

1 from the panel?

2 DR. MABREY: Mr. Chairman, I'd like to
3 make a motion. I move that the panel approve with
4 conditions, option number two.

5 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
6 Mabrey.

7 Is there a second for the motion?

8 DR. MAYOR: Second.

9 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
10 Mayor.

11 Now, Dr. Mabrey, since you did state that
12 this is approvable with conditions, would you like to
13 introduce the first condition?

14 DR. MABREY: Yes. First, that there be a
15 post approval study. I realize that that's already
16 presented in the material that we have, but I'd like
17 to just for the record be assured that there is a post
18 approval study, and I'm comfortable with the way it's
19 presented on page 20 of our handout, although I would
20 make one modification as suggested by Dr. Mayor that
21 we have some radiographic follow-up at ten years as
22 well.

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1 I don't think we need radiographic follow-
2 up at years six, seven, eight, and nine. I try not to
3 bring all of my patients back to the office that
4 frequently either, but because this has a particular
5 propensity for failure and we don't know what the
6 long-term failure results would be, I would add
7 radiographic follow-up at ten years.

8 PANEL CHAIRPERSON NAIDU: Is there a
9 second for this modification?

10 DR. MAYOR: I would concur.

11 PANEL CHAIRPERSON NAIDU: The motion on
12 the floor right now is to approve with condition, the
13 first condition being radiographic follow-up at ten
14 years as one of the prerequisites.

15 Is there any discussion on this condition?

16 Dr. Skinner? Oh, Dr. Blumenstein.

17 DR. BLUMENSTEIN: I don't know whether I
18 need to make this as another motion or ask for
19 modification, but the size of the study should be
20 based on statistical principles and criteria for
21 success.

22 PANEL CHAIRPERSON NAIDU: Dr. Mayor, is

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1 that acceptable?

2 DR. BLUMENSTEIN: I would concur.

3 Mr. Melkerson?

4 MR. MELKERSON: Just a point of
5 clarification. You said vote for approval. You're
6 only voting on this condition.

7 PANEL CHAIRPERSON NAIDU: That's correct.
8 We're just going on the conditions so far.

9 MS. ADAMS: And can you repeat the
10 condition that we're considering?

11 PANEL CHAIRPERSON NAIDU: The condition is
12 to have a post market approval study with a
13 radiographic follow-up of ten years. That is the
14 condition on the floor right now.

15 Dr. Blumenstein has added another
16 condition that the size of the study be statistically
17 significant.

18 Is there a second for that motion?

19 MS. SCUDIERO: Wait. Is Dr. Blumenstein's
20 comment, is that meant to be added as part of the
21 description of the post approval study?

22 DR. BLUMENSTEIN: If it isn't added, then

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1 I'll make it as a separate motion.

2 MS. SCUDIERO: Okay.

3 DR. BLUMENSTEIN: So I don't care.

4 MS. SCUDIERO: I believe that we can sort
5 of like friendly amendments to a condition if it's
6 agreeable with the person who made the motion and he
7 who seconded it.

8 DR. MABREY: I'm very agreeable.

9 MS. SCUDIERO: That's good.

10 DR. MAYOR: As am I.

11 DR. MABREY: Just ask my wife.

12 PANEL CHAIRPERSON NAIDU: Great. So the
13 motion, again, the condition for motion, the
14 modification condition is post market approval study
15 with the radiographic follow-up at ten years, with the
16 size of the study to be determined.

17 DR. SKINNER: Statistically.

18 PANEL CHAIRPERSON NAIDU: Statistically
19 significant.

20 Is there discussion on this motion? Dr.
21 Kim? Dr. Skinner?

22 DR. SKINNER: I thought I was agreeing

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1 with Dr. Blumenstein earlier when he said that he
2 thought it was unlikely that a study would be very
3 valuable unless it was a very large study.

4 I think that any information we get from
5 such a study is going to come out after we've either
6 abandoned the procedure or we've already decided it's
7 a great procedure.

8 If we wait ten years we're going to be
9 past. We're not going to have any information to
10 really derive from that. If we want ten-year data, we
11 should get the data from Dr. McMinn's study group that
12 already has five years in.

13 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
14 Skinner.

15 DR. KIM: Can I make a comment to that
16 effect?

17 PANEL CHAIRPERSON NAIDU: Yes.

18 DR. KIM: On this subject. I would agree
19 there are actually two issues here. The one is it's
20 long-term efficacy, and I would agree to have to do a
21 randomized controlled trial to look at that specific
22 question would be too burdensome.

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1 But there's a main question that's still
2 open, and that is its short-term safety and efficacy
3 in the hands of multiple surgeons at multiple sites.
4 That has not been clearly shown, and I don't think it
5 is fair to just look at Dr. McMinn's first 200 since
6 he may have done this type of surgery before.

7 So I think the utility of a randomized
8 controlled trial at least the way we do it at the FDA
9 is it only lasts for two years, and it's really to
10 look at big, egregious, early problems that we can
11 identify and address prior to releasing a device out
12 into the general public.

13 So I guess what I'm trying to say is I
14 would agree with Dr. Blumenstein that a post market
15 study needs to be done. It needs to be a good study
16 based on sound study principles and statistics.

17 PANEL CHAIRPERSON NAIDU: Dr. Mabrey, do
18 you have something to add?

19 DR. MABREY: Yes. If I could just comment
20 on Dr. Skinner's analysis. I was under the assumption
21 that the sponsor had already agreed to perform this
22 post approval study and would be collecting at least

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1 questionnaires at ten years; is that correct?

2 And I see nodding heads out there. So I'm
3 just suggesting that while you're collecting the
4 questionnaires at ten years that I think it would be
5 useful to see what the femoral neck at least looks
6 like at that time.

7 MR. VELEZ-DURAN: Understood.

8 PANEL CHAIRPERSON NAIDU: Thank you.

9 Dr. Blumenstein, you had something to add?

10 DR. BLUMENSTEIN: Well, I was just going
11 to mention that you could put another condition on the
12 approval for the long-term radiographic follow-up of
13 patients already in the study, as I intend to do for a
14 randomized clinical trial.

15 DR. SKINNER: I'll raise you three aces.

16 (Laughter.)

17 PANEL CHAIRPERSON NAIDU: Yes. Do you
18 want to vote on the condition?

19 MS. SCUDIERO: Dr. Mabrey, would you like
20 to restate your condition? Maybe we need to go back
21 to square one so that we don't get confused?

22 DR. MABREY: My condition is that in

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1 addition to the post approval study proposed by the
2 sponsor, as outlined on page 20, that in addition to
3 collecting clinical data at ten years, that we collect
4 radiographic data at ten years.

5 I don't mean to imply that we should wait
6 those ten years before we finally bring this device to
7 market.

8 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
9 Mabrey.

10 Ms. Adams.

11 MS. ADAMS: Well, I would just like to
12 make a comment to Dr. Kim's point. He's said a couple
13 of times and I've even been convinced of it that we
14 don't have long-term data, and in the break I spent
15 some time revisiting it.

16 I think we should keep very much in mind
17 that we've heard that there have been 33,000 implants
18 in 23 countries. There were 140 surgeons that were
19 included for 3,300 cases with five-year follow-up.
20 That's pretty significant.

21 So I want to be very cautious about
22 implying that we only have a short period of time of

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1 information here and pressing upon the sponsor that
2 there should be some significant amount of study added
3 to them.

4 I think they've been gracious in
5 indicating that they would be willing to do additional
6 study, but I think that that would be a very high bar
7 compared to what we typically see and maybe not
8 necessary.

9 PANEL CHAIRPERSON NAIDU: Thank you, Ms.
10 Adams.

11 Any other comment? Is Whittington? Dr.
12 Skinner? Dr. Kim? Dr. Mabrey? Dr. Blumenstein? Dr.
13 Mayor?

14 Okay. So the first condition for the post
15 market study is in addition to the post market study
16 proposed by the sponsor that there be long-term
17 clinical data at ten years and also X-ray data at ten
18 years. Shall we vote on this condition?

19 DR. MABREY: And statistical principles
20 used to determine the study size.

21 PANEL CHAIRPERSON NAIDU: And also
22 statistical principles used to determine study size.

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1 MS. ADAMS: That's a lot of conditions.
2 As a point of procedure -- and I'm new. We just
3 trained yesterday -- we were told that the idea was to
4 have a condition and vote on the condition, and I
5 think we've got three, or at least two with a
6 statistical issue.

7 PANEL CHAIRPERSON NAIDU: Right. There
8 are two ways to address this long-term data. One is
9 to follow Dr. McMinn's original cohort all the way to
10 ten years and report on that data or take Dr.
11 Blumenstein's condition that there be a new cohort
12 established, statistical significant sample size.

13 Mr. Melkerson?

14 MR. MELKERSON: I would actually vote on
15 your proposal from Dr. Mabrey, which is basically
16 study as proposed, ten-year radiographic, and the
17 statistical sample size. The issue of can you address
18 that by other comments from Dr. Skinner may be another
19 issue for a motion and you're going to vote it up or
20 vote it down.

21 PANEL CHAIRPERSON NAIDU: Okay. Why don't
22 we vote on this condition then? Post market approval

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1 study as indicated by the sponsor plus radiographic
2 follow-up and clinical follow-up for ten years which
3 is statistically significant. Let's have a vote on
4 that motion.

5 Dr. Mayor?

6 DR. MAYOR: I would vote affirmative.

7 PANEL CHAIRPERSON NAIDU: Dr. Blumenstein?

8 DR. BLUMENSTEIN: Yes.

9 PANEL CHAIRPERSON NAIDU: Dr. Mabrey?

10 DR. MABREY: Yes.

11 PANEL CHAIRPERSON NAIDU: Dr. Kim?

12 DR. KIM: Yes.

13 PANEL CHAIRPERSON NAIDU: Dr. Skinner?

14 DR. SKINNER: Yes.

15 PANEL CHAIRPERSON NAIDU: Ms. Whittington?

16 MS. WHITTINGTON: We're not voting.

17 PANEL CHAIRPERSON NAIDU: Okay. I'm
18 sorry.

19 There is a unanimous consensus from the
20 voting panel that the post market study be performed
21 as drafted in the original PMA, plus clinical data and
22 X-ray data from ten years be reported based on sound

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1 statistical principles. Is that acceptable?

2 MR. MELKERSON: Yes.

3 PANEL CHAIRPERSON NAIDU: Is there a
4 second condition that anybody else would like to
5 introduce? Dr. Blumenstein.

6 DR. BLUMENSTEIN: I would like to make as
7 a condition of approval the conduct of a randomized
8 clinical trial that would help establish the relative
9 efficacy of this device with respect to the other
10 predicate devices based on sound statistical
11 principles.

12 PANEL CHAIRPERSON NAIDU: Mr. Melkerson?

13 MR. MELKERSON: Point of clarification. A
14 new study would not be supported by an approval. If
15 you need new clinical data to support efficacy, that
16 is actually a reason for not approving a product.

17 PANEL CHAIRPERSON NAIDU: Thank you.

18 So is anybody to second this motion made
19 by Dr. Blumenstein? He wants a randomized controlled
20 trial study based on a comparison to a predicate
21 device. Is anybody to second that motion?

22 (No response.)

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1 PANEL CHAIRPERSON NAIDU: Since I see no
2 second for this condition, do we have any other
3 outstanding conditions that we would like to make?

4 DR. KIM: Can I ask a question about a
5 condition? Can you make a condition where the sites
6 are limited to that group of centers that would be
7 doing the post market surveillance and not be
8 considered a new study?

9 So my motion would be to limit the release
10 of this product to a select number of sites to be
11 determined based on the statistical need of the
12 numbers of the patients to look at this post market
13 approval study.

14 I don't know if I even understand that.

15 (Laughter.)

16 DR. SKINNER: Could I comment on that?

17 DR. KIM: Yes.

18 DR. SKINNER: If this device is as popular
19 as it has been implied, you're basically giving a
20 license to print money to five or six or whatever
21 sites. I don't think you want to go there.

22 PANEL CHAIRPERSON NAIDU: Thank you, Dr.

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1 Skinner.

2 DR. KIM: Well, Mark, can you elaborate on
3 whether or not you would consider that a condition
4 that's equivalent to a nonapprovable recommendation
5 because it's a study?

6 MR. MELKERSON: This is Mark Melkerson.

7 I wouldn't answer the question that way.
8 If we are approving a product, we are approving it for
9 distribution. You can put limitations on that, but in
10 terms of a limited distribution, most restrictions on
11 conditions of approval are related to potentially
12 training or other methods, but in terms of approval,
13 we are approving it for marketing in the U.S.

14 DR. KIM: Then I retract that condition.

15 PANEL CHAIRPERSON NAIDU: Dr. Mabrey?

16 DR. MABREY: Oh, before Dr. Kim retracted
17 his condition I was going to suggest that the sponsor
18 clarify their roll-out plan. It sounded like they
19 were going to restrict it to 15 champion surgeons at
20 restricted sites for at least -- it sounded like at
21 least the first 150 cases if you're going to do ten
22 cases per surgeon, and that sounded almost like what

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1 Dr. Kim was proposing anyway.

2 If I can ask the sponsor to comment, do I
3 have that correct on your initial roll-out?

4 MR. VELEZ-DURAN: Yes, you're correct.

5 DR. MABREY: Thank you.

6 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
7 Mabrey.

8 MR. VELEZ-DURAN: I'm sorry. I misspoke.

9 DR. THOMAS: This is Marc Thomas.

10 If I did leave that impression, that
11 wasn't correct. We weren't going to limit it to 15
12 surgeons. We want to get a geographical
13 representation of America's surgeons regionally to
14 train them in the U.K. so they can come back and be
15 the faculty to train surgeons here as is the world
16 wide template training for the Birmingham that's being
17 done in countries such as the U.K. and Australia.

18 There was no limitation of numbers as such
19 with that application, but it was going to be
20 restricted to a number of surgeons that we have
21 thought of between 30 and 50, but once again have not
22 restricted ourselves to a number.

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1 PANEL CHAIRPERSON NAIDU: Thank you

2 If we do not have any additional
3 conditions, we should go back to voting on the main
4 motion. The motion on the table is to approve with
5 conditions, the only condition being clinical and
6 radiographic follow-up at ten years along sound
7 statistical principles for the post approval study as
8 outlined by the sponsor in the submitted PMA.

9 All those in favor for the motion, please
10 raise your hands.

11 (Show of hands.)

12 DR. KIM: Can I clarify? Are we voting on
13 just the condition or are we voting on the
14 approvability with this condition?

15 PANEL CHAIRPERSON NAIDU: We're voting on
16 the main motion, approvability with this condition.

17 Dr. Mayor?

18 DR. MAYOR: Are we submitting votes at
19 this point?

20 PANEL CHAIRPERSON NAIDU: Yes.

21 DR. MAYOR: Affirmative.

22 PANEL CHAIRPERSON NAIDU: Dr. Blumenstein?

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1 DR. BLUMENSTEIN: No.

2 PANEL CHAIRPERSON NAIDU: Dr. Mabrey?

3 DR. MABREY: Affirmative.

4 PANEL CHAIRPERSON NAIDU: Dr. Kim?

5 DR. KIM: I vote no.

6 DR. SKINNER: Affirmative.

7 PANEL CHAIRPERSON NAIDU: The motion
8 passes. The motion passes to approve with conditions,
9 the condition being a post market study with
10 radiographic and clinical follow-up at ten years based
11 on sound statistical principles.

12 Now, I'd like to go back to each panel
13 member and ask for the reason as to why they approved
14 yes versus no. Why don't we start off with Dr.
15 Skinner?

16 DR. SKINNER: Well, I think that this
17 device has shown that the data that has been presented
18 in favor of this device has shown that it's
19 reasonable. It's safe. It's efficacious, and I think
20 that even though the post-market study that has been
21 suggested I think is unreasonable, I think it's the
22 lesser of two evils. So I think this is a better

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1 motion than trying to get a different motion.

2 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
3 Skinner.

4 Dr. Kim.

5 DR. KIM: This technology is promising,
6 and there is clearly a place for some type of
7 technology in the younger, more active patients that
8 will likely outlive a standard total hip replacement,
9 but unfortunately, the information that was provided
10 by the sponsor on this particular implant is
11 insufficient to make several important conclusions.

12 First, we do not know of any safety issues
13 as it relates to early widespread use of this implant.

14 Again, this speaks to the issue of the learning
15 curve. If there are or will be significant issues
16 with the learning curve, these should be identified
17 and addressed prior to the release to the general
18 public. This is only possible in a well controlled
19 study throughout multiple sites and surgeons.

20 I do not think that evaluating Dr.
21 McMinn's first 200 cases will be sufficient to address
22 this important question as it does not take into

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1 account differences in clinical practice even among
2 experienced or referral based surgeons.

3 Number two, although I'm confident that
4 Dr. McMinn can use this device safely and effectively,
5 there's lack of sufficient evidence that this will be
6 the case in the U.S. when a wide variety of surgeons
7 will implant this device. I see no compelling reason
8 why this device does not need to satisfy some basic
9 study criteria for its approval.

10 I do not believe or encourage sponsors to
11 present the FDA this type of study, and I would
12 encourage the future Dr. McMinn's of this world to take
13 the extra effort to collect data that will be more
14 meaningful and more compelling and more applicable to
15 the U.S. population.

16 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
17 Kim.

18 Dr. Mabrey, you voted yes, and your
19 reasons?

20 DR. MABREY: Well, I think there is
21 substantial amount of data out there to support the
22 clinical efficacy of this device, and as far as its

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1 applicability to surgeons within the United States,
2 like I say, I appreciate Dr. Thomas coming forward and
3 sharing his experiences with it. I just reviewed
4 their abstract on line and they're very honest about
5 pointing out the problems they saw at the beginning of
6 their use of this device.

7 I see quite an analogous situation with
8 another procedure that's currently, if I may be so
9 bold to say, running rampant throughout the U.S., and
10 that's the use of two incision, mini incision total
11 hip, which did not require any type of approval, and
12 has a steep learning curve, and yet many surgeons have
13 continued to adopt it and it looks like the initial
14 adopters learned from their mistakes, conveyed those
15 findings on to subsequent surgeons and thus steep
16 learning curves were avoided.

17 For those surgeons coming later, I would
18 suggest -- well, I'm assuming that Dr. Thomas doesn't
19 have to go all the way back to England to learn how to
20 put this device in, but if his experience is anything
21 like everyone else's, I feel comfortable that the
22 learning curve will be there.

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1 I would encourage the sponsor to be honest
2 about the learning curve, but I don't see it as being
3 as steep as suggested in Dr. Mont's presentation at
4 the academy this year.

5 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
6 Mabrey.

7 Dr. Blumenstein, you voted not.

8 DR. BLUMENSTEIN: First I'd like to echo
9 Dr. Kim's comments and especially the lack of an
10 estimate on the variability across surgeons, and then
11 my second reason is that in my opinion there wasn't an
12 adequate control on this trial, and I gave those
13 reasons earlier.

14 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
15 Blumenstein.

16 Dr. Mayor.

17 DR. MAYOR: I voted yes based on the
18 reassurances that I gained regarding safety and
19 efficacy for this device, without implying any
20 satisfaction with the design of the study.

21 Further, I would suggest that future
22 applicants should not assume that significant savings

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1 can be achieved by following its example.

2 PANEL CHAIRPERSON NAIDU: Thank you, Dr.
3 Mayor.

4 Ms. Adams, do you have any comments to
5 add?

6 MS. ADAMS: I do want to return to the
7 comments that I made earlier about the congressional
8 mandate for least burdensome, and I'm not going to
9 sound like a broken record, but I want to remind
10 everyone that Congress indicated that they wanted to
11 insure the timely availability of safe and effective
12 new products that would benefit the public and insure
13 that our nation continues to lead the world in new
14 product innovation and development.

15 They indicated their goal was to
16 streamline the regulatory process, reduce the burden
17 and improve patient access to breakthrough
18 technologies.

19 In FDA's own guidance as a response to
20 that, they've indicated that it is their goal to
21 consider alternatives to randomized controlled trials;
22 that there should be an effort to look at valid non-

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1 U.S. data, paper PMAs, literature controls, and that
2 sort of thing.

3 I respect every one of my colleagues at
4 the panel here, but I would say that I'm not so
5 certain that we're still, even though this was issued
6 in 1997, considering the mandate of Congress and that
7 that is something that we should be trying to consider
8 as we deliberate in future panels.

9 Thank you.

10 PANEL CHAIRPERSON NAIDU: Ms. Whittington?

11 MS. WHITTINGTON: I would echo that the
12 public certainly is always interested in a better
13 mousetrap and hopefully this is a better total hip.
14 It's the FDA's responsibility to make sure that it's a
15 safe and effective device. So I think the caution to
16 safety is the post market study, and that that does
17 insure that findings will be reported across the
18 sites.

19 The emphasis on education of the
20 practitioners I think cannot be understated as Dr.
21 Mabrey had indicated earlier, as well as good
22 education to both the surgeon and the public as to the

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1 fact that this is a new device and it needs to be used
2 in the right person, by the right surgeon at the right
3 time.

4 PANEL CHAIRPERSON NAIDU: Thank you, Ms.
5 Whittington.

6 Anymore comments from the panel?

7 (No response.)

8 PANEL CHAIRPERSON NAIDU: Mr. Melkerson,
9 have we addressed all of the issues adequately?

10 MR. MELKERSON: I believe you have, but I
11 do want to again ask your opinion regarding this
12 device.

13 PANEL CHAIRPERSON NAIDU: Yes, I am with a
14 yes mainly because I think there is enough valid
15 scientific data, albeit there are issues with the
16 study. It is a retrospective design based on a single
17 surgeon's experience. We have approved such PMAs
18 before. It is an innovative device. I think we need
19 the device.

20 I think, with the post market approval
21 study that's stipulated here as a condition of
22 approval, I think this device will be a good addition

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1 to the surgical armamentarium.

2 Thank you.

3 MR. MELKERSON: Thank you.

4 I would also like to thank you for
5 standing in on short notice as Acting Chair. We
6 regretfully had to identify Dr. Kirkpatrick's father
7 passed away, and that's the reason why he's not there,
8 and that's why he shows up as being the Acting Chair
9 on our list of panel attendees.

10 Thank you.

11 PANEL CHAIRPERSON NAIDU: Thank you, Mr.
12 Melkerson. It was a pleasure.

13 The meeting is now adjourned.

14 (Whereupon, at 4:22 p.m., the meeting in
15 the above-entitled matter was concluded.)

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NEAL R. GROSS

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CERTIFICATE

This is to certify that the foregoing transcript
in the matter of: Orthopedic and Rehabilitation
Devices Panel Meeting
Open Session

Before: U.S. Food and Drug Administration
Center of Devices and Radiological
Health

Date: September 8, 2005

Place: Gaithersburg, MD

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.



Eric Hendrixson