard to remember all of the abnormalities in all of the areas so I take a second run or a third run and look for pulmonary nodules and abnormalities and make more notes. My instinct is that it would not be an issue.

DR. TRIPURANENI: As I read through this again, I guess now that we have Dr. Stark's comments and others, the second paragraph is an interesting paragraph. I don't want to wordsmith. That is certainly not my expertise.

If you look at the first sentence in the
second paragraph, it kind of vents with the other recognized causes of a suboptimal view. I'm just raising the question. Potentially a radiologist could actually bar the system by looking at the indications. I'm not saying he will. The hole in the whole system there he could actually say, "I can slack off a little bit."

The system is going to pick up the nodule there." I think once again always and never are very important to really put it on the face kind of stating it every single time. The whole system is predicated on those two.

DR. CONANT: I think there could also be further contraindications in the warnings and precautions. I mean, again, just emphasizing the always and the nevers but I'm not sure you can dictate what people actually do.

DR. STARK: But isn't it fair to say that given the combination that they are making a claim here that it relieves you of fatigue and distraction or other recognized causes of suboptimal review. I mean, these are bold statements that are going to be
used by marketing people to radiologist to look at this.

DR. CONANT: Where does it say "relieves?"

DR. STARK: I'm sorry. It lapses. I misconstrued it. The chance of observational lapses by the reader due to fatigue. Well, the next patient that the same radiologist read after having to deal with these false positives, one could make an argument there's more risk to the next patient.

DR. CONANT: One way to deal with this is basically the second paragraph nobody really likes a lot because who wants to read about our lapses and fatigue, right? Maybe that's not necessary here if always and never is emphasized. Is that happy?

DR. STARK: I think if the FDA has our point that we are unhappy with the language, I'll leave it at that.

DR. CONANT: We don't like to be called tired and distractable.

DR. IBBOTT: Mr. Burns.

MR. BURNS: If I remember correctly earlier during your presentation, you indicated this
algorithm does not work with low dose chest CT. Correct?

DR. CASTELLINO: No, I did not. I said that the clinical cases that were collected for the ROC study were all clinically indicated studies. That is, they did not contain any type of screening low-dose exam. In our test database a substantial number of the cases are, in fact, low-dose CT scans and performs quite well in that, or equivalently well in that. But specifically for the ROC study they just happen to be clinically indicated exams like you see in most hospital practices or out-patient practices.

MR. BURNS: Okay. So what you have in the warnings regarding the MAS levels covers that issue. Correct?

DR. CASTELLINO: Correct.

DR. IBBOTT: All right. Then let's move on again to the fourth question. I think we have an indication where we're going on this one, too. If the PMA were to be approved, please discuss whether the above or any other issues not fully addressed in the

PMA (A) require post-market surveillance measures in
addition to the customary medical device reporting. Several people have suggested that they would like to see additional studies done if this device were to be approved. Those of you who have called for that, would you like to elaborate?

DR. STARK: Well, I've mentioned -- actually seen data. I'm not inclined to argue with the perceptions because I think it's likely correct that low-dose contrast but the public needs to see this. This needs to be written down somewhere so it's objective and hopefully some statistics can be applied to it.

Artifacts due to common thoracic interventions such as excision of one of these nodules, a clip left behind, radiation and damage, patients who can't put their arm over their head. I think those are the major things that are medical in nature. I think one of the things -- there needs to be something negotiated with the FDA in terms of minimum.

You've got already minimum CAT scan or technology but as CT technology evolves what would
trigger a change in surveillance. It may be a different category but under this if this PMA were approved, again, the technical experts at the FDA need to negotiate what is some minimum quantum change in the technology that would require a new PMA and review. Is it going to remain a class three device or what would it be? Is it going to be a 510(k) application of substantial equivalence?

Again, I alluded to earlier I don't know what algorithm is used here and I'm not a computer scientist but what is a trivial change to a layman may be very significant to a copyright attorney or a radiologist. If the algorithm switched entirely to being, say, a MIP of subtraction or something like that, at some point there has to be some disclosure and review, I would think, of the performance.

DR. O'SHAUGHNESSY: Can I just comment on that last point? They are very well established guidelines that FDA has with manufacturers as to what requires a change. Any change in the product has to be evaluated against certain criteria and then those will be based on the approved labeling. Everything
that the panel contributes here today will go into
deciding what changes in the product require further
review by FDA.

DR. STARK: Well, then for the FDA's sake
I'm not aware of what those are and they will do
diligently well to merge that with some of the
insights we have learned today because certainly we've
heard a lot of novel things today that are novel to
everybody in this room. They are going to be novel to
the people that developed those guidelines perhaps
with the breast nodule detection in mind but they may
not be totally opposite here.

DR. CONANT: The things that I raised
before just to summarize, and I'm not sure where they
fit in preapproval or post-approval because I'm not
sure if we made that decision yet but, again, it's a
case-based analysis versus multiple nodules,
quadrants, all that. You've heard that multiple
times. A little more insight based on case-based
analysis of false positives and false negatives.

I think that's really important. We've
been talking a lot about the false positives but I
think the false negatives are fascinating. What
happens when you've got really defuse lung disease?
One of the exclusion criteria here was greater than 10
nodules. I mean, what about someone who has -- I
don't know what disease that would be but a gazillion
-- yeah, sarcoid, right. Granulomas everywhere, old
TB, whatever. Where can this really be used
effectively and where does it really just fall down.

Also your cases were over 19 years of age.

What happens in the pediatric? You know people are
going to start applying this everywhere. That just
came to me recently. That has to be included, I
guess, in the labeling and certain analyzed. Whether
it's pre-post approval, I mean, that's what we're here
for.

DR. SOLOMON: I would just add the
thoughts on making the study more real life so
collecting data maybe on the perspective fashion that
will essentially test the system in real life
conditions. Real-life conditions for the doctor,
real-life conditions of diseases and everything, and I
guess a real-life test essentially.
DR. TRIPURANENI: I would recommend the same. I think whether it's pre or post I think there needs to be a follow-up study of the patients that are going to go through this to see what is the clinical impact ultimately.

DR. IBBOTT: All right. Well, I think we're on the verge then of deciding if it's going to be a pre or a post-approval study. Unless there are other concerns that you want to address now, I suggest that we move on.

We now come to a second half-hour open public hearing session. If there are any individuals wishing to address the panel, please raise your hands and identify yourselves at this time. Seeing none, then we move on.

Before we move to the panel recommendations and vote, is there anything additional the FDA would like to address?

DR. DOYLE: Now that the panel discussion is over, we would ask the sponsors to go back to their seats, please.

DR. WAGNER: Fear not. I will not make a
technical comment but since Dr. Blumenstein's position is heavily influenced by some of his statistical comments, I would just like to tell you that the issue about correlation across modalities has been addressed in the literature by a number of authors including myself and it's at the bottom of the third page of the references there.

Modalities are not a random effect but cases and readers are. The entire correlation structure is accommodated by the model here. Also the sampling scheme does sample the intra-reader variability, as I said this morning. Two out of three of your points are, in fact, addressed in the literature. Thank you.

DR. IBBOTT: And, finally, is there anything else the sponsor would like to address?

DR. O'SHAUGHNESSY: No, thank you. We appreciate the questions very much.

DR. IBBOTT: Thank you.

DR. DOYLE: All right. We will now move to the panel's recommendations concerning PMA P030012. The Medical Device Amendments to the Federal Food,
Drug, and Cosmetic Act (the Act) as amended by the Safe Medical Devices Act of 1990, allows the Food and Drug Administration to obtain recommendation from an expert advisory panel on designated medical device premarket approval applications, PMAs, that are filed with the agency.

The PMA must stand on its own merits and your recommendation must be supported by safety and effectiveness data in the application or by applicably publicly available information. Safety is defined in the Act as reasonable assurance based on valid scientific evidence that the probable benefits to health under conditions of intended use outweigh any probable risks.

Effectiveness is defined as reasonable assurance that in a significant portion of the population, the use of the device for its intended uses and conditions of use when labeled will provide clinically significant results.

Your recommendation options for the vote are as follows: Approvable if there are no conditions attached. Approvable with conditions. The panel may
recommend that the PMA be found approvable subject to specified conditions such as physician or patient education, labeling changes, or further analysis of existing data. Prior to voting all the conditions should be discussed by the panel.

Finally, not approvable. The panel may recommend the PMA is not approvable if the data do not provide reasonable assurance that the device is safe or if a reasonable assurance has not been given that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling. If the vote is for not approvable, the panel should indicate what steps the sponsor may take to make the device approvable.

DR. IBBOTT: All right.

DR. TRIPURANENI: May I ask you to read the effectiveness statement again please? I want to listen to it again.

DR. DOYLE: I would be happy to do that. Effectiveness is defined as reasonable assurance that in a significant portion of the population, the use of the device for its intended uses and conditions of use
when labeled will provide clinically significant results.

DR. TRIPURANENI: Thank you.

DR. IBBOTT: Would anyone on the panel care to make a motion?

DR. BLUMENSTEIN: I move "not approvable."

DR. IBBOTT: It's been moved not approvable. Is there a second to this motion?

DR. STARK: I'll offer a second.

DR. IBBOTT: I'm sorry?

DR. STARK: I would offer a second.

DR. IBBOTT: All right. It's been moved and seconded. Is there discussion then of this motion?

DR. KRUPINSKI: Can we discuss the procedure? Do we discuss it --

DR. STARK: And then vote.

DR. IBBOTT: And then we will vote.

DR. KRUPINSKI: On that motion?

DR. IBBOTT: On this motion.

DR. KRUPINSKI: And then it takes two-thirds to --
DR. STARK: Majority.

DR. KRUPINSKI: Majority.

DR. STARK: If that motion doesn't pass, then we'll ask for another motion.

DR. CONANT: I'll say something. I think there is a lot of very rich data here. There's more data we'd like, of course, that they don't have like follow-up studies to your follow-ups. You know, what happened to the patients. But within the data that they've given us, I'm sure they can look at it by case and look at false positives, even false negatives.

I would hesitate to jump yet to not approvable without at least getting that data that should be obtainable without IRBs and all that stuff because you guys should have it on those spreadsheets by patient and have a second look at that. That's where I stand with the non-approvable part.

DR. SOLOMON: I agree with what you just said. I mean, I think we're put in a difficult position here. I think all of us seem to be asking for more clinically relevant case data. It seems like something you might have but we don't have that...
information right now. That's difficult when the statement for efficacy says clinically significant results and it's hard for us without having necessarily those clinically relevant information. I think that pretty much sums up the issue right there.

DR. TRIPURANENI: As a clinician we have high-tech in radiation therapy using lots of machines and equipment to follow-up things right in there. Having practiced for more than 20 years, I have come to believe that any process you improve typically improves the patient outcomes. Sometimes I believe it's a leap of faith but I think most of the things that you do in the clinic that you improve usually improves the outcome.

I would like to believe that actually the fact that you can actually pick up a few more modules I think eventually will translate into some sort of positive impact on patient management. I really would love to see some data. In fact, that's where I have the dilemma. I asked Mr. Doyle to repeat the effectiveness statement right there.

I think if you follow the rule of the law
right there, I have to make a real leap of faith that actually this is improvement. My personal belief is that any improvement in the process will improve the care so I have to really make the leap of faith to actually work for it but I think it's a dilemma, as Dr. Solomon said, that we're all in. I really would love to see some clinical data.

DR. KRUPINSKI: Just to be specific, I think what we're after is on a patient basis how many normals were then converted to a false positive to abnormal and then how many false negative patients and back and forth on each one. I mean, all possible combinations. I think that is specifically what we're looking for.

DR. STARK: If I could offer another analogy, a brief one.

DR. IBBOTT: Are you addressing the motion?

DR. STARK: Yes, I think so. I'll be brief. The issue of approving gadolinium DTPA for MR scanning of the brain was obvious, as it is here, as we've heard from statisticians and clinicians. Given
the constraints of this study it's really obvious to us that this technology likely makes things better. But unlike the decision to approve gadolinium at a cost of billions of dollars because we saw a few anecdotes where it made things better, no one had an argument that it could make things worse or make things less efficient. Here there are serious concerns that the marginal improvement in efficacy which is perhaps buried in the statistics is offset by a much more obvious risk to the patients here. Forgive me if that's not on the point of the motion but I think the panel has done a lot of soul searching and that's the reason why I think we have hesitated -- my hesitation.

DR. IBBOTT: It seems to me that this device provides information that is not available otherwise and more information is usually better. I share your concern to some extent. Certainly not to the degree that you do, I think, though, that people may misuse the device or take advantage of it to relax in their own vigilance. I think the sponsor can address that.
Yes, Dr. Ferguson.

DR. FERGUSON: It seems to me that the company has followed very carefully the suggestions of the FDA and I applaud them for that. I don't think that we should necessarily penalize them for that unless that's the will of the group here because we are advisers only to the FDA. I would side with those who think that more information is required and I think it's been outlined very, very well what that information should be but I don't think -- I would not vote for nonapprovable.

DR. IBBOTT: Is there anymore discussion before we prepare for a vote?

MS. BROGDON: Dr. Mehta?

DR. MEHTA: Yes, I'm here. I can hear the conversation.

MS. BROGDON: Do you have a comment?

DR. MEHTA: No, actually I don't have anything to add at this point.

DR. IBBOTT: All right. Well, in that case we will proceed to the vote.

MS. BROGDON: Dr. Mehta can vote if he
wishes.

DR. MEHTA: Actually, I'm uncomfortable voting because quite a bit of the time it was breaking up and I feel it would do an injustice to the sponsor for me to vote if I've not heard everything clearly.

DR. IBBOTT: All right. Fair enough.

DR. SOLOMON: Can I ask one question? As far as the categories go if the nonapprovable and the approvable with conditions, where would going back to your data and coming up with some of this clinical evidence that we're asking for fall into?

DR. IBBOTT: Well, at the moment we are voting on a motion to declare this application not approvable. If that motion passes, then that's the end of the discussion here.

DR. DOYLE: But I think Dr. Solomon's question is where would reanalysis of existing data?

DR. STARK: Yes, that was the question based on your definition.

DR. DOYLE: That could be part of approvable with conditions. That comes under that definition.
DR. STARK: Would non-approvable also invite the manufacturer to resubmit answering the same questions? This doesn't go away forever.

DR. DOYLE: No. In fact, if that were the case, we would ask each one of you to recommend what you think the sponsor should do to make the advice approvable.

DR. MOORE: Can I make a point? I would also second Dr. Conant's point that I think a lot of the data that's being asked by the panel is in the data that the sponsor has available. I think that really should be taken into consideration.

Particularly if we're thinking about additional studies here whether it be post-market or pre-market. Obviously if it was non-approvable that would be pre-market. We really need to think about the reasonableness and what it would take for a sponsor to do that.

I think the companies worked very well with FDA in trying to identify what is appropriate. I think it's not only FDA that's kind of worked on that but sort of the industry of what's appropriate for
evaluating this. I think that needs to be taken into consideration.

DR. IBBOTT: All right. We will proceed to the vote then and I'll remind you that the motion is not approvable. I'll ask you to state whether you vote yes which means that you are in favor of declaring not approvable, or no in which case you disagree with the motion and would consider a different motion, or abstain. We note that Dr. Mehta has abstained. Dr. Krupinski, I would like to start with you.

DR. KRUPINSKI: No.

DR. IBBOTT: No. Thank you. Dr. Conant.

DR. CONANT: No.

DR. IBBOTT: Thank you.

DR. FERGUSON: No.

DR. IBBOTT: Dr. Solomon.

DR. SOLOMON: No.

DR. IBBOTT: Dr. Blumenstein.

DR. BLUMENSTEIN: Yes.

DR. IBBOTT: Dr. Tripuraneni.

DR. TRIPURANENI: No.
DR. IBBOTT: Dr. Start.

DR. STARK: Yes.

DR. IBBOTT: All right. Well, we have two in favor, five opposed, and one abstention. This motion does not carry. We now come back to entertaining another motion. I would like to ask if someone on the panel would like to make a motion.

DR. KRUPINSKI: Approve with conditions.

DR. IBBOTT: The motion is approve with conditions. Is there a second?

DR. FERGUSON: Second.

DR. IBBOTT: Dr. Ferguson. Now, we've had quite a bit of discussion but perhaps other Dr. Krupinski or Dr. Ferguson would like to speak to the motion. I'm sorry. The next step is to establish the conditions.

DR. KRUPINSKI: One at a time?

DR. IBBOTT: One at a time, yes.

DR. KRUPINSKI: One condition would be for the post-analysis of the by-patient data

DR. IBBOTT: And each condition requires a second.
DR. CONANT: Second.

DR. IBBOTT: Dr. Conant seconded. Now, is there discussion about this condition that would be attached to a motion to approve with conditions?

DR. STARK: My question is does the motion imply or should we specify that we are saying that's a condition where the FDA must be satisfied before the product is permitted to be marketed?

DR. IBBOTT: That is the meaning of conditions, that it is approvable once the conditions are satisfied.

DR. STARK: Okay. And approvable means it would be subject to FDA approval?

DR. IBBOTT: That's right. We're making a recommendation to the FDA which they then consider.

DR. TRIPURANENI: Dr. Krupinski, could you elaborate the condition? I didn't understand. I'm sorry.

DR. KRUPINSKI: Basically what we want instead of the ROC analysis based on the quadrants is to say, okay, here is a patient who is classified as normal. How many times did the radiologist call that
normal and then because of the CAD called it false positive. And vice versa where they initially called it false positive did the CAD make them now call it true negative.

Then how many patients no matter how many nodules they had radiologist says false negative, the CAD correctly turns them to true positive. And vice versa how many times did the radiologist call it true positive and the CAD made them reverse their patient decision and call it false negative.

DR. TRIPURANENI: Are you asking for a post-marketing analysis or a pre-market analysis?

DR. KRUPINSKI: No, re-analysis of the existing data.

DR. TRIPURANENI: Okay. Thank you.

DR. STARK: Is it also implied that the FDA -- that's a specific question but I think it is implied -- I'm asking is that implied that is to -- certainly not to the exclusion, I would think, of the many other questions the FDA might have based on our discussion today, or should we add our own conditions and try to broaden that? I think so many things have
been raised here today. I'm so impressed personally with the qualifications of the FDA staff, the clinical staff, Dr. Sacks, the statisticians, that I would want to give them broad discretion and encourage them, in fact, insist that in addition to answering your question that they address many of the other issues that they will see fit to recognize in the transcripts of this proceeding.

DR. KRUPINSKI: I'm not sure how broad each division has to be.

DR. DOYLE: There's no requirement either way. Keep in mind that the FDA will interpret these conditions so that you can state them in broad terms and we certainly will work with the sponsor to refine them to specific actions. You don't have to spend a lot of time wordsmithing these conditions is what I'm basically saying.

DR. IBBOTT: Dr. Blumenstein.

DR. BLUMENSTEIN: Let me have clarification here. Are we talking about conditions prior to approval or post-approval conditions? I'm a
little confused about that.

    DR. IBBOTT: These are conditions prior to approval.

    Yes, Nancy.

    MS. BROGDON: If you have post-approval conditions you want to include here, then you should.

    DR. IBBOTT: Thank you.

    DR. KRUPINSKI: So those would be like follow-up on new patients. That would be a post-approval?

    DR. IBBOTT: A post-approval for condition for approval.

    MS. BROGDON: I'm sorry. I didn't understand your question.

    DR. IBBOTT: If we impose conditions that cannot be met until after the device is marketed, then how can that be a condition for approval? Or is it a recommendation at that point?

    MS. BROGDON: These are all recommendations. If some of them are about post-approval data, then just identify them as such and we'll know how to sort them out.
DR. IBBOTT: Thank you.

MS. BROGDON: If you have things that you are specifically looking for, you ought to name them in your conditions.

DR. IBBOTT: Good.

DR. CONANT: I think things that are pre-approval conditions before we get to post-approval.

DR. IBBOTT: Let's deal with them one at a time.

DR. DOYLE: Let's try and deal with this one condition.

DR. IBBOTT: By the way, we need to vote on each condition so before you --

DR. CONANT: I seconded hers, didn't I?

DR. IBBOTT: Yes. And are you speaking to that condition?

DR. CONANT: No.

DR. IBBOTT: Let's vote to make sure we're in agreement to attach this condition and then we'll come back and add more conditions. Is there any other discussion about this condition? Then let's ask Dr. Mehta again if he wishes to vote on these conditions.
MS. BROGDON: Dr. Mehta, do you wish to vote on any of the conditions?

DR. MEHTA: I think I'm going to abstain on that as well.

DR. IBBOTT: All right.

Dr. Krupinski.

DR. SOLOMON: The only other thing on her condition is to -- I mean, it was a very broad statement. Obviously the implication is that the statistics remain favorable on the case analysis. I mean, it's implied.

DR. IBBOTT: Good point. Yes.

DR. KRUPINSKI: Yes.

DR. IBBOTT: Thank you. Dr. Conant.

DR. CONANT: Yes.

DR. FERGUSON: Yes.

DR. SOLOMON: Yes.

DR. BLUMENSTEIN: Yes.

DR. TRIPURANENI: Yes.

DR. STARK: Yes.

DR. IBBOTT: All right. Unanimously in favor of that condition.
Now, at this point, Dr. Conant, you could introduce another condition.

DR. CONANT: Always and never. Labeling issues. I think everybody agrees on that to clarify the labeling addressing the many issues we did.

DR. IBBOTT: Is there a second?

DR. KRUPINSKI: Second.

DR. IBBOTT: It's been seconded. Do you want to elaborate on just how you would like them to do that?

DR. CONANT: Nobody really liked the second paragraph about fatigue and lapses and to really emphasize this always and never and to have the radiologist be ethical and moral and all those good things. And to really downplay the issues of statistical significance, to try to lay off that if possible.

I think even right now the efficiency issues we don't really know that or we haven't quantitated that so I wouldn't go there either. Not even soft pedal I wouldn't go there. I'm sure other people have other things to include in that condition.
DR. IBBOTT: Dr. Krupinski.

DR. KRUPINSKI: I think we should maybe consider the possibility of adding the always never to the software. Not only are you trained on it but, say, maybe every 20th case because you can keep track of who logs in, the reminder comes up so it's made a part of their conscientiousness and you just don't have it in that initial three-hour training session because no one is going to read the manual. We know that so if it's not in the initial three hours. In addition as a later reminder.

DR. IBBOTT: Any other comments regarding this condition? All right. Then I think we are ready to vote on this one.

Dr. Krupinski.

DR. KRUPINSKI: Yes.

DR. CONANT: Yes.

DR. FERGUSON: Yes.

DR. SOLOMON: Yes.

DR. BLUMENSTEIN: Yes.

DR. TRIPURANENI: Yes.

DR. STARK: Yes.
DR. IBBOTT: Unanimously in favor again. Then we'll -- oh, I'm sorry. Dr. Mehta. He's abstaining from all these, we think. One abstention.

Would someone like to entertain another condition?

DR. FERGUSON: The issue of formalized training for those that are going to use the device. I like the idea of a CD-ROM. I don't have to spell those out. Everybody knows what those would be. Most of the panel feels that it's appropriate to spell out a time. I don't think it's necessary for this device personally.

DR. IBBOTT: Are you suggesting that the condition mandate training when the device is sold?

DR. FERGUSON: Yes, I am.

DR. IBBOTT: Is there a second?

DR. KRUPINSKI: Second.

DR. IBBOTT: Dr. Krupinski. Anymore discussion about this condition?

DR. TRIPURANENI: Could you elaborate, Dr. Ferguson, what exactly in broad context. You want the technicians to be trained and you want a CD-ROM to be
given with some cases of false positives, false negatives?

DR. FERGUSON: Yes. I think we've talked about all of those things before. I can't remember all of them or elaborate on them but I think they have a clear idea of what we need to have rather than somebody buys the instrument and puts it in. I think we need a little more than just having a technician, if you will, or an M.D. even. I don't know what level this person is that goes in for two or three hours to train. This will be protective for you as well as the patients.

DR. IBBOTT: I'd like to comment. Also I support this and I would like to see the sponsor consider some sort of remote review. This is digital data with DICOM. There probably are mechanisms that a review could be done sort of looking over the shoulder but from a distance so that it wouldn't necessarily -- the training session wouldn't be restricted to the time that the company's representative is on site.

Any other comments? Okay. Then we'll vote on this motion. Dr. Krupinski, we'll start with
you again.

DR. KRUPINSKI: Yes.

DR. CONANT: Yes.

DR. FERGUSON: Yes.

DR. SOLOMON: Yes.

DR. BLUMENSTEIN: Yes.

DR. TRIPURANENI: Yes.

DR. STARK: Yes.

DR. IBBOTT: One abstention and the remaining all vote yes. All right. Are there other conditions?

DR. TRIPURANENI: I'd like to propose a first marketing surveillance. The reason for that is I think the amount of patients that they have even though they are going to do the pre-marketing analysis of the data, I'm afraid we may not have enough number of patients to really tell us what is going on there. They looked at the quadrants and the number of nodules increase and all those things. When you look at alive human beings and the clinical impact, the significance is going to change. I think it's going to be really small.
I would like to propose that we give the broad description to the FDA to kind of come up with something in their best judgment post-marketing surveillance where they can actually track that it really have a clinical significance.

DR. KRUPINSKI: Second.

DR. IBBOTT: Thank you. Any discussion?

DR. CONANT: I think this is part of this. I'm interested in the impact of the CAD and other disease detection. I don't quite know how to do this so I would want panel members to help with this. For example, ground glass opacities and things like that. I wonder if this might not impact one's detection of some of these other things.

Again, it's broadening the population and I would recommend that they do a study with less strict criteria looking at a more prospective group and analyzing the impact of the CAD on the interpretation. Why you would have to look at the interpretation before application of the CAD of all diseases and look at it after. I don't know if that is of interest to anyone else.
DR. SOLOMON: I think that is essentially what the post-market study would be is to look at any changes that come about as a result of the CAD usage.

DR. CONANT: Very general, right?

DR. KRUPINSKI: Not just on nodules but other things as well.

DR. CONANT: Yeah, like mediastinal adenopathy. It's that distraction aspect I think someone brought up earlier.

DR. IBBOTT: It would be difficult for us to design a useful study in the next 10 minutes.

DR. STARK: But is a potential condition of approval to limit its approval to patients like those studied and perhaps data can be shown to the FDA so it could be approvable for use with contrast media. We've heard that's possible and we haven't voiced any objections to that but conditional approval that it not be applied to patients with obvious artifacts, other lung disease such as ground glass nodules or pneumonia. It hasn't been studied in children and I don't know if we're obligated to point that out and ask for that.
DR. CONANT: They did have other diseases in their first group but they didn't look at how the - - there were others, emphysema, ground glass, post-op, all that stuff. I'm not sure you can restrict it.

DR. STARK: Have they shown us enough that they can market to all comers or is it a condition of approval that this would be marketed to all?

DR. IBBOTT: This would be a new condition.

DR. STARK: Either an amendment to the existing motion or a new one.

DR. IBBOTT: The motion is for a post-marketing study which would certainly address the issues that you've mentioned.

DR. STARK: I didn't realize we had moved to the --

DR. IBBOTT: Yes. This motion we are discussing now is for a post-marketing study. Surveillance.

DR. MOORE: Just to make a point of clarification to Dr. Stark's comments, I think in the company's labeling they have made it very clear that
there are certain types of abnormalities that are not appropriate for this device. I think some of the labeling already takes into consideration some of the points that you've raised.

DR. IBBOTT: Let's come back to the discussion on the post-marketing surveillance. Then, if necessary, we'll discuss the labeling again. Further discussion? If not, let's vote on this motion for post-marketing surveillance.

DR. KRUPINSKI: Yes.

DR. CONANT: Yes.

DR. FERGUSON: Yes.

DR. SOLOMON: Yes.

DR. BLUMENSTEIN: Yes.

DR. TRIPURANENI: Yes.

DR. STARK: Yes.

DR. IBBOTT: And one abstention. All right.

DR. STARK: I'm sorry if I missed the boat. I didn't realize we had closed the window and moved on.

DR. IBBOTT: I don't think we've closed
any windows. We jumped to a motion to attach a condition or recommendation for post-approval surveillance but I don't think that prevents us from considering more conditions to approval.

DR. STARK: Well, if I can, to catch up, I've jotted down three to consider. All of these are, of course, subject to the FDA staff's decision.

DR. DOYLE: Hopefully one at a time.

DR. STARK: Yes. I would suggest that until it has been proved otherwise, which means in the current condition it hasn't been proved, that there be no claims, expressed or implied, of clinical significance. And that there be no use of the term significance.

I'm not just talking about lawyering this but in spirit as well as the letter of this recommendation, significance or the like except, as I discussed before, in the very narrow reference to ROC statistics and even then with some type of explicit disclaimer that that's not -- was in a nonclinical setting.

The only thing significant we've seen are
statistics that are in a nonclinical setting and those
have help assure us of the safety and efficacy but I
don't think that should lead clinical radiologist to
have to juggle claims of significance.

DR. SOLOMON: Do you see that being
dependent upon the results of this clinical analysis
that we're talking about?

DR. STARK: I don't think so. I would not
say that satisfying anything that we have made as a
condition would release them from this condition, but
if the FDA finds additional data have established that
this is clinically significant, then I would say the
FDA should be free to waive that condition as a
separate condition.

DR. IBBOTT: All right. This is a
condition you would place on the labeling that the
manufacturer must meet for approval.

DR. STARK: Yes.

DR. IBBOTT: Are your other -- you
mentioned that you had three items. Do they also
address the labeling?

DR. STARK: They are labeling, yes.
DR. IBBOTT: So perhaps we could group them together?

DR. STARK: Well, they might fail one at a time.

DR. IBBOTT: Then let's get a second on this one.

DR. KRUPINSKI: Can I ask is labeling the same as advertising?

DR. DOYLE: It comes under labeling

DR. KRUPINSKI: It is? Okay.

DR. IBBOTT: Is there a second?

DR. FERGUSON: Second.

DR. IBBOTT: All right, Dr. Ferguson. Okay. Any further discussion about this? This would be another condition placed on approval to presumably modify the labeling -- existing labeling and certainly when designing any new labeling to avoid claims of clinical significance.

DR. CONANT: I'm not quite sure we can do that yet. I want to see their data first. I think that could come later but I don't want to close the door on their data so I would be hesitant to vote yes.
I'm sorry.

DR. STARK: I'm just saying if there is no more data or if the FDA finds that data insufficient.

DR. CONANT: Yes, sure. I trust that the FDA will do that but I'm not sure -- yeah, it's kind of a condition on a condition. It's sort of one step at a time. I think we have asked a big condition of looking at the data and that may all not show any kind of significance, clinical or other that we are asking for and then that becomes obvious. I don't get that really.

DR. IBBOTT: Dr. Blumenstein.

DR. BLUMENSTEIN: I'm going to vote no on this because I feel that I trust the FDA to deal with that given that we have a preapproval condition for clinical data.

DR. IBBOTT: Any further discussion?

DR. CONANT: One other. Sorry. David, in spirit I agree very much with what you're saying but we already voted and yes'ed a condition on labeling saying they had to take the stuff out. We did that a couple steps ago. I think we have suggested that we
really feel this is important by voting on that. And then, again, the FDA is going to take it from there.

DR. IBBOTT: I think I feel the same way that we have asked them to do some more analyses of the existing data. The FDA may determine that detracts from the significance.

DR. STARK: I'd be happy to withdraw the motion if there is a consensus, or we better take a vote.

DR. IBBOTT: I think we can just go ahead and vote if that's all right. I should ask, though, is there anymore discussion before we vote? Dr. Krupinski?

DR. KRUPINSKI: No.

DR. CONANT: No.

DR. FERGUSON: Yes.

DR. SOLOMON: No.

DR. BLUMENSTEIN: No.

DR. TRIPURANENI: No.

DR. STARK: Yes.

DR. IBBOTT: There were two yeses and five nos and one abstention. So that motion is defeated.
Are there motions for other conditions to attach to
the approval.

DR. STARK:  I have two more and I'll be
brief.

DR. IBBOTT:  Sorry.

DR. STARK:  That's okay.  I would ask that
it be added to the label something to the effect or
spirit of the following words.  "Careful rereading or
second reading may be equally or more safe and
effective in a clinical setting."

DR. DOYLE:  Could you say that again?

DR. STARK:  "Careful rereading or second
rereading may be equally or more safe and effective
than a computed second reading in a clinical setting."

DR. IBBOTT:  Is there a second for this
motion?

DR. FERGUSON:  Is that a directive to the
radiologists rather than the instrument?

DR. STARK:  It's a directive for -- I'm
intending it, and forgive me for exploring this, but
what a radiologist faced with purchasing this or using
it will be told.  I am proposing that he should be
told that if he simply reread the scan himself or had a colleague double read it, that actually might be more efficient and safe than this product.

DR. KRUPINSKI: But you don't have any data to support your contention.

DR. STARK: That's why I said may be. They don't have any data to support theirs. I'm trying. I've only got one more.

DR. TRIPURANENI: I have difficulty with this.

DR. IBBOTT: We're looking for a second.

DR. STARK: If I don't have a second it goes. We'll move on.

DR. IBBOTT: No seconds. All right.

DR. STARK: Last, it's the same family. I'm just probing this boundary between nonapprovable and approvable with conditions. Not demonstrated safe or effective until there's data in patients with artifacts, concomitant lung disease, contrast media use, or pediatric populations.

DR. KRUPINSKI: Doesn't this come under the post-surveillance type stuff that we were asking
for?

DR. STARK: I thought labeling. Condition of the labeling.

DR. CONANT: I think we are asking again for the data to be analyzed and included in that by case is looking at -- I mean, there were cases with artifacts and things like that. I think that is part of what the false negative and false positive analysis is going to provide us with. Again, it's a limited case set but depending on what that shows, the next set may be --

DR. STARK: If it is understandable to the FDA that we are assuming they are going to check this, I'm saying that we haven't seen these data and I was asking as a condition that the FDA ask to see it. I was just making that a motion. I mean, I know we can assume that they'll do this anyway.

I'm just trying to make it a specific direction. Of course, this is all advice and they can ignore all of this but if there is a consensus that they should do this, then that is, I think, the purpose of the motion I'm making which is to ask them
DR. IBBOTT: Go ahead.

DR. CONANT: Could it be that we could put this in the first condition which was the first preapproval condition that was to go back and look at these cases and we talked about by-case compared to by-nodule and quadrant, etc. Do you want to step back and beef that one up a little bit?

DR. SOLOMON: I think procedurally that will be a problem.

DR. CONANT: We can't do that? Okay.

DR. IBBOTT: We can address this motion with the understanding that, in fact, that is what will happen. We can deal with this motion independently at the first.

DR. CONANT: Could you reword your motion or could you restate it again? I didn't mean reword it. Just say it again.

DR. STARK: Yeah, and certainly someone -- I think all of these we are understanding that we haven't wordsmithed these. I'm simply suggesting that until the FDA sees data, which we hope is available,
it should be a condition of premarket approval that
the product will be labeled as not demonstrated safe
or effective, or safe and effective with the use of
contrast media in the presence of artifacts or
concomitant lung disease or in pediatric patients.

DR. KRUPINSKI: From a nonclinician --

DR. FERGUSON: It's totally unexplored. I
don't think we can suggest that the FDA look at these
because I don't think we can put that into a formal
motion because those things are unexplored as far as I
know.

DR. CONANT: I think that you're saying
that the labeling should read this but the point is if
it doesn't get approved and it doesn't follow this
condition that we first said about reanalyzing the
data, there's no labeling here because it's not going
anywhere. You're already jumping to labeling based on
the data. It's kind of contradictory

DR. STARK: I am suggesting that if it is
approved based on whatever, but we see no data on
contrast media, artifacts, pediatrics, or lung disease
that the labeling contain these restrictions.
DR. CONANT: If we see no data on those things.

DR. STARK: If the FDA is not satisfied with the data which includes not seeing any further data.

DR. CONANT: Okay.

DR. IBBOTT: The sponsor has indicated that their data do include cases with contrast and cases with artifacts. Are you suggesting that when they do the reanalysis that we've already asked them to do that they also pay attention or conduct an analysis to look specifically at the impact of artifacts or with versus without contrast?

DR. STARK: Yes. I'm saying that they say they have data that we haven't seen and that if they -- offering them a choice of either satisfy the FDA that when they offer statistics on their data that it's convincing and labeling shouldn't apply or simply say we can market it and simply market it with the warning that if you patient has artifacts we haven't demonstrated safety and efficiency -- sorry, safety and efficacy.
DR. IBBOTT: So, yes. I'm not going to try and rephrase your motion but I believe that you're asking that the reanalysis we've asked them to do contain those elements to look at artifacts, contrasts. There were no pediatric patients so we won't include that.

Then depending on the results the labeling should be modified to indicate that the device is not appropriate for pediatric patients. For example, if the data don't support its use in pediatric patients. Is that right?

DR. STARK: That's correct.

DR. DOYLE: We need a second

DR. IBBOTT: Yes. We need a second.

DR. KRUPINSKI: The pediatric issue, I just talked to a clinician, could be significant. I mean, if the CAD --

DR. CONANT: I'm not really sure about this. I haven't looked at a pediatric chest -- well, actually I do on the weekends.

DR. IBBOTT: No one will ever know.

DR. CONANT: It won't get out of this
room. Obviously kids were not analyzed. It was 19 and above so obviously pediatrics should be a contraindication. That should be included in the labeling. I think we all agree about that definitely.

DR. STARK: I think if we don't make a motion it's not obvious at all because I could wear the other hat.

DR. CONANT: I think I brought that up earlier when I said that has to be one of the things that we address with looking back over the data. At least, I'm sorry if I didn't. I don't remember what the transcript was but that's got to be something in the label and it's not in the contraindication line. The artifacts we could talk about as a motion. That sounds like a good idea. Maybe separate out from the artifacts and other things.

DR. STARK: I don't know where we are in pediatrics. Do we need a separate motion? Are you suggesting that I bifurcate this already complicated thing? I'm just trying to point the FDA to satisfy yourself on these things or exclude them.

DR. CONANT: I think there's a difference
here of what there may be data on versus what there isn't a chance in hell they are going to be able to analyze because there's no babies or kids. I think it is different. I think it's two separate issues so I would say separate it.

DR. STARK: If you don't mind, why don't you make the motion on the pediatrics.

DR. CONANT: Contraindication no. Is it 19 and over? Eighteen. Sorry. No one under 18 should be analyzed with this.

DR. STARK: I'll amend my motion by dropping the word pediatrics. We can deal with that then and then you can have --

DR. IBBOTT: You've withdrawn. It wasn't seconded so that motion is withdrawn.

DR. STARK: I think we are still discussing it. I would like to say that until the FDA is satisfied from the existing data set or some other data set but not -- I'm suggesting it's a restriction because we haven't seen the data here that it be a condition that it be marked not demonstrated safe or effective in patients with concomitant lung disease or
with lung disease -- known lung disease, scanning artifacts, or with contrast media. Again, we know they have data on contrast media. I hope it will convince the FDA but I'm asking that we require that.

DR. CONANT: Should we put pediatric under 18 first?

DR. STARK: I eliminated that from my motion hoping that you would carry forward with yours afterwards.

DR. CONANT: Okay.

DR. IBBOTT: You're seconding his motion?

DR. CONANT: No. He told me to do it independently so I just did that.

DR. IBBOTT: We need a second for the motion he just made.

DR. STARK: I think I'm trying to bargain with you.

DR. IBBOTT: You guys have to decide.

DR. CONANT: I think that is still part of the one we already passed where we've asked for further analysis of the existing data. I think we have already covered that. That's why I'm not
seconding it because I think we are already asking them. I mean, if you reanalyze the data and they find that they can't support what you want, then yours is a condition on the condition that they don't find it. But if they do the analysis and find it, then your condition isn't needed.

DR. STARK: I think it's sufficiently likely that they are not going to have statistically convincing data on artifacts or post-op patients or patients with pneumonia. I am trying to attach a condition that will help the FDA simply say put in the label you should be careful and not use it in these patients because it's unproved. I believe they have data on contrast media but I'm lumping them all of them in the same.

I'm saying these are identifiable important subsets just like the pediatrics issue. I'm simply saying specifically look at the analysis for these things and assuming that there is not satisfaction here in some of them, please label the product appropriately.

DR. IBBOTT: Dr. Tripuraneni.
DR. TRIPURANENI: I think there are lumpers and splitters. I'm a lumper. I think FDA is hearing what we are saying and I think rather than go down to the final nitpicking and actually spell out everything, I would rather leave it to the broad discretion of the FDA to decide the best in their best judgment. I really don't support this element.

DR. IBBOTT: We don't have a second yet. Is anyone willing to second the motion? All right. Does someone want to make the other motion regarding pediatric patients?

MS. BROGDON: May I make a comment first? I just wanted to describe how we treat contraindications. We use the term contraindication to mean something you shouldn't do because there are data that say you must not do that. There must have been some sort of demonstration of harm. Short of that, there are warnings and there are cautions and other things that you can say in the labeling that don't reach the level of contraindication.

DR. IBBOTT: Good distinction. Thank you.

DR. CONANT: Maybe this is a post-
marketing study. They've got to apply it to kids. I don't know if that -- maybe it's just a warning saying there is no data to support this use under 18.

DR. KRUPINSKI: Somewhere it has to be stated or brought out in the manual or in the warnings or somewhere there is obviously not a contraindication but it should be there somewhere.

DR. STARK: The rocket scientist in me says that why are children different than adults and it's probably going to work. But as a human, as a parent, I have a hard time saying these are just small adults. On the other hand, the admonitions of lumping and leaving it to the FDA, this is all on record, I've spoken. My conscious is satisfied. I'm going to leave it to someone else to make a motion.

DR. IBBOTT: This is certainly something that could be included in a recommendation for a post-market study and I think we have probably done that or implied that.

Any other conditions people would like to attach?

DR. CONANT: Have we figured out the
pediatric one?

DR. IBBOTT: We have not. I have made the assumption that the sponsor and the FDA understand from the discussion that a post-market study would include pediatric patients.

Yes, Nancy.

MS. BROGDON: I'm advised that since the sponsor has not indicated that it is -- could be used in pediatric patients, FDA would in most circumstances include some sort of statement in the labeling that it has not been studied and it is not intended for use in children.

DR. CONANT: There you go. I'll second that motion.

DR. STARK: I say yes.

DR. IBBOTT: The relief is palpable. I think unless there are other motions for conditions, we are ready to vote on the main motion which is for approval with conditions, the conditions being those we've just discussed.

DR. DOYLE: The ones that were seconded and approved.
DR. IBBOTT: That's right. So we do have the motion and so unless there is any further discussion on the main motion, we'll proceed to a vote on the motion to approve with -- as approvable with conditions.

DR. KRUPINSKI: Yes.

DR. CONANT: Yes.

DR. FERGUSON: Yes.

DR. SOLOMON: Yes.

DR. BLUMENSTEIN: Yes.

DR. TRIPURANENI: Yes.

DR. STARK: Yes.

DR. IBBOTT: And with Dr. Mehta's abstention the rest of the votes are all in favor so that motion carries. We have declared this approvable with conditions and we've approved a number of conditions. At this point we go around the room and ask the voting members to explain the reasons for their vote. Dr. Krupinski, again, we'll start with you and ask you to identify the reason for your vote on the decision as approvable with conditions and also on the recommendations. You can probably summarize
your reasoning.

DR. KRUPINSKI: Why doesn't somebody else start because, I mean, it seems like I would just say the entire conversation we just had all over again. I agreed with all the changes or the conditions that we brought up. I think they satisfied the questions we had throughout the day and so I voted yes.

DR. IBBOTT: I think that's fine.

Dr. Conant.

DR. CONANT: That's basically the same with me. I'm just concerned about how the statistics -- how the analysis will differ with case-based versus actionable nodules and quadrants. I, again, applaud you all for the beautiful study you have done and answering the questions given to you by the FDA.

I hope you have this data to show us because I think this could be a wonderful tool. As these things go they only get better over time. I think it really could have benefit to patients. But I really need that data.

DR. IBBOTT: Dr. Ferguson.

DR. FERGUSON: I agree with everything she
said.

DR. IBBOTT: Dr. Solomon.

DR. SOLOMON: I think you should be applauded for dealing with the problem that is an important clinical problem. I think there are two issues that the panel is charged with. The first one being safety. I think the issues of always and never are the issues on safety and I think there are ways you can address these and we have discussed those today.

The second issue that we are charged with is efficacy. I think the key word there is clinical efficacy and I'm not sure we were able to see exactly the clinical efficacy with the way the data was cut up and divided so that we think that if you were to look at it again with that in mind, it might be able to get through to the FDA.

DR. IBBOTT: Dr. Blumenstein.

DR. BLUMENSTEIN: I was disappointed that neither the sponsor came forward with clinical analysis, and I'm also disappointed that the FDA didn't require that of them, especially since our criteria before approval for efficacy has clinical
efficacy mentioned in it. I'm also discomforted by the unique properties of this study designed that may lead to inaccurate assessment of the ROC methodology.

DR. IBBOTT: Dr. Tripuraneni.

DR. TRIPURANENI: I would like to congratulate R2 for actually coming up with this new concept. You are a pioneer in the CAD and it's good and bad. It's bad that being the first one we are going to hold you to a higher standard because we have ideas about what is right and what is wrong. Somebody else that is going to come after you their life would be a lot easier because they are going to learn from your mistakes. On the other hand, I think you have done a very good job on this.

I personally think actually any improvement in the process actually will ultimately lead to the improvement in care. I think it's important actually that we continue to pursue to improve the processes that ultimately improve the care. That is the reason why I think we attach those amendments and I firmly believe it will make a positive impact on the patients. That is the reason
why I vote yes with amendments.

    DR. IBBOTT: Dr. Stark.

    DR. TRIPURANENI: Can I just add one thing? I really would like to see FDA asking for clinically efficacy because I participated in the Cardiovascular Devices Panel, as I say, participated on the other side of the table a couple of times and they kept pointing the table to where is the clinical data, where is the clinical efficacy. I would ask the sponsors to give us some clinical data when appropriate.

    DR. IBBOTT: Dr. Stark.

    DR. STARK: Well, first, as lead clinical reviewer I would like to thank everybody on the panel, everybody in the audience, especially R2 for listening carefully and responding to my many adversarial comments. I think that was part of my role here today to be both the adversary as well as one of the voting judges. I thank the chair. It's been a very efficient, respectful proceeding.

    Having said that, I, again, agree with Dr. Blumenstein's assessment as a statistician. I note
that both the lead reviewers had a viewpoint strongly held that was overwritten by the rest of the committee and I can now step back and agree with Dr. Conant who has emphasized, and those reading the transcript would not have seen her facial expression and the movement of her fist in terms of emphasizing that we are now relying on the FDA staff to continue diligently what they have already said is a nearly overwhelming task. Not just for their manpower and resources but for their range of skills. I think this committee and the people in this room and a larger group, I believe, needed to address this again to relook at these data but I accept that I have been outvoted and we will now rely on what is clearly a very competent, energized and well-supported FDA staff to essentially accomplish the same thing that Dr. Blumenstein and I were pushing for but as Dr. Conant and the majority have voted. Thank you.

DR. IBBOTT: Thank you. I would like now to ask the nonvoting representatives to comment on the recommendations that have been made. Ms. Moore.

DR. MOORE: Although I did not vote, I
think I would have been in agreement with the panel on recommending this for approval. I think that any improvement in our ability to detect nodules that are not being detected is an important step forward and I commend R2 on their efforts and view of the data and trying to move this technology forward.

DR. IBBOTT: Mr. Burns.

MR. BURNS: The conditions satisfy the concerns that I had regarding the study size and the data set and the small change in the area under the ROC. I think by analyzing the data we will see if there is some better significance with the data.

DR. IBBOTT: Good. Thank you. I would like to just give Dr. Mehta a chance to make any comments he might have.

Dr. Mehta, do you have any comments?

DR. MEHTA: No. I think I just want to thank Geoff Ibbott for doing an excellent job of running the meeting. Although I didn't hear all the proceedings, I think I heard enough to concur with what actually happened. Thank you, everybody.

DR. IBBOTT: Thank you, Dr. Mehta.
Mr. Doyle.

DR. DOYLE: Before we adjourn for the day, I would like to remind the panel members that they are required to return all the materials that were sent pertaining to the PMA itself. Materials you have with you may be left at your table and any other should be sent back to me at the FDA as soon as possible.

DR. IBBOTT: Thank you. Finally, I would like to thank the speakers and the members of the panel for their preparation and participation in this meeting. I would like to especially thank Dr. Stark and Blumenstein for serving as lead reviewers for the panel and doing an excellent job of summarizing this and helping the rest of us understand it.

And I would like to thank the sponsors for graciously responding to the many questions that were aimed at them and for putting on an excellent presentation.

Since there is no further business, I would like to adjourn this meeting of the Radiological Devices Panel. Thank you.

(Whereupon, at 5:20 p.m. the meeting was
adjourned.)