

1 company, is adequate.

2 CHAIR KIRKPATRICK: Thank you.

3 Dr. Goodman?

4 MEMBER GOODMAN: I would agree.

5 Greater than 50 percent of total hip and knee
6 replacements are done by people who do less
7 than ten per year. This is a very specialized
8 operation, total ankle arthroplasty, and I
9 think that the investigators have really taken
10 quite a bit of time and effort to make sure
11 that the people who do these operations are
12 very well versed in them, trained by experts,
13 and go home with a video so they can review it
14 just before the case. Thank you.

15 CHAIR KIRKPATRICK: Thank you.

16 Dr. Wright?

17 DR. WRIGHT: I agree with Dr.
18 Goodman. I have had personal experiences with
19 some of these similar courses. And I found
20 that the thing that was helpful is also having
21 the chance to have a reference later on down
22 the road where there is someone you can call

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1 and get repeat information, sort of an ongoing
2 continuing medical education program.

3 But I think that the program that
4 they have put forward is actually more than
5 satisfactory.

6 CHAIR KIRKPATRICK: Thank you.

7 Ms. Whittington?

8 MS. WHITTINGTON: This is why I
9 asked the question about the new surgeons and
10 if this is how you created the program on
11 their experience. So I think it is very
12 comprehensive.

13 I agree with Dr. Wright that having
14 someone to dialogue with after especially
15 unusual cases or before for planning and now
16 with electronic radiographs, it makes that
17 really easy. I think that is wonderful.

18 CHAIR KIRKPATRICK: Thank you.

19 Ms. Adams?

20 MS. ADAMS: No comments.

21 CHAIR KIRKPATRICK: Thank you.

22 Dr. Mayor?

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1 DR. MAYOR: It is a classical
2 question of how good is good enough. To take
3 Dr. Goodman's observations a little further,
4 there are statistically valid -- excuse my
5 assumption -- assertions that when your rate
6 of surgical procedures drops below 50 a year,
7 your rate of success drops, too.

8 I know there are some colleagues
9 and residents that I have taught who can
10 perform impeccably after two or three
11 experiences. And others who just are never
12 going to get it right.

13 So I think practically speaking, it
14 is not unreasonable to set the goal -- to
15 examine the outcomes at a threshold of 15.

16 CHAIR KIRKPATRICK: Thank you.

17 Dr. Pfeffer?

18 DR. PFEFFER: This is acceptable.
19 I'd encourage Link to set up a visitation
20 program so novices can easily visit experts
21 and also to make sure that they continue with
22 what they said here on page two that there

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1 will be basically one cadaver per enrollee in
2 this course.

3 CHAIR KIRKPATRICK: Thank you.

4 Dr. Propert?

5 DR. PROPERT: No additional
6 comments.

7 CHAIR KIRKPATRICK: Thank you.

8 I have a comment that is personal
9 as opposed to the Chair related and that is I
10 think we saw two different learning curves in
11 this presentation of data. One was the
12 learning curve of the device implant structure
13 where they actually did some changes to the
14 instrumentation as a result of that. And the
15 other is the surgeons themselves.

16 I would suggest that the 15 number
17 is a little high. And I think if they were to
18 do it with their continued access surgeons
19 that had not been part of training with the
20 other gentlemen, they would probably find
21 their learning curve is a little bit shorter
22 because the people involved with the IDE went

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1 through a lot of the big headaches at the
2 developmental stages.

3 So now getting back to my Chair's
4 comments, it sounds like the Panel generally
5 agrees that the training program would be
6 adequate and acceptable, that there was a
7 reminder about the hospital's being
8 responsible for credentialing and not the FDA,
9 which I'm sure you don't need a reminder of,
10 and that the Panel did raise some concerns or
11 suggestions.

12 One is a concern about the casual
13 surgeon -- or not the casual but the
14 infrequent surgeon, and that would be somebody
15 doing one or less or two or three a year. But
16 that is, again, something that the FDA
17 wouldn't be able to do anything about.

18 But another alternative benefit
19 that the people have suggested is to have a
20 hotline or a website with direct dialogue on
21 trying to, you know, gain information about
22 patients, suggestions about potential

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1 pitfalls, and that sort of thing.

2 Does that adequately address your
3 question?

4 MR. MELKERSON: Yes, thank you.

5 CHAIR KIRKPATRICK: Thank you.

6 Question five?

7 MR. PINDER: The applicant has made
8 and proposed numerous modifications to both
9 surgical technique and instrumentation during
10 the course of the studies. The applicant has
11 indicated that these modifications are
12 adequate and have contributed to a decrease in
13 the adverse events associated with
14 implantation of the STAR ankle from the
15 pivotal study to the continued access.

16 Please discuss the adequacy of the
17 surgical technique and instruments, tabs eight
18 and nine, available for insertion of the STAR
19 ankle.

20 CHAIR KIRKPATRICK: Thank you.

21 We will begin with Dr. Goodman.

22 MEMBER GOODMAN: Well, surgical

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1 technique, ever for established operations,
2 changes all the time. The original total hip
3 replacements done by Sir John Charnley have
4 changed dramatically. We are using smaller
5 incisions and various different techniques.

6 And I think, as documented in the
7 book that I was given and in the talks I heard
8 today, that the investigators are making a
9 very solid effort at trying to go through
10 their misadventures, if you want to call it
11 that, and try and standardize and improve the
12 technique, for example, the institution of K-
13 wires through the malleolus and different ways
14 of trying to make things go even more
15 smoothly.

16 The technique, I'm sure, will
17 change for all operations over time. And what
18 we are seeing now, what I've seen, I think,
19 certainly makes the mark.

20 CHAIR KIRKPATRICK: Thank you.

21 Dr. Wright?

22 DR. WRIGHT: It was my observation

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1 that there were numerous modifications but I
2 was more impressed with the surgical
3 experience. I think the techniques will
4 continue to be ongoing. And I think that the
5 surgical experience was probably more
6 contributory to better results. And so I
7 think that they have adequately satisfied this
8 question.

9 CHAIR KIRKPATRICK: Thank you.

10 Ms. Whittington?

11 MS. WHITTINGTON: Nothing
12 additional.

13 CHAIR KIRKPATRICK: Ms. Adams?

14 MS. ADAMS: No comment.

15 CHAIR KIRKPATRICK: Thank you both.

16 Dr. Mayor?

17 DR. MAYOR: I don't think anyone
18 expects that this is a static process.
19 Obviously it involved significant progressive
20 improvement in both technique and
21 instrumentation from its initiation.

22 But I would only suggest even with

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1 the suggestion that my view that it is
2 probably adequate in both regard to technique
3 and instrumentation, that efforts be made to
4 keep the avenues of communication open with
5 the European experience so that any benefits
6 that they may be able to accord ours here on
7 the continent of the United States would be
8 able to be taken advantage of.

9 CHAIR KIRKPATRICK: Thank you.

10 Dr. Pfeffer?

11 DR. PFEFFER: It's adequate.

12 CHAIR KIRKPATRICK: Thank you.

13 Dr. Propert?

14 DR. PROPERT: No additional
15 comments.

16 CHAIR KIRKPATRICK: Thank you.

17 Dr. Skinner?

18 DR. SKINNER: I would only make one
19 comment. One of the definitions of an
20 orthopedic surgeon is someone who modifies the
21 operation first then they try it.

22 (Laughter.)

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1 DR. SKINNER: Other than that, I
2 would say that I agree with the other Panel
3 members.

4 CHAIR KIRKPATRICK: I would like to
5 comment as an individual again. And that is I
6 agree with everything everybody said however
7 if I was doing a PMA, I would not bring of
8 list I intend to do to a protocol. I would
9 bring a revised protocol.

10 We have a page of it looks like
11 eight or ten bullet items that you say you
12 will include. And I was very disappointed it
13 was not already revised for our consideration.
14 And as such, you know, the surgical technique
15 manual, I think, needs to be modified.

16 Now speaking as the Panel Chair, in
17 general the Panel believes that the training
18 manual is adequate and the training program
19 would be sufficient to take care of things.

20 Do you have further concerns about
21 this issue, Mr. Melkerson?

22 MR. MELKERSON: None at this time.

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1 CHAIR KIRKPATRICK: Thank you.

2 Question six?

3 MR. PINDER: Under CFR 860.7(d)(1),
4 safety is defined as reasonable assurance
5 based on valid scientific evidence that the
6 probable benefits to health under conditions
7 of intended use when accompanied by adequate
8 directions for use and warnings against unsafe
9 use outweigh any probably risks

10 Considering additional risks of
11 surgical complications for the subject device,
12 please discuss whether the clinical data in
13 the PMA provide reasonable assurance that the
14 device is safe.

15 CHAIR KIRKPATRICK: Thank you.

16 We will start with Dr. Wright.

17 DR. WRIGHT: I think that the
18 applicant has given me reasonable assurances
19 that the device is safe.

20 CHAIR KIRKPATRICK: Thank you.

21 Ms. Whittington?

22 MS. WHITTINGTON: I would also

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1 agree that I think that they have given us
2 information that leads me to believe it is
3 safe. And I think probably the most important
4 information to me was the use of a tool that
5 gives the patient's perspective and real
6 functionality and impact on their lives. And
7 I think that that is what most impresses me
8 about the safety.

9 CHAIR KIRKPATRICK: Thank you.

10 Ms. Adams?

11 MS. ADAMS: I think the answer is
12 yes. And, again, from an industry
13 perspective, thinking about the volume of data
14 that has been presented here as compared to
15 ankles that we know are on the market today
16 with no clinical data, I think they have gone
17 beyond the definition of reasonable.

18 CHAIR KIRKPATRICK: Thank you.

19 Dr. Mayor?

20 DR. MAYOR: Strictly within the
21 temporal constraints imposed with regard to
22 the collection of data for this application, I

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1 would have to conclude that safety has been
2 demonstrated.

3 CHAIR KIRKPATRICK: Thank you, Dr.
4 Mayor.

5 Dr. Pfeffer?

6 DR. PFEFFER: Safety has been
7 demonstrated but the issue of warning against
8 unsafe use is the key sentence I think here.
9 And we have to make sure at some point to
10 discuss how to pass along to the user the
11 information that has been learned by the
12 continued access cohort group. And who the
13 ankle is appropriate for.

14 CHAIR KIRKPATRICK: May I follow up
15 with that to ask you if you have suggested
16 revisions to either indications or
17 contraindications?

18 DR. PFEFFER: I would quote Dr.
19 Mann, what he said earlier, we need a
20 plantargrade foot in order to have an ankle
21 succeed. And that has to be emphasized as the
22 main pillar of safety. A plantargrade foot.

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1 CHAIR KIRKPATRICK: Thank you.

2 Dr. Propert?

3 DR. PROPERT: I do not think there
4 is sufficient scientific evidence here that
5 the device is safe. I'm empathetic and
6 applaud the sponsor's attempts to work on a
7 very difficult problem.

8 But I think the inherent biases in
9 the study designs, some of which could not be
10 fixed, and the uncertainty in the results, I'm
11 not willing to say that there is no reasonable
12 doubt that it is not safe. I don't think it
13 has been shown safe.

14 CHAIR KIRKPATRICK: Thank you.

15 Dr. Skinner?

16 DR. SKINNER: I would have to say
17 that from my understanding of what is going on
18 today and from my reading before, that the
19 STAR ankle is not inferior to ankle
20 arthrodesis. And, therefore, I think that it
21 is safe from that viewpoint.

22 CHAIR KIRKPATRICK: Thank you.

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1 Dr. Goodman?

2 MEMBER GOODMAN: I think, given the
3 information that we have and judging this
4 ankle against its peers, if I can use that
5 term, it is as safe as its peers which are
6 already on the market. Whether it is as safe
7 as an ankle arthrodesis is in a bit of a
8 question given the data that we were
9 presented.

10 CHAIR KIRKPATRICK: Thank you.

11 Mr. Melkerson, I believe that the
12 Panel is in a split decision on this one.
13 Some favor safe -- and without taking a vote I
14 think they would suggest that the majority
15 slightly would be in favor of saying it is
16 safe.

17 However, several of the Panel
18 members indicated that safety was within the
19 constraints of the study, as given. And by
20 that, I seem to hear that they are concerned
21 about long-term durability beyond the 48
22 months or the 24 months of the pivotal study

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1 and the continued access. They are worried
2 about very long-term durability such as five
3 and ten years.

4 Also, there was some concern about
5 whether the specific warnings and indications
6 were appropriately phrased with some concern
7 especially about the plantargrade foot being
8 an essential component of a successful
9 outcome.

10 There was some safety concerns with
11 regard to the biases inherent into the design
12 and the uncertainty of the statistical outcome
13 that would lead to a concern about safety.

14 And then others commented on it
15 seems as safe as what is out there.

16 And so putting all those together
17 as full comments, that would be our answer.

18 Does that adequate address the
19 issues of discussion for the safety?

20 MR. MELKERSON: It is adequate at
21 this time. Thank you.

22 CHAIR KIRKPATRICK: Thank you.

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1 Question seven please.

2 MR. PINDER: Under CFR 860.7(e)(1),
3 effectiveness is defined as reasonable
4 assurance that in the significant portion of
5 the population, the use of the device for its
6 intended uses and conditions of use when
7 accompanied by adequate directions for use and
8 warnings against unsafe use will provide
9 clinically-significant results.

10 Considering the study outcomes,
11 please discuss whether the clinical data in
12 the PMA provide reasonable assurance that the
13 device is effective.

14 CHAIR KIRKPATRICK: Thank you.

15 We will begin with Ms. Whittington.

16 MS. WHITTINGTON: I have a couple
17 comments and I'm not sure that these are
18 specific or right on. Adequate directions of
19 use, I wanted to address that phrase, and
20 certainly the OR technique we just discussed.

21 But as we have heard responses to
22 several things today, I think that there needs

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1 to be realistic parameters in the patient
2 education materials that you included with the
3 packet of materials we got to include a level
4 of function at six months. There were two
5 times during the data presentation that
6 someone alluded to four months in a cast or
7 continued partial weight bearing. And that
8 certainly is not what is indicated in the
9 patient education material that I read in the
10 book.

11 In addition, someone said that --
12 and I quote, "You need rigorous post-op
13 education for increased post-op compliance,"
14 which, again, I did not see that rigorous an
15 inclusion of education materials for the
16 patient who is going to receive this.

17 Is it effective? It looked like to
18 me that it was effective. I know we've looked
19 back and forth at some of the statistical
20 things and I'm sure my colleagues will some of
21 them disagree with me, but from the patient's
22 perspective it seems that it would be more

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1 effective than an arthrodesis which changes
2 the gait and effects more than just the ankle.

3 CHAIR KIRKPATRICK: Thank you.

4 Ms. Adams?

5 MS. ADAMS: Well, I'm not qualified
6 to say from a statistical standpoint. Today
7 is your day, Dr. Propert.

8 But I do want to just emphasize
9 that when we are talking about reasonable
10 assurance, this language comes right out of
11 the law.

12 And I want to make sure that even
13 though I understand your concerns, Dr.
14 Propert, we're not supposed to be weighing in
15 on beyond any possibility of doubt. Basically
16 the standard is reasonable assurance. So I
17 want to be sure that we are all on the same
18 page with respect to that.

19 CHAIR KIRKPATRICK: Thank you.

20 Dr. Mayor?

21 DR. MAYOR: I'm going to launch a
22 discussion at first of the writing that came

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1 with this application. Making a few
2 observations that more reveal my semantic bias
3 than anything else but may also be worth
4 thinking about in terms of editorial
5 corrections that would be useful to make as
6 you go forward.

7 I'm not satisfied or happy with the
8 term primary arthritis. I don't know of any
9 knowledge that we have that suggests that any
10 arthritis is primary. Idiopathic would seem
11 to me more appropriate meaning that the
12 patient is pathetic and the clinician is an
13 idiot.

14 (Laughter.)

15 DR. MAYOR: We just don't know why
16 it is there but it is not primary.

17 Another observation is that there
18 are no relative contraindications for this
19 surgical procedure. And I thought there
20 probably should be one. For instance, the
21 proscription against putting it in anyone who
22 has ever had a bone infection in the limb near

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1 the ankle would seem to me excessive. Because
2 we certainly confront that issue with hip and
3 knee replacement.

4 And infection in a prior time of
5 life is not an absolutely contraindication to
6 doing the procedure, recognizing that there is
7 an increased concern and possibility of
8 complications.

9 Lower extremity vascular
10 insufficiency was supposed to be assessed by
11 doppler vascular pressure. I don't think that
12 is what doppler assessment does. It looks at
13 flow but it doesn't tell you about pressure.
14 So that might want to be either expunged or
15 reworded.

16 Very strong recommendation in
17 several places suggested we should determine
18 the existence of an allergic status. How do
19 you do that? We don't have any reliable way.

20 And with the increased prevalence of piercing
21 --

22 CHAIR KIRKPATRICK: Dr. Mayor, may

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1 I ask if these are issues that might be
2 related towards indications of should be
3 approvable or are they more related to
4 definition of whether it is effective or not?

5 DR. MAYOR: These would be more
6 related to the finished product were it to be
7 judged approvable.

8 CHAIR KIRKPATRICK: May I ask you
9 to confine your comments now to the
10 effectiveness question? Or do you find them
11 intimately related?

12 DR. MAYOR: I just looked at
13 adequate directions for use and warnings
14 against use as being --

15 CHAIR KIRKPATRICK: Okay.

16 DR. MAYOR: -- a place to go. And
17 if you would prefer I didn't, I won't.

18 CHAIR KIRKPATRICK: Well, if we
19 discuss them now, that's fine. Then we won't
20 discuss them in as much detail later if you
21 cover it now.

22 DR. MAYOR: Well, I don't have a

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1 lot of additional ones to --

2 CHAIR KIRKPATRICK: Okay.

3 DR. MAYOR: -- touch on. And I
4 will bring up a couple of other issues
5 subsequently. But my major concern is that in
6 regard to long-term effectiveness, the data
7 that we have and the studies that were done
8 both preclinically and in the process of
9 follow up, particularly with regard to
10 retrieval analysis of implants recovered at
11 revision is not adequate to demonstrate
12 effectiveness.

13 CHAIR KIRKPATRICK: Thank you.

14 Dr. Pfeffer?

15 DR. PFEFFER: You mention
16 effective, it means effective compared to
17 what. I would agree with Dr. Goodman that the
18 STAR is clearly as effective as other ankles
19 that are in use in the world and specifically
20 the United States. And I am intimately aware
21 of that literature.

22 Based upon this study, I'm not

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1 still convinced necessarily which is more
2 effective -- a fusion in the appropriate
3 patient or a total ankle. But the weakness of
4 this study is the arthrodesis arm. And I
5 think we should keep our focus on the total
6 ankle arm which convinces me that it is both
7 effective and adequately safe.

8 CHAIR KIRKPATRICK: Thank you.

9 Dr. Propert?

10 DR. PROPERT: To use the correct
11 language this time, I am reasonably assured
12 that this device is effective.

13 CHAIR KIRKPATRICK: Dr. Skinner?

14 DR. SKINNER: I think that the
15 effectiveness comes down to the BP score. And
16 I think it is inappropriate to exclude the
17 range of motion from that. And with the range
18 of motion score, it is quite apparent to me --
19 it is even reasonably assured to me that it is
20 effective.

21 CHAIR KIRKPATRICK: Thank you.

22 Dr. Goodman?

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1 MEMBER GOODMAN: I'm reasonably
2 assured as well.

3 CHAIR KIRKPATRICK: Thank you.

4 Dr. Wright?

5 DR. WRIGHT: I'm assured.

6 CHAIR KIRKPATRICK: Dr. Wright said
7 he is assured but he is not assured at how to
8 turn on his microphone.

9 DR. WRIGHT: I was going to say I
10 was assured that it was reasonably effective
11 but --

12 (Laughter.)

13 DR. WRIGHT: -- but I think that
14 the sponsors have convinced me.

15 CHAIR KIRKPATRICK: Thank you.

16 Mr. Melkerson, in regards to
17 Question No. 7, it appears that there is a
18 reasonable assurance of effectiveness. Again,
19 points were made as to comparisons and some
20 allusion was made to that it might be better
21 compared against other ankles and with
22 historical controls it certainly is as

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1 effective as other ankles.

2 There were some concerns about the
3 details of intended uses and warnings which
4 were brought up which I'm sure will have
5 further discussion later.

6 Does that adequately address this
7 question?

8 MR. MELKERSON: It is adequate at
9 this time. Thank you.

10 CHAIR KIRKPATRICK: Thank you.

11 Question 8 please.

12 MR. PINDER: All right. This is
13 the final question and it concerns the post-
14 approval study.

15 Within Tab 13 of the Panel pack,
16 the applicant has proposed to conduct a two
17 component post-approval study which includes a
18 long-term follow-up component with the rate of
19 device revision or removal as the primary
20 outcome and a short-term 12-month physician
21 learning curve component with a rate of
22 measured complications as the primary outcome.

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1 Please comment on the follow post-
2 approval study issues. So I guess we'll just
3 take this one bullet by bullet.

4 CHAIR KIRKPATRICK: Excuse me just
5 a moment. Mr. Melkerson would like to make a
6 comment.

7 MR. MELKERSON: Just as a point of
8 clarification, that is if you recommend
9 approval with one of those conditions being
10 post approval. So when you are answering this
11 question, it would be in that context.

12 CHAIR KIRKPATRICK: Is the Panel
13 clear on that? This is not necessarily part
14 of everything unless we decide that there
15 would be a post-approval study later. And so
16 under that assumption if we were to suggest a
17 post-approval study do we consider this
18 question.

19 Thanks.

20 Please proceed.

21 MR. PINDER: Okay. So should we
22 tackle one through four individually? Or do

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1 you want them read as a whole?

2 CHAIR KIRKPATRICK: I would propose
3 that we start with it as a whole first.

4 MR. PINDER: Okay.

5 CHAIR KIRKPATRICK: And if we have
6 trouble with the whole, then we will go to
7 individuals. Thank you.

8 MR. PINDER: Okay. All right.

9 A radiographic evaluation, the
10 adequacy of intervals and frequency of
11 radiographic assessment, the necessity for
12 mandatory radiographic measurements, the
13 necessity for radiographic measurement on all
14 patients to be performed by independent
15 radiologists, and the relevant radiographic
16 parameters to measure.

17 DR. PFEFFER: May I ask a quick
18 question?

19 CHAIR KIRKPATRICK: Yes.

20 DR. PFEFFER: So I just want to
21 make sure this has been clarified. This says
22 on page two again, x-rays will be performed as

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1 a matter of good clinical practice. In
2 addition, clinically indicated anterior and
3 posterior x-rays will be taken.

4 Link has revised that to state that
5 x-rays will be taken at each visit?

6 MR. GREENBERG: Yes, that is
7 correct.

8 DR. PFEFFER: All right.

9 CHAIR KIRKPATRICK: Okay? Any
10 other questions or clarification on the
11 radiographic evaluation which is four items
12 under Item A?

13 I see a puzzled look.

14 DR. WRIGHT: I don't think they
15 said at every visit. And I don't think we
16 want to have x-rays taken at every visit. I
17 think they gave us a time frame for weight-
18 bearing x-rays, which I thought was
19 satisfactory. Correct?

20 CHAIR KIRKPATRICK: One, two, four,
21 and eight was it?

22 DR. WRIGHT: Zero.

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1 CHAIR KIRKPATRICK: And then
2 annually?

3 DR. WRIGHT: I think they said
4 zero, two --

5 MEMBER GOODMAN: Zero, one, two,
6 four, and eight.

7 CHAIR KIRKPATRICK: Okay.

8 MEMBER GOODMAN: I wrote it down.

9 CHAIR KIRKPATRICK: Okay.

10 DR. WRIGHT: That's fine.

11 CHAIR KIRKPATRICK: So zero months,
12 one month, two months.

13 MEMBER GOODMAN: Years.

14 CHAIR KIRKPATRICK: Sorry, years,
15 sorry, you got it. Zero meaning immediate
16 post-op, one year, two year, four years, and
17 eight years. Is that what I understand the
18 sponsor is proposing?

19 MR. GREENBERG: Yes, that is
20 correct.

21 CHAIR KIRKPATRICK: Okay. So we
22 are not going to look among each other. We

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1 are asking you now.

2 MS. WHITTINGTON: Nothing before 12
3 months at all?

4 CHAIR KIRKPATRICK: They have a
5 post-op and then a 12-month view. Was it pre-
6 op or post-op? The zero is post-op or pre-op?
7 I'm asking the sponsor to please clarify.

8 DR. COUGHLIN: You need both.

9 CHAIR KIRKPATRICK: There will be
10 both a pre- and post-op.

11 DR. COUGHLIN: Correct.

12 CHAIR KIRKPATRICK: And then there
13 will be additional post-ops at one, two, four,
14 and eight years.

15 DR. COUGHLIN: Correct.

16 CHAIR KIRKPATRICK: Does that
17 clarify the intervals? Thank you.

18 Do we need further clarification on
19 any of the other items under A, B, C, or D?
20 I'm sorry. I meant one, two, three, and four.

21 We are only addressing A, the radiographic
22 assessment. Okay. Since it seems clear to

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1 everybody, we'll start with Ms. Adams.

2 Do we want to try and take all A,
3 B, and C together? I think that might be a
4 little complicated.

5 MS. ADAMS: I'm happy to comment at
6 this point.

7 CHAIR KIRKPATRICK: Go ahead.

8 MS. ADAMS: My comments are related
9 to all of the questions. And it is probably
10 fortuitous that this one has started off with
11 me because this is the area I have the
12 greatest angst. In fact, I'm having chest
13 pain right now.

14 I want to remind my colleagues on
15 the Panel that this is very unusual for us at
16 this point in a Panel to stop and take a look
17 at what the sponsor has proposed for a post-
18 approval study, to hear from the FDA about
19 their concerns about the post-approval
20 studies, and to debate the post-approval
21 studies. This is something new that is
22 happening within CDRH.

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1 The FDA is trying very hard to work
2 with the sponsors to get these questions out
3 on the table earlier. But there is not a
4 process. We are kind of learning as we go we
5 are all saying. And this is extremely
6 unusual. So that is the first part of my
7 comment.

8 The second part of it is I think it
9 is very important for us to think in terms of
10 what this kind of new discussion is going to
11 mean to the industry.

12 And I say that because it is one
13 thing when we are talking about drug-eluting
14 stents and there are hundreds of thousands of
15 patients. It is another thing when we are
16 talking about an ankle, a total ankle that
17 maybe there are four, five, six thousand cases
18 that are going to be seeing this.

19 To do the kinds of things that are
20 being suggested has a huge cost associated
21 with it. When we talk about bringing people
22 back for radiographs, following up for eight

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1 years, these things are things that have a
2 major cost impact.

3 I could go through all of these. I
4 won't go by line by line. We've already heard
5 about the challenges associated with getting
6 people back. Those of us who have done post-
7 approval studies knows this is one of the
8 biggest challenges is continued enrollment and
9 continued follow up.

10 So not to say that post-approval
11 studies should not be done, not to say that we
12 shouldn't entertain a lot of these good ideas
13 that FDA has put forward, but I want to remind
14 my colleagues on the Panel that we are braving
15 new territory here. And what we say will have
16 an impact on other companies that come to
17 Panel.

18 CHAIR KIRKPATRICK: Thank you, Ms.
19 Adams. We need to stick to the process we
20 have been given. We can't alter it based upon
21 what we need to do or what we think we should
22 be doing or alterations and that sort of

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1 thing.

2 Let me recognize Mark for a moment.

3 He had a comment.

4 MR. MELKERSON: I think in terms of
5 process, you could delay looking at this
6 question should you get to the point of a
7 conditional approval with one of the
8 conditions being a post-approval study. What
9 I was thinking I was trying to get to is you
10 can take the prerogative as a Panel to make
11 that cut.

12 CHAIR KIRKPATRICK: Yes, I would
13 suggest that based upon what I have heard,
14 while I can't surmise what people would vote,
15 my Panel experience is that a post-approval
16 study is almost necessary in issues of long-
17 term durability.

18 So knowing that from past
19 experience, I would suggest we go ahead and
20 address these issues now. And then if we vote
21 for the post-approval study, we can just say
22 the post-approval study, as proposed, if we

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1 get to that point.

2 Would anyone else from FDA wish to
3 comment? Please identify yourself when you
4 reach the mic. Push the button.

5 DR. MARINAC-DABIC: My name is
6 Danica Marinac-Dabic. I'm the Chief of
7 Epidemiology Branch. That is the unit that is
8 in charge of review, monitoring, and oversight
9 of the post-approval studies.

10 I just would like to comment on Ms.
11 Adams' comments about how unusual this part of
12 the process is. I would like to just state
13 again that the CDRH is undergoing the post-
14 market transformation. You all had learned
15 about the changes in the post-approval studies
16 program which are designed to raise the bar
17 and the scientific rigor of the post-approval
18 studies.

19 Our team had spent time to identify
20 these issues that are important as important
21 public health questions. I know that cost is
22 certainly one of the things that we would like

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1 to consider. However, the main concern is
2 what are the post-market questions that the
3 post-approval study should answer.

4 CHAIR KIRKPATRICK: Thank you.

5 I think in summary, yes, we are
6 paving new ground. But it appears to be
7 appropriate ground to consider. In addition,
8 as the FDA looks at this, even if we decide to
9 vote it with options, they may want to
10 consider what we have in discussion on this
11 issue.

12 In addition, I would like to take
13 them as letters as opposed to all
14 comprehensive because I have identified one
15 that would eliminate them from having to do
16 something that is rather expensive. So if
17 that is okay, we'll go letter by letter.

18 So first of all, we'll go to -- oh,
19 Mark had a recognition again. Thanks.

20 MR. MELKERSON: Just one point in
21 terms of issues related to cost are not part
22 of our purview but should be something that

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1 you would keep in your own considerations.

2 CHAIR KIRKPATRICK: Absolutely. We
3 put patient safety and the benefit of our
4 patients first. But we also have to, you
5 know, consider issues of whether it is a
6 realistic option to require some post-
7 marketing studies.

8 Thank you.

9 So let's go over Item A,
10 radiographic evaluation. Can you comment on
11 whether that would be adequate or inadequate
12 for a post-approval study if we decide that
13 one is appropriate?

14 Ms. Adams? Item A, the
15 radiographic findings.

16 MS. ADAMS: And you are just
17 looking for adequate or inadequate?

18 CHAIR KIRKPATRICK: Is that not
19 what the FDA is asking for? Whether that
20 would be an adequate approach to radiographic
21 findings or whether we need to add to that. I
22 think it is just discussing whether you think

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1 that is good enough or you would want more x-
2 rays or less x-rays? Or would you modify that
3 in any?

4 MS. ADAMS: Well, the only comment
5 I would make is to Item 4, which we have
6 discussed at length today, which again is what
7 are the appropriate and relevant radiographic
8 parameters to measure. What is most
9 predictive of clinical success? Or are they
10 even? So I'll just reemphasize that.

11 CHAIR KIRKPATRICK: Thank you.

12 Dr. Mayor?

13 DR. MAYOR: This is a two-articular
14 interface implant. And will produce debris.
15 And will produce very fine particulate debris.

16 As time passes beyond four years,
17 there is a real concern that we need to know
18 individual patients are responding with regard
19 to the possibility of osteolytic reactions to
20 those particles. It is clear from previous
21 studies in hip and knee arthroplasty patients
22 that you don't pick up early signs of

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1 osteolysis with plain films.

2 So I think what I would suggest is
3 that beyond five years, if any indication of
4 unusual wear appears to be indicated on plain
5 film studies that are reasonably rigorously
6 done so that the geometry can be assessed
7 properly, that a CT study may need to be
8 pursued in order to answer that question.

9 CHAIR KIRKPATRICK: Thank you.

10 Dr. Pfeffer?

11 DR. PFEFFER: Well, I'm comfortable
12 with what we outlined as the requirement for
13 radiographs.

14 CHAIR KIRKPATRICK: Thank you.

15 Dr. Propert?

16 DR. PROPERT: No additional
17 comments.

18 CHAIR KIRKPATRICK: Thank you.

19 Dr. Skinner?

20 DR. SKINNER: Well, I have real
21 problems with the whole idea of a post-
22 approval study. I'm not certain what

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1 information we want to get out of that study,
2 if any. If we see these total ankles failing,
3 what are we going to do? Are we going to take
4 the prosthesis off the market? What change is
5 going to be made?

6 We are talking about what -- a
7 couple hundred patients followed for a period
8 of time. I'm not sure what information we are
9 going to get.

10 CHAIR KIRKPATRICK: And we're not
11 debating the post-approval study issue. We
12 are debating whether the radiographic findings
13 would be appropriate.

14 DR. SKINNER: Well, that is where
15 I'm going --

16 CHAIR KIRKPATRICK: Okay.

17 DR. SKINNER: -- because I don't
18 see any reason for doing the radiographs in
19 that study.

20 CHAIR KIRKPATRICK: Okay. Thank
21 you.

22 Dr. Goodman?

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1 MEMBER GOODMAN: I agree with the
2 radiographic evaluation. I would also
3 recommend that they truly be rated by
4 independent radiologists. And that all the x-
5 rays be rated by the same group of
6 radiologists.

7 CHAIR KIRKPATRICK: Thank you.
8 Dr. Wright?

9 DR. WRIGHT: I would change the
10 word radiologist or give the examiner some
11 leeway in there whether they could have an
12 investigator or a physician or a surgeon, not
13 just a radiologist because I don't think
14 radiologists are expert at reading
15 musculoskeletal x-rays, number one.

16 Number two, I think -- I'm not sure
17 how we would go with the first part of Panel
18 Question 8. But I think the second bullet is
19 actually a bit onerous in that they have a
20 short-term 12-month physician learning curve.

21 So I think what has been approved
22 here is more than satisfactory.

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1 CHAIR KIRKPATRICK: We'll be
2 talking about the learning curve in Item F as
3 well.

4 DR. WRIGHT: I'm sorry.

5 CHAIR KIRKPATRICK: Sorry, there
6 are two pages to that question. Thank you.

7 Ms. Whittington?

8 MS. WHITTINGTON: I agree with the
9 radiographic follow up and I might remind the
10 company that it is not only a cost to you but
11 it is the cost to the patient as they pay
12 their co-pay and take time off work and go in
13 for those visits. It is also a cost to the
14 physician in terms of productive time.

15 CHAIR KIRKPATRICK: Thank you.

16 In summary on the radiographic
17 evaluation, it appears that there is near
18 unanimous agreement that radiographs would be
19 appropriate in follow up at the schedule
20 discussed and itemized through our discussion.

21 There is some concern as to the
22 interpreter of those radiographs. It should

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1 be an experienced examiner, familiar with the
2 device. But not a surgeon of the study group
3 necessarily. So it should be an independent
4 person but somebody that understands the
5 principles involved.

6 And there also appeared to be a
7 reasonable suggestion of if radiolucencies do
8 develop, that a CT is the best way to evaluate
9 them because of the confounding variables of
10 having metallic implants hiding potential
11 radiolucency and lytic lesions.

12 Does that adequately address Item A
13 under Panel Question 8?

14 MR. MELKERSON: I believe so.

15 CHAIR KIRKPATRICK: Thank you.

16 Moving on to Item B --

17 MEMBER GOODMAN: May I just make a
18 point because I think you mentioned CT scans.

19 I would modify that to say CT scan or another
20 modality because there is now emerging
21 evidence that other methods of evaluation of
22 osteolytic lesions may be just as effective

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1 and possibly with the decreased chance of
2 increasing of radiographic exposures.

3 CHAIR KIRKPATRICK: So revise that
4 to an axial imaging study of relevance. Is
5 that fair?

6 Thank you.

7 Item B, would you like to proceed
8 please?

9 MR. PINDER: Comparing STAR ankle
10 arthroplasty to a control EG arthrodesis or
11 another type of arthroplasty and the specific
12 long-term outcomes to be compared.

13 CHAIR KIRKPATRICK: So I would
14 interpret that as to do they need a control
15 group for a post-approval study.

16 We will start with Dr. Mayor.

17 DR. MAYOR: I would conclude no.

18 CHAIR KIRKPATRICK: Thank you.

19 Dr. Pfeiffer?

20 DR. PFEFFER: No.

21 CHAIR KIRKPATRICK: Thank you.

22 Dr. Propert?

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1 DR. PROPERT: I think this is the
2 hardest question on this list. And I think
3 this question maybe what was underlying the
4 previous discussion you brought up, Dr. Mayor,
5 about hypothesis-driven study design.

6 I'm a statistician. Everybody
7 should have a control group. But I think as
8 long as they could get adequate historical
9 controls or controls from the literature from
10 other well-designed studies, that would be
11 sufficient.

12 CHAIR KIRKPATRICK: Thank you.

13 Dr. Skinner?

14 DR. SKINNER: This goes to my
15 previous comments. Without a control group, I
16 wouldn't be able to get this through my IRB.
17 So, again, I don't see a reason for doing a
18 study if you don't have a control group. But
19 I don't think a control group is necessary.

20 CHAIR KIRKPATRICK: Thank you.

21 Dr. Goodman?

22 MEMBER GOODMAN: No control group

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1 is necessary. And I could get it through my
2 IRB.

3 CHAIR KIRKPATRICK: Thank you.

4 Dr. Wright?

5 DR. WRIGHT: No.

6 CHAIR KIRKPATRICK: Thank you.

7 Ms. Whittington?

8 MS. WHITTINGTON: No.

9 CHAIR KIRKPATRICK: Thank you.

10 Ms. Adams?

11 MS. ADAMS: No further comment.

12 CHAIR KIRKPATRICK: Thank you.

13 With regard to Item B, it appears
14 that a control group is nearly unanimously not
15 felt to be necessary. And those that do feel
16 strongly about a control would be willing to
17 accept historical controls or comparative
18 controls of other ankles in the literature.

19 Does that adequately address Item
20 B?

21 MR. MELKERSON: I believe so.

22 CHAIR KIRKPATRICK: Thank you.

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1 Proceed to Item C please.

2 MR. PINDER: Addressing the long-
3 term outcome of STAR ankle patients who
4 experience revision or convert to arthrodesis
5 after STAR ankle failure, including those STAR
6 ankle patients who failed in the continued
7 access study.

8 CHAIR KIRKPATRICK: Would you mind
9 rephrasing that as a specific question? In
10 other words, should we say how should we
11 address the outcome of those patients? Or
12 should we address those that experience
13 revision? What is the specific nature of that
14 question.

15 MR. PINDER: Should they be
16 addressed.

17 CHAIR KIRKPATRICK: Okay. Should -
18 - so the question would be should the long-
19 term outcome of STAR ankle patients who
20 experience revision or convert to arthrodesis
21 after a STAR failure be addressed in the post-
22 approval study?

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1 And we will go to Dr. Pfeffer
2 first.

3 DR. PFEFFER: Yes.

4 CHAIR KIRKPATRICK: Thank you.

5 Dr. Propert?

6 DR. PROPERT: Yes.

7 CHAIR KIRKPATRICK: Thank you.

8 Dr. Skinner?

9 DR. SKINNER: Yes what?

10 CHAIR KIRKPATRICK: Yes -- if you
11 say yes, you are agreeing that any of the
12 revisions and failures should be included in
13 the post-approval group reporting.

14 DR. SKINNER: Yes.

15 CHAIR KIRKPATRICK: Yes. Thank
16 you.

17 Dr. Goodman?

18 MEMBER GOODMAN: Yes.

19 CHAIR KIRKPATRICK: Thank you.

20 Dr. Wright?

21 DR. WRIGHT: No.

22 CHAIR KIRKPATRICK: No. Would you

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1 like to add some discussion on that just so
2 the FDA knows your feeling of difference.

3 DR. WRIGHT: Well, I think that as
4 has been demonstrated, there are many reasons
5 for a revision. And I don't think it -- I
6 think some of them are mechanical and related
7 to the device and some of them are not. And
8 so I don't think we would gain anything by
9 having an extensive review on some obscure
10 reasons for failure. I guess I was --

11 CHAIR KIRKPATRICK: Thank you. So
12 to summarize your concern is there may be non-
13 device-related reasons for revision.

14 DR. WRIGHT: Yes.

15 CHAIR KIRKPATRICK: Okay. Thank
16 you.

17 Ms. Whittington?

18 MS. WHITTINGTON: Yes, I think
19 there should be. And they may be going to a
20 surgeon who is not included in the study. So
21 you need to let the patient know that if they
22 have a revision, we ask them to report it to

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1 help us with outcomes.

2 CHAIR KIRKPATRICK: Thank you.

3 And Ms. Adams?

4 MS. ADAMS: Well, I just want to
5 clarify. The sponsor said that they do intend
6 to follow up patients for a long period of
7 time, which I think we have all said we want
8 to see. But the way this is worded makes it
9 look like we are talking about following up
10 patients who have had a revision or
11 arthrodesis. So am I misreading this?

12 CHAIR KIRKPATRICK: I think the
13 point of the question -- please correct me if
14 I'm wrong -- is that they specifically want to
15 include analysis of those that have revision
16 in the post-approval study.

17 Is that correct, Mark?

18 MR. MELKERSON: My understanding of
19 the question was -- and it relates to a
20 question that came up -- is what happens if
21 you need to revise and what is the impact on
22 the patient? So that is part of the question.

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1 The other part of the question is
2 reasons for revisions. And as you were
3 describing, there will be different reasons
4 for revision and that would be part of usually
5 an endpoint of any post-approval study looking
6 at revision.

7 But I think the question was is
8 there an easy conversion as described by the
9 sponsor in their packages that would be easy
10 to -- in other words, is there an assessment
11 of that information or data supporting that?

12 CHAIR KIRKPATRICK: Does that
13 clarify?

14 MS. ADAMS: So let me just make
15 sure I've got it right. So right now we have
16 patients in the continued access study who
17 failed. And what you are asking is should we
18 continue to follow them.

19 MR. MELKERSON: The sponsor has
20 made a statement and it is actually in their
21 Panel pack as well that the conversion to
22 arthrodesis -- in other words, should you need

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1 to revise, it is easy to convert to
2 arthrodesis. And I think what the question
3 also relates to is is there data to support
4 that statement or claim?

5 MS. ADAMS: So then we would be
6 talking about collecting data on the revision
7 itself? Okay.

8 DR. WANG: I just want to -- can I?

9 CHAIR KIRKPATRICK: That sounds
10 like an affirmative answer.

11 MS. ADAMS: I'm not clear.

12 CHAIR KIRKPATRICK: Are you going
13 to clarify this issue?

14 DR. WANG: Yes.

15 CHAIR KIRKPATRICK: Go ahead.

16 DR. WANG: I think the questions
17 basically address for the STAR ankle patients
18 who have a revision or convert to arthrodesis
19 you their long-term outcome are because the
20 STAR ankle author has proposed an alternative
21 arthrodesis. In the early stage, they may
22 show bad results. But by the long end, is

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1 this prosthesis going to fail?

2 So for the patient who had a
3 revision, it will fail earlier. For example,
4 a patient fails in the continued access study,
5 how their long-term outcome are compared to
6 arthrodesis. With revision information also
7 important for the clinician and patient to
8 know before they receive these arthroplasty.

9 CHAIR KIRKPATRICK: For an extreme
10 example, if 50 percent of those revised end up
11 with an amputation because they go through the
12 process of having a revision, it fails. They
13 go to arthrodesis, it fails. Gets infected.
14 And they end up getting an amputation. That
15 would be something we would all want to know
16 going into this at the beginning.

17 DR. WANG: Right, right, yes.

18 CHAIR KIRKPATRICK: An extreme,
19 with all due respect to the sponsors, I never
20 expect that. Okay?

21 Thank you.

22 So Dr. Mayor, your comment on this.

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1 DR. MAYOR: I think IMC does raise
2 those two questions that we have touched on
3 briefly. One is to know whether or not the
4 arthroplasty event has compromised the long-
5 term outcome subsequent to revision.

6 And two, beyond that, I feel that
7 this subsection should also include some
8 fairly strong wording that indicates an
9 analysis of the retrieved implant components
10 should be pursued. Whether pursued by the
11 sponsor or by some agent that they designate,
12 I don't have any strong feelings about. But
13 they should be pursued.

14 CHAIR KIRKPATRICK: Thank you.

15 Mr. Melkerson, it seems that
16 uniformly yes, this group of patients should
17 be analyzed, followed, and answers yielded
18 with -- I think there was one descent.

19 And then an additional comment was
20 made that looking at the retrievals would be
21 important in this group to see if there is
22 other lessons to be learned.

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1 Does that adequately address Item
2 C?

3 MR. MELKERSON: I believe so, yes.

4 CHAIR KIRKPATRICK: Thank you, Mr.
5 Melkerson.

6 Next, Item D. Shall I read it?

7 It states the appropriate length of
8 follow up -- eight years currently is
9 proposed.

10 We will start with -- let's see,
11 where do I go now -- this is Dr. Probert. Is
12 the eight-year time an appropriately proposed
13 length for the long-term follow up in the
14 post-approval study should be approve it?

15 DR. PROPERT: I think it is very
16 optimistic but I think it is fine.

17 CHAIR KIRKPATRICK: Thank you.

18 Dr. Skinner?

19 DR. SKINNER: I agree.

20 CHAIR KIRKPATRICK: Thank you.

21 Dr. Goodman?

22 MEMBER GOODMAN: That's fine.

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1 CHAIR KIRKPATRICK: Thank you.

2 Dr. Wright?

3 DR. WRIGHT: Yes.

4 CHAIR KIRKPATRICK: Thank you.

5 Ms. Whittington?

6 MS. WHITTINGTON: I agree.

7 CHAIR KIRKPATRICK: Thank you.

8 Ms. Adams?

9 MS. ADAMS: I agree with Dr.

10 Propert.

11 CHAIR KIRKPATRICK: Thank you.

12 Dr. Mayor?

13 DR. MAYOR: We are frequently asked
14 by patients about the ten-year follow up and
15 the literature is also very attentive to the
16 question of what does the ten-year cadre look
17 like. If we are going to do it for eight
18 years and be optimistic as surgeons generally
19 have to be, I don't see any reason not to
20 extend it to ten.

21 CHAIR KIRKPATRICK: Thank you.

22 And Dr. Pfeffer?

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1 DR. PFEFFER: That's a good point
2 made by Dr. Mayor but the eight is all right
3 with me.

4 CHAIR KIRKPATRICK: Thank you. So
5 --

6 MS. ADAMS: Dr. Kirkpatrick?

7 CHAIR KIRKPATRICK: Yes, ma'am?

8 MS. ADAMS: I'm sorry. Can I make
9 one additional comment?

10 CHAIR KIRKPATRICK: Is it to argue
11 against the ten years?

12 MS. ADAMS: No.

13 CHAIR KIRKPATRICK: Oh, okay, sure.

14 MS. ADAMS: The only thing I want
15 to mention is that eight years from now the
16 device that is on the market probably won't be
17 this one. So I think we have to weigh what we
18 are going to find out eight years from now
19 against that.

20 CHAIR KIRKPATRICK: So, yes, it was
21 in relevance to the ten years.

22 (Laughter.)

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1 CHAIR KIRKPATRICK: Mr. Melkerson,
2 it appears that the Panel has uniform
3 agreement that eight to ten years would be an
4 appropriate length of follow up. There are
5 concerns on both sides but a long-term follow
6 up, as currently proposed, is appropriate.

7 Does that adequately answer Item D?

8 MR. MELKERSON: Yes, thank you.

9 CHAIR KIRKPATRICK: Thank you.

10 Okay, Item E, measures to minimize
11 loss to follow up and compensatory measures
12 taken when it occurs. So that sounds more
13 like a discussion than a yes or no.

14 And we will begin with Dr. Skinner.

15 DR. SKINNER: I've got no idea how
16 to minimize the loss to follow up and what
17 measures to take.

18 CHAIR KIRKPATRICK: Thank you.

19 Dr. Goodman?

20 MEMBER GOODMAN: I have a good idea
21 of how to do it. I just don't have the
22 resources to do it for all my patients. I

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1 think we all, as surgeons and researchers,
2 want to have 100 percent follow up forever.
3 And how to do this in a cost-effective manner
4 is really the question that we can't answer
5 and are trying to.

6 But I think it is a good idea. And
7 how the FDA and the sponsor want to arrange to
8 do that should be mutually agreed upon.

9 CHAIR KIRKPATRICK: Thank you.

10 Dr. Wright?

11 DR. WRIGHT: Yes. I agree with Dr.
12 Skinner. I haven't heard any measures to
13 minimize loss or the compensatory measures
14 taken when it occurs. So while I agree it is
15 a great idea, I'm not sure what we are
16 recommending.

17 CHAIR KIRKPATRICK: Thank you.

18 Ms. Whittington?

19 MS. WHITTINGTON: Short of an RFD
20 implanted with it, I don't know how you would
21 ever find them.

22 CHAIR KIRKPATRICK: Thank you.

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1 Ms. Adams?

2 MS. ADAMS: Well, I think the
3 question is here because Dr. Wang did a nice
4 job of raising concerns about post-approval
5 studies. And when he said this, I thought
6 that was legitimate.

7 I think one of the things we have
8 is this number that when we work with FDA,
9 they look for 80 to 85 percent follow up. I
10 think it is going to be almost impossible to
11 get anywhere close to that.

12 And I've seen companies do things
13 like drive taxis out to people's houses and
14 bring them ten hours back to where they need
15 to go and you still don't get those numbers.
16 So it is going to be a real practical
17 challenge.

18 CHAIR KIRKPATRICK: Thank you.

19 And Dr. Mayor?

20 DR. MAYOR: I have no idea how to
21 do this and yet we approach, as arthroplasty
22 surgeons, virtually all of our patients in an

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1 effort to make them understand that they need
2 to be followed forever.

3 CHAIR KIRKPATRICK: Thank you.

4 DR. MAYOR: So yes and no.

5 CHAIR KIRKPATRICK: Thank you.

6 And Dr. Pfeffer?

7 DR. PFEFFER: I think the idea of
8 Link putting an implantable chip into the
9 ankles is a great one. Some GPS -- I know
10 they have that for kids now. So just a
11 suggestion. But otherwise I have no specific
12 ideas.

13 CHAIR KIRKPATRICK: For the record,
14 I believe that was an intent at humor.

15 (Laughter.)

16 DR. PFEFFER: For the record.

17 CHAIR KIRKPATRICK: Thank you.

18 Dr. Propert?

19 DR. PROPERT: I think I will follow
20 that with no additional comments.

21 CHAIR KIRKPATRICK: Thank you one
22 and all.

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1 I would like to add one other thing
2 that Ms. Whittington pointed out earlier is
3 the patient education on the importance of
4 getting information back to company if not the
5 surgeon would be an appropriate means of
6 trying to help with that.

7 But, again, I don't think that is
8 something within the purview of FDA
9 requirements unfortunately. I'm just making
10 clear that the patient education materials
11 emphasize it is probably as far as you could
12 go.

13 So in summary on Item E, everybody
14 agrees that every effort should be made but
15 nobody knows how to do that.

16 Does that adequately address your
17 Question E?

18 MR. MELKERSON: Well, we'll work
19 with it.

20 CHAIR KIRKPATRICK: Thank you, Mr.
21 Melkerson.

22 Finally, F, please comment on the

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1 sufficiency of the proposed learning curve
2 investigation. They proposed five new
3 surgeons, 125 patients, with 12-month follow
4 up. And the selection of new investigators.

5 So what I interpret this to mean is
6 they anticipate market approval. But then
7 they will restrict access to it.

8 Can you clarify that for me? You
9 are saying you are going to have widespread
10 dissemination and marketing of the device but
11 you will select five new surgeons that you
12 will study prospectively on their learning
13 curve? We need you to please speak into the
14 microphone to answer those aspects.

15 MR. GREENBERG: We hope that we are
16 going to have all the surgeons go through a
17 training program. All of them get certified.

18 But then we will select five to be members of
19 this post-market study portion.

20 CHAIR KIRKPATRICK: Okay. So to
21 confirm, you might have 100 people that go
22 through the training program. Out of those

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1 100 people, you will see if there are five
2 that you anticipate will be relatively high-
3 volume surgeons. And you will enroll them in
4 a study of 25 patients each, roughly, for a
5 12-month follow up.

6 MR. GREENBERG: If they are
7 willing, yes.

8 CHAIR KIRKPATRICK: If they are
9 willing, correct.

10 MR. GREENBERG: That is correct.

11 CHAIR KIRKPATRICK: Okay. Thank
12 you.

13 So for the Panel, the question
14 would be that sort of learning curve
15 evaluation be sufficient?

16 And we will start with Dr. Goodman.

17 MEMBER GOODMAN: I think that is
18 the definition of a selection bias. I mean I
19 don't understand how you can pick five
20 surgeons, let's say, out of 100, maybe high
21 volume, maybe intermediate volume, maybe low
22 volume.

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1 As a surgeon, I would want to know
2 what the average surgeon who would do this
3 procedure not once a year -- I don't know how
4 many times per year -- would do -- what his
5 complication or her complication rate would
6 be? What are the problems that they
7 encounter?

8 I think for the company to pick
9 five surgeons is going to bias any results
10 that they get. And I would encourage the
11 investigators to think of a more fair and
12 appropriate way to select their surgeons.

13 CHAIR KIRKPATRICK: Thank you.

14 Dr. Wright?

15 DR. WRIGHT: I agree with Dr.
16 Goodman. I'm not sure what adding a new group
17 of new investigators would accomplish here.
18 So, you know, I'd probably like to let the
19 market run its course. And have an overview
20 of all surgical experience. Thanks.

21 CHAIR KIRKPATRICK: Thank you.

22 Ms. Whittington?

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1 MS. WHITTINGTON: I would agree. I
2 don't see how you can assess the learning
3 curve because the first people out of the gate
4 are going to be these fellows and residents
5 who have been working with the primary
6 surgeons. And they aren't going to a true
7 reflection of what the learning curve really
8 is because they have had a remedial course for
9 a long period of time.

10 CHAIR KIRKPATRICK: Thank you.

11 Ms. Adams?

12 MS. ADAMS: No comments.

13 CHAIR KIRKPATRICK: Thank you.

14 Dr. Mayor?

15 DR. MAYOR: While the motivation
16 may be admirable I think the likelihood of a
17 useful product from this effort is very, very
18 small. It's like shooting fish in a barrel.
19 So I don't think I'd want to do that to the
20 fish.

21 CHAIR KIRKPATRICK: Thank you.

22 Dr. Pfeffer?

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1 DR. PFEFFER: I don't see the need
2 for this group.

3 CHAIR KIRKPATRICK: Thank you.

4 Dr. Propert?

5 DR. PROPERT: Yes, I agree with the
6 previous comments but I would also put out a
7 personal plea that at least a couple of the
8 surgeons involved in this treat patients who
9 are very different than what was done in the
10 study so far. And specifically I'm looking at
11 a non-weight, low-income people.

12 CHAIR KIRKPATRICK: Thank you.

13 Dr. Skinner?

14 DR. SKINNER: I basically agree
15 with Dr. Wright. Unless the company were able
16 to pick five ungifted surgeons to get an idea
17 of what type of care they could give --

18 CHAIR KIRKPATRICK: Who would do a
19 low volume.

20 CHAIR KIRKPATRICK: Thank you.

21 It sounds to me with regard to Item
22 F that the Panel appreciates the sincerity and

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1 the high vision of trying to study the
2 learning curve but is uncertain it is
3 unrealistic. And we don't have good methods
4 to analyze that learning curve.

5 We do recognize the effort of the
6 sponsors in attempting to design a way to do
7 that. But it sounds like most of us do not
8 feel it is a very realistic way to do it. And
9 may not provide valuable information as
10 designed.

11 Does that adequately address Item
12 F?

13 MR. MELKERSON: Yes, thank you.

14 CHAIR KIRKPATRICK: Thank you very
15 much.

16 With that, I will take the Chair's
17 prerogative to suggest that we will have a
18 break.

19 Immediately following the break, we
20 will have our second open public comment
21 period. If you know you would like to speak,
22 if you would please address Ron Jean so we can

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1 know that, that will help streamline our
2 process after the break.

3 Please reconvene at 3:15. Thank
4 you.

5 (Whereupon, the foregoing matter went off the
6 record at 3:06 p.m. and
7 went back on the record
8 at 3:19 p.m.)

9 CHAIR KIRKPATRICK: Thank you for
10 returning in a timely way.

11 We will now proceed to the second
12 open public hearing. We have heard of one
13 request to take a few minutes at the
14 microphone from Dr. Gill who also presented in
15 the morning.

16 So, Dr. Gill, if you would like to
17 come forward, you may have five minutes.

18 DR. GILL: Thank you. This has
19 been an enlightening, interesting, and
20 important experience.

21 I would like to point out that in
22 terms of the importance of microdissection and

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1 careful analysis of studies and also, as has
2 been pointed out by the FDA Panel, the fact
3 that clinical studies have problems, and I
4 agree with that, I think it is also important
5 to point out that clinical use has had
6 extremely important clarifications in the
7 field of total joint arthroplasty.

8 I personally don't know all of the
9 studies or preliminary data that was or wasn't
10 done in many of the aspects that have failed
11 in total joint arthroplasty but I'll mention a
12 few that have become realized as failures
13 during clinical use, which is like a clinical
14 study.

15 The use of Teflon, the use of poly
16 improvements such as poly 2 and hylamer,
17 metal-backed polyethylene patellas, titanium
18 bearing surfaces, core locking mechanisms,
19 excessive poly wear due to excessively high
20 contact stresses on designs that we really
21 didn't understand, cement disease, particle
22 disease, and the list goes on and on.

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1 In total joint arthroplasty in the
2 last 35 years the field has been rife with
3 often dismal failures. Despite that, the
4 other side of the coin is we have learned
5 tremendously from this clinical use.

6 And there are hundreds of thousands
7 of patients who have benefitted enormously not
8 only in the great reduction of pain, not only
9 in the improved function, not only in their
10 cardiovascular benefits, which has been proven
11 by Michael Reese in California with both total
12 hip and total knee patients.

13 But many patients tell us that it
14 literally gives them a new lease on life. So
15 despite the difficulties which have been so
16 common in this important field, there is a
17 great deal of benefit that has come out of it.

18 I have been personally impressed by
19 this I would call it microdissection, which is
20 going on, and I fully understand and agree
21 with the concept that has taken place today
22 because it is a necessity to protect our

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1 public. But I would also like to point out
2 that the elephant in the room here today that
3 has been eluded to only partially and
4 infrequently, are the Class II devices.

5 I don't know how much analysis has
6 been given to those but as these very
7 important discussions take place on a Class
8 III device, we must remember that the Class II
9 devices are currently being put in routinely
10 by experienced, excellent surgeons, and by the
11 other group that was talked about just before
12 our break.

13 And although there are good
14 successes with the Class II device, which is
15 documented in the literature, there is also
16 documentation in JBJS by Ted Hansen and others
17 in Europe of the problems that we have seen
18 with Class II devices. And so although I
19 agree with everything that is being done and I
20 applaud it, I think we have to remember that
21 the elephant in the room, so to speak, is
22 being used currently.

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1 Thank you for this opportunity to
2 observe this important event.

3 CHAIR KIRKPATRICK: Thank you, Dr.
4 Gill.

5 I will request that the
6 transcriptionist refer to his disclosure that
7 he gave the first time he spoke.

8 (Repeated from earlier disclosure.)

9 DR. GILL: I'm Lowell Gill. I
10 practice orthopedic surgery in Charlotte,
11 North Carolina, surgery of the lower
12 extremity. I do have royalty agreements with
13 the KMI Integra Company, KMI, which was bought
14 out by Integra for a design of a total ankle
15 arthroplasty named the Eclipse. That is a
16 sort of reverse conflict in the sense that I
17 stand to lose royalties if this product
18 becomes popular.

19 I also have a consulting agreement
20 with the Stelkast Company on outcomes work for
21 the total knee. And I have a royalty
22 agreement with the Zimmer Company for design

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1 work on total knees.

2 I also -- my travel here and
3 probably some additional expenses will be paid
4 for by the Link Company.

5 (End of previous disclosure.)

6 CHAIR KIRKPATRICK: Are there
7 additional speakers that wish to come forward?

8 Please come forward and identify yourself.
9 Are there any further speakers that wish to
10 come forward for the open public comment?

11 Thank you. You have five minutes.

12 MS. MCGUCKIAN: Thank you.

13 Good afternoon. My name is Rachel
14 McGuckian and I speak here today representing
15 the Orthopedic Surgical Manufacturers
16 Association, OSMA. OSMA is a trade
17 association with over 30 member companies and
18 we welcome this opportunity to provide general
19 comments at today's Panel meeting.

20 OSMA's comments should not be taken
21 as an endorsement of the products being
22 discussed today. We ask, instead, that our

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1 comments be considered during today's Panel
2 deliberations. These comments represent the
3 careful compilation of the member companies'
4 views.

5 OSMA was formed over 45 years ago
6 and has worked cooperatively with the FDA, the
7 American Academy of Orthopaedic Surgeons, the
8 American Society for Testing and Materials,
9 and other professional medical societies and
10 standard development bodies.

11 These collaborations have helped to
12 ensure that orthopedic medical products are
13 safe, of uniform high quality, and supplied in
14 quantities sufficient to meet national needs.

15 Association membership currently includes
16 over 30 companies who produce over 85 percent
17 of all orthopedic implants intended for
18 clinical use in the United States.

19 OSMA has a strong invested interest
20 in ensuring the ongoing available of safe and
21 effective medical devices. The deliberations
22 of the Panel today and the Panel's

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1 recommendations to the FDA will have a direct
2 bearing on the availability of new products.

3 We make these comments to remind
4 the Panel of the regulatory burden that must
5 be met today. We urge the Panel to focus its
6 deliberations on the product's safety and
7 effectiveness based on the data provided.

8 Of course, the FDA is responsible
9 for protecting the American public from drugs,
10 devices, food, and cosmetics that are either
11 adulterated or unsafe or ineffective.
12 However, FDA has another role -- to foster
13 innovation.

14 The Orthopedic Devices Branch is
15 fortunate to have available a staff of
16 qualified reviews, including a Board-certified
17 orthopedic surgeon, to evaluate the types and
18 value of applications brought before this
19 Panel. The role of this Panel is also very
20 important to the analysis of data in the
21 manufacturer's application and to determine
22 the availability of new and innovative

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1 products in the U.S. marketplace.

2 Those of you on the Panel have been
3 selected based on your expertise and training.

4 And you also bring the view of practicing
5 clinicians who treat patients with
6 commercially-available products.

7 OSMA is aware that you have
8 received training from FDA on the law and the
9 regulation and we don't intend to repeat that
10 information today but we do want to emphasize
11 two points that might have a bearing on
12 today's deliberation.

13 The first is reasonable assurance
14 of safety and effectiveness and the second,
15 valid scientific evidence. As to the first,
16 there is a reasonable assurance that a device
17 is safe when it can be determined that the
18 probable benefits outweigh the probable risks.

19 Some important caveats associated
20 with this overly-simplified statement include
21 valid scientific evidence and proper labeling
22 and that safety data may be generated in the

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1 laboratory in animals or in humans.

2 There is reasonable assurance that
3 a device is effective when it provides a
4 clinically sufficient result. Again, labeling
5 and valid scientific evidence play important
6 roles in this determination.

7 The regulation and the law clearly
8 state that the standards be met as a
9 reasonable assurance of safety and
10 effectiveness. Reasonable is defined as
11 moderate, fair, and inexpensive.

12 As to the second point, valid
13 scientific evidence, the regulation states
14 that well-controlled investigations shall be
15 the principle means to generate the data used
16 in the effectiveness determination.

17 The following principles are cited
18 in the regulation as being recognized by the
19 scientific community as essentials in a well-
20 controlled evaluation and investigation: a
21 study protocol, method of selecting subjects,
22 method of observation and reporting of

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1 results, and comparison of results with a
2 control.

3 The Panel has a very important job
4 today. You must listen to the data presented
5 by the sponsor, evaluate the FDA
6 presentations, and make a recommendation about
7 the approvability of the sponsor's
8 application.

9 We speak for many applicants when
10 we ask for your careful consideration. And
11 please keep in mind that the standard is
12 reasonable assurance, balancing the benefits
13 with the risks. Regulatory standard is not
14 proof beyond a shadow of a doubt.

15 And when considering making
16 recommendations for further studies, please
17 remember that the FDA takes these
18 recommendations seriously as a consensus of
19 the Panel as a whole and they may delay the
20 introduction of a useful product or result in
21 burdensome and expensive data collection.

22 Therefore, you play an important

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1 role in reducing the burden of bringing new
2 products that you and your colleagues use in
3 treating patients to the market.

4 Please be thoughtful in weighing
5 the evidence and remember the standard is
6 reasonable assurance of safety and
7 effectiveness. And that there is a legally
8 broad range of valid scientific evidence to
9 support the determination.

10 OSMA thanks the FDA and the Panel
11 for the opportunity to speak today. Our
12 association trusts that its comments are taken
13 in the spirit offered to help the FDA decide
14 whether to make a new product available for
15 use in the U.S. marketplace.

16 OSMA members are present in the
17 audience and are available to answer questions
18 any time during the deliberations today.

19 Thank you very much.

20 CHAIR KIRKPATRICK: Thank you very
21 much. And thank you also for your
22 association's partnership in helping our

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1 patients.

2 We will now proceed to see if there
3 is any further comment or clarification from
4 the FDA, either Mr. Melkerson or Mr. Pinder?

5 MR. MELKERSON: No, thank you.

6 CHAIR KIRKPATRICK: Thank you.

7 I will take the Chair's prerogative
8 to interject to see if there is any further
9 comment from any Panel member that might want
10 to speak.

11 Dr. Pfeffer?

12 DR. PFEFFER: I have a question for
13 Link that I neglected earlier. What intention
14 is there to make tibial trials available?
15 Tibial trials, I think there is some
16 controversy on that issue.

17 MR. GREENBERG: At this time, there
18 are no plans to make tibial trials. We are
19 concerned about what happens to the delicate
20 bone bed with the implantation of a trial that
21 is tight enough and good enough to give you
22 representation of what is going to happen but

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1 that is still going to protect the bone bed.

2 Dr. Anderson in his paper did have
3 trials and the results were nothing to write
4 home about honestly. So right now we do not
5 plan to do it.

6 DR. PFEFFER: So this is not a cost
7 issue? It's a real technical issue.

8 MR. GREENBERG: We can make those
9 trials cheaply and easily but we do not think
10 they are wise at this time.

11 DR. PFEFFER: Thank you.

12 CHAIR KIRKPATRICK: Any further
13 comment or concern about the studies or
14 questions or anything else from the Panel
15 members?

16 (No response.)

17 CHAIR KIRKPATRICK: Thank you.

18 The sponsor now has a time to
19 clarify, comment, or make any other statement.

20 You will have up to 15 minutes. Would the
21 sponsor like to comment?

22 DR. CLANTON: Yes, they would.

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1 CHAIR KIRKPATRICK: Please proceed.
2 Thank you.

3 DR. CLANTON: So how should we
4 summarize 124 years of ankle arthritis
5 surgical care beginning in 1882 with Dr.
6 Albert's first ankle fusion? Thirty-plus
7 years of research on ankle arthroplasty, 20
8 years of clinical information from Europe on a
9 three-part ankle, and seven years of our own
10 specific study with the STAR ankle?

11 Well, I believe that we -- and the
12 big we here, the FDA, Panel members, and the
13 investigators -- we really all have a shared
14 goal and objective in this. We want to help
15 our patients with ankle arthritis. And do so
16 without excessive risk.

17 Primum non nocere -- first do no
18 harm is more than just a slogan. It is a
19 foundation of what we do as physicians and
20 surgeons. The care of patients suffering from
21 debilitating ankle arthritis has presented a
22 dilemma for patients and doctors for many

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1 years.

2 The options are limited with non-
3 operative care, utilizing bracing, ambulatory
4 aids, and medication often failing to provide
5 adequate relief of pain, correction of
6 deformity, and/or improvement in function.
7 Surgical care has primarily been a fusion of
8 the arthritic ankle, eliminating the joint and
9 thereby eliminating motion in the ankle joint.

10 It is a good operation, reducing
11 pain, improving deformity, and improving
12 function. But is well known among surgeons
13 and patients that it is not without its own
14 problems. Some do not fuse or fuse in an
15 improper position. Some become infected.

16 And more commonly we are seeing the
17 long-term stress transfer effects on the
18 adjacent joints, resulting in late
19 osteoarthritis changes that require further
20 surgery. This further surgery can only be a
21 fusion leading to further stiffness in the
22 ankle/hindfoot complex.

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1 With the successes of hip and knee
2 arthroplasty witnessed by patients, they have
3 come to expect similar options of the ankle.
4 Failures of first generation total ankles were
5 discouraging but further design advances have
6 improved the results, a similar evolution to
7 what was seen in the knee and hip
8 arthroplasty.

9 This current multi-center clinical
10 trial is the most detailed and the only
11 prospective study of ankle arthroplasty or
12 ankle arthrodesis. The study results clearly
13 demonstrate that the STAR ankle does what we
14 want and what patients want. It eliminates
15 pain better than a fusion. It improves
16 function better than a fusion.

17 And it allows range of motion,
18 something that a fusion cannot do.
19 Intuitively one would expect this motion to
20 mean that arthritis in adjacent joints will be
21 lessened.

22 Are the results durable? For this

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1 we must turn to the European literature.
2 There has been 20 years of work on three-part
3 ankles and several studies show greater than
4 90 percent ten-year survivorship. There are
5 some catastrophic events there but certainly
6 nothing that suggests that it is more than we
7 would expect.

8 The number of major complications
9 has been very low and rarely effects long-term
10 outcome. And finally, what happens if it does
11 fail? What do you do?

12 Well, in that event, you convert it
13 to an ankle arthrodesis. The literature
14 suggests that this can be done effectively and
15 efficiently.

16 We believe, and our patients have
17 confirmed, that the STAR ankle is a valuable
18 addition to the options for treatment and for
19 severe ankle arthritis. And I hope that the
20 Panel agrees.

21 CHAIR KIRKPATRICK: Thank you.

22 The sponsor does have a few more

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1 minutes if you would like to have another
2 speaker.

3 MR. GREENBERG: Thank you.

4 I just wanted to say that I wanted
5 to thank everyone for giving us the time
6 today.

7 Ankle arthroplasty, you know, has
8 never been envisioned to be a procedure that
9 has tens of thousands of implants. It is a
10 low-volume procedure.

11 As the sponsor, I can say we have
12 no interest in anything but having the best
13 possible surgical outcomes for the doctors,
14 for the patients. We have listened very
15 closely to what you have had to say here about
16 the patient, and having patient information,
17 having trained surgeons, be able to reach out
18 to a mentor, maybe one of these gentlemen
19 here.

20 I apologize for the manual.
21 Believe me, they will be updated with all of
22 the new techniques, with all of the new

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1 instrumentations, with all the information
2 that we have gathered today and we have
3 gathered over the last seven years on patient
4 selection.

5 And we will do our utmost to make
6 sure that it is a successful procedure for the
7 patients and the surgeons and the United
8 States' population.

9 Thank you very much.

10 CHAIR KIRKPATRICK: Thank you, Mr.
11 Greenberg.

12 Now I would like to see if Ms.
13 Whittington, as the consumer rep, has any
14 comments or additional summary that you'd like
15 to make.

16 MS. WHITTINGTON: I appreciate your
17 attentiveness as I discussed issues in the
18 patient education materials. I really
19 encourage you to solicit them as partners in
20 this endeavor because they are making science,
21 along with the surgeons, to help improve
22 healthcare for those coming after them. And

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1 people really do understand that. And we
2 don't always give them that benefit of the
3 doubt.

4 Please don't let me see an ad on TV
5 that everybody should have this. And I have
6 to tell that is probably what I say at every
7 meeting because it frustrates me no end at the
8 marketing that occurs on the part of companies
9 who want to sell more product.

10 And please be honest and
11 transparent in your marketing as if it were
12 your mother. I practice with a physician who
13 always says we have to pass the yo mamma test.

14 And please always remember that it is your
15 mother watching and reading whatever you put
16 out.

17 CHAIR KIRKPATRICK: I would just
18 editorialize to say that some of the comments
19 you made might be relevant to after we vote.
20 But it is okay to do it after we vote as well.
21 Especially yo mamma.

22 (Laughter.)

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1 CHAIR KIRKPATRICK: Thank you.

2 Ms. Adams, would you like to
3 represent anything from industry before we
4 have a vote?

5 MS. ADAMS: No.

6 CHAIR KIRKPATRICK: Thank you very
7 much.

8 Our next job is to proceed to the
9 vote. We are now ready to vote on the Panel's
10 recommendation to the FDA on this PMA.

11 Panel members, we will refer to the
12 voting options flowchart that is in our blue
13 folders if you don't already have it out.

14 Dr. Jean will also read the Panel
15 recommendation options and assist us with the
16 flow of what we can vote on and how we vote.

17 Dr. Jean?

18 DR. JEAN: The Medical Device
19 Amendments to the Federal Food, Drug, and
20 Cosmetic Act, as amended by the Safe Medical
21 Devices Act of 1990, allows the Food and Drug
22 Administration to obtain a recommendation

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1 from an expert Advisory Panel on designated
2 medical device premarket approval applications
3 that are filed with the Agency.

4 The PMA must stand on its own
5 merits and your recommendation must be
6 supported by safety and effectiveness data in
7 the application or by applicable publicly
8 available information.

9 The definitions of safety,
10 effectiveness, and valid scientific evidence
11 are as follows:

12 Safety, there is reasonable
13 assurance that a device is safe when it can be
14 determined, based upon valid scientific
15 evidence, that the probable benefits to health
16 from use of the device for its intended uses
17 and conditions of use, when accompanied by
18 adequate directions and warnings against
19 unsafe use, outweigh any probable risks.

20 Effectiveness, as defined in 21 CFR
21 Section 860.7(e)(1), there is reasonable
22 assurance that a device is effective when it

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1 can be determined, based upon valid scientific
2 evidence, that in a significant portion of the
3 target population, the use of the device for
4 its intended uses and conditions of use, when
5 accompanied by adequate directions for use and
6 warnings against unsafe use, will provide
7 clinically significant results.

8 Valid scientific evidence, as
9 defined in 21 CFR Section 860.7(c)(2), valid
10 scientific evidence is evidence from well-
11 controlled investigations, partially
12 controlled studies, studies and objective
13 trials without matched controls, well-
14 documented case histories conducted by
15 qualified experts, and reports of significant
16 human experience with a marketed device from
17 which it can fairly and responsibly be
18 concluded by qualified experts that there is
19 reasonable assurance of the safety and
20 effectiveness of a device under its conditions
21 of use.

22 Isolated case reports, random

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1 experience, reports lacking sufficient details
2 to permit scientific evaluation, and
3 unsubstantiated opinions are not regarded as
4 valid scientific evidence to show safety or
5 effectiveness.

6 Your recommendation options for the
7 vote are as follows:

8 Approval, if there are no
9 conditions attached.

10 Approvable with conditions, the
11 Panel may recommend that the PMA be found
12 approvable subject to specific conditions such
13 as physician or patient education, labeling
14 changes, or a further analysis of existing
15 data. Prior to voting, all of the conditions
16 should be discussed by the Panel.

17 Not approvable, the Panel may
18 recommend that the PMA is not approvable if
19 the data do not provide a reasonable assurance
20 that a device is safe or the data do not
21 provide a reasonable assurance that a device
22 is effective under the conditions of use

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1 prescribed, recommended, or suggested in the
2 proposed labeling.

3 Following the voting, the Chair
4 will ask Panel member to present a brief
5 statement outlining the reasons for his or her
6 vote.

7 CHAIR KIRKPATRICK: Thank you, Dr.
8 Jean.

9 Are there any specific questions
10 from the Panel about these voting options or
11 our instructions on how to vote?

12 (No response.)

13 CHAIR KIRKPATRICK: Seeing no
14 questions on the process, I will ask if there
15 is anyone on the Panel who would like to make
16 a motion.

17 I see that there is all kinds of
18 excitement about an opinion.

19 Dr. Wright?

20 DR. WRIGHT: I'll make a motion
21 that we approve with conditions.

22 CHAIR KIRKPATRICK: There is a --

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1 DR. PFEFFER: Second.

2 CHAIR KIRKPATRICK: -- motion by
3 Dr. Wright and a second by Dr. Pfeffer for
4 approvable with conditions.

5 Now we will discuss the motion, not
6 the conditions at this point. Is there any
7 discussion on the motion of approval with
8 conditions?

9 (No response.)

10 CHAIR KIRKPATRICK: My
11 understanding was we have to discuss the
12 motion first. However, seeing that there is
13 no discussion on the motion, we can now
14 propose a first condition.

15 Now do we have to -- just a matter
16 of process -- do we now vote for the motion
17 approvable with conditions? And then go with
18 each condition? Or do we take it as a package
19 at the end?

20 MR. MELKERSON: As a package.

21 CHAIR KIRKPATRICK: So, it has
22 moved and seconded that we have approvable

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1 with conditions. I would entertain a motion
2 for the first condition.

3 Sorry, Dr. Pfeffer?

4 DR. PFEFFER: I have a general
5 question. When warnings are given with an
6 orthopedic device of this type, they are
7 usually contained within a package that never
8 sees the patient's eyes. The package is
9 opened up in the operating room and the
10 patient never sees it.

11 Does the FDA have the inclination
12 or ability to change that? Because the main
13 condition I have is that whatever conditions
14 we come up with, the patient sees.

15 CHAIR KIRKPATRICK: Would the FDA
16 like to comment, Mr. Melkerson?

17 MR. MELKERSON: With recent
18 approvals in packages, there is also patient
19 labeling. And if I am hearing correctly, you
20 can specify what you would like to see in that
21 patient labeling.

22 DR. PFEFFER: Patient labeling is

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1 something given out to the patient prior to
2 the procedure.

3 CHAIR KIRKPATRICK: So, Dr.
4 Pfeiffer, it sounds like that means that if you
5 would like to propose the first condition,
6 including patient information pamphlet, and
7 specify specifics you would like contained in
8 that, that would be a good starting point.

9 DR. PFEFFER: I'd like to think
10 about it for a moment now that I know that
11 that is possible.

12 CHAIR KIRKPATRICK: Thank you.
13 Dr. Goodman?

14 MEMBER GOODMAN: One of the
15 conditions that I would like to put forth is
16 that there be a post-approval study with
17 independent radiographic analysis that would
18 encompass preoperative and postoperative x-
19 rays, in the immediate postoperative period,
20 at one, two, four, and eight to ten years.

21 Would you like me to repeat that,
22 Mr. Chairman?

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1 CHAIR KIRKPATRICK: Actually I was
2 just going to ask if there is a second for
3 that. And I see one with Dr. Wright.

4 DR. WRIGHT: Second.

5 CHAIR KIRKPATRICK: Okay. So it
6 has been moved and seconded for a post-
7 approval study. As we had extensive
8 discussion on the nature of a post-approval
9 study before, can I ask would that simply be
10 consistent with -- would your motion be
11 consistent with what was previously discussed?

12 MEMBER GOODMAN: Yes.

13 CHAIR KIRKPATRICK: And would your
14 second also be?

15 (No response.)

16 CHAIR KIRKPATRICK: So that was a
17 yes for the transcriptionist.

18 Thank you.

19 Is there further discussion on that
20 motion? Mr. Melkerson?

21 MR. MELKERSON: Just a point of
22 clarification. If you could specify what

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1 questions you would like to have addressed by
2 that post-approval study, I think that would
3 be beneficial.

4 CHAIR KIRKPATRICK: Thank you, Mr.
5 Melkerson.

6 Dr. Goodman, can you make a listing
7 of the specific questions you would like
8 addressed?

9 MEMBER GOODMAN: Well, we've
10 discussed clinical and radiographic parameters
11 some of which the investigators have already
12 outlined. The clinical ones would include the
13 BP rating system and others that the
14 investigators feel are appropriate, including
15 possibly rating systems approved by the
16 Association of Foot and Ankle Surgeons.

17 The radiographic parameters were
18 outlined. And they including standing x-rays
19 of the feet with specific radiographic
20 parameters as agreed upon between the
21 investigators and the FDA that would reflect
22 radiographic performance of the prosthesis.

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1 CHAIR KIRKPATRICK: Is that
2 consistent with your second, Dr. Wright?

3 DR. WRIGHT: Absolutely.

4 CHAIR KIRKPATRICK: Thank you.

5 Is there further discussion on this
6 particular motion?

7 Dr. Skinner?

8 DR. SKINNER: I understand that Dr.
9 Goodman wants to collect a lot of data but I'm
10 not sure that gives Mr. Melkerson the
11 direction that I think he is asking for.

12 What do you do with the data and
13 why do you want the data?

14 CHAIR KIRKPATRICK: Dr. Goodman?

15 MEMBER GOODMAN: I'd first like to
16 ask Mr. Melkerson if he agrees with that
17 statement.

18 MR. MELKERSON: In terms of
19 question, I think as our post-approval study
20 representative identified one potential
21 question or hypothesize would be does the
22 revision rate increase, decrease? Does the

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1 radiographic evidence show that there is
2 progression to what you would consider
3 potential for failure? Those are the types of
4 questions that would be beneficial to identify
5 that you would want answered by the parameters
6 that you were describing.

7 CHAIR KIRKPATRICK: May I take a
8 stab at --

9 MEMBER GOODMAN: Sure.

10 CHAIR KIRKPATRICK: -- what I would
11 summarize from what has been said today?

12 MEMBER GOODMAN: Please.

13 CHAIR KIRKPATRICK: That the post-
14 approval study, and this would be a friendly
15 amendment if you agree, the post-approval
16 study would be to demonstrate the safety by
17 evaluating for further device failures as time
18 proceeds, compare it to historical controls,
19 and to outcome of ankle fusions in the
20 literature as opposed to having an ongoing
21 study of it as a concurrent control.

22 And it would be look at long-term

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1 safety issues should the devices fail, much
2 like Dr. Mayor was concerned with --
3 polyethylene failure at five and ten years.

4 And that the effectiveness would
5 also be evaluated in this post-approval study,
6 when relevant. As these failures occur and
7 safety issues occur, then the effectiveness
8 would also be evaluated in concurrence.

9 MEMBER GOODMAN: Great.

10 CHAIR KIRKPATRICK: Dr. Wright,
11 would you concur with that rephrasing of the
12 reason and intent of the motion?

13 DR. WRIGHT: I'm not -- boy, I'm
14 not going to ask you to reread that one but
15 the thought that went through my mind was
16 comparing this to other ankle arthroplasty
17 procedures rather than fusions. I think we've
18 done that.

19 And I think we can go -- the thing
20 that I am really concerned about is these
21 Panels have a tendency to pile on after we
22 approve. And they just add onerous

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1 requirements which I never see as a Panel
2 member years down the road.

3 I'm not sure if anyone ever does
4 anything about it but think I'd just like to
5 conjugate the one thing into two things.
6 Post-marketing survey, x-rays that we
7 discussed, and the surgical techniques course
8 that was discussed. I'd like to incorporate
9 those two. Maybe you don't want me to do
10 that.

11 CHAIR KIRKPATRICK: If I could
12 defer the --

13 DR. WRIGHT: Okay, sorry.

14 CHAIR KIRKPATRICK: -- the learning
15 curve study --

16 DR. WRIGHT: Okay.

17 CHAIR KIRKPATRICK: -- because that
18 was so controversial before.

19 DR. WRIGHT: Okay.

20 CHAIR KIRKPATRICK: Let's see if we
21 can add it as a separate condition and keep
22 this condition to just the post-approval study

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1 on the patients and implants.

2 Dr. Goodman?

3 MEMBER GOODMAN: The reason I
4 brought this up was because there was some
5 question of radiographic safety. Clinically
6 the prostheses seem to do well but there were
7 situations where there were prostheses which
8 subsided or changed their position. And there
9 was a question also with regards to the
10 statistical analysis as to whether the safety
11 issue was firmly met given the criteria first
12 established by the investigators.

13 And that's why I think that a post-
14 approval study, as we have just discussed,
15 would help ensure the safety and efficacy.

16 CHAIR KIRKPATRICK: So if I just
17 may confirm, we've had the motioner and the
18 seconder agree with my rephrasing of the
19 motion, correct?

20 (No response.)

21 CHAIR KIRKPATRICK: Okay. And the
22 emphasis, of course, is on the safety of the

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1 devices long term. And whether radiographs
2 would preclude a safety event.

3 Mr. Melkerson?

4 MR. MELKERSON: In terms of safety,
5 the burden for approvability is safety has
6 been demonstrated with the data that you have.

7 And what you are looking at is for long-term
8 safety.

9 And one other point of
10 clarification to Dr. Wright. The post-market
11 initiative also as these studies go forward,
12 you will be getting updates. And you actually
13 can go to the FDA website to identify the
14 current status of those. It is already up on
15 the web.

16 But in subsequent Panel meetings,
17 the feedback from these studies will be
18 presented in periodic updates.

19 CHAIR KIRKPATRICK: So to rephrase
20 the safety concern, the Panel has already felt
21 that the safety of a 24-month study was
22 adequate for approval. However, there are

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1 concerns about the long-term safety of the
2 device. And so that is why we want the post-
3 approval study to look at the safety.

4 We also believe that the
5 effectiveness was well shown at the 24 months.

6 And we hope that as safety concerns come up,
7 that that can help us understand the
8 effectiveness long term.

9 The Panel did not seem to have a
10 major concern about the deterioration of the
11 clinical scores over the four- to ten-year
12 time span as they do the safety issues of the
13 device failure.

14 Does that adequately address the
15 motion there? Ms. Adams, do you have a
16 comment?

17 MS. ADAMS: Yes, I would just like
18 to make comment and that is regarding the
19 portion of the motion that is related to
20 independent radiographic review. From the
21 standpoint of somebody who might have to go
22 away and conduct that, there is a significant

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1 burden associated with the independent
2 radiographic reviews.

3 So I'd just like to put to the
4 Panel the question of is it absolute necessary
5 it be an independent review? Or could we
6 allow the FDA and the sponsor to work through
7 how that radiographic review be handled?

8 CHAIR KIRKPATRICK: If I may
9 clarify, the FDA and the sponsor will identify
10 that. We don't dictate that. We can only
11 comment on what we would recommend.

12 MS. ADAMS: But that is part of his
13 motion.

14 CHAIR KIRKPATRICK: That is part of
15 our recommendation.

16 Is there further discussion on the
17 independent review? Are we questioning
18 whether that is appropriate to be in the
19 motion?

20 DR. SKINNER: I would like to
21 request a change in the motion and the second
22 to remove independent.

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1 CHAIR KIRKPATRICK: Would that be
2 considered a friendly amendment between the
3 two of you? To remove the independent review?
4 And allow it to be a surgeon investigator
5 only?

6 DR. SKINNER: I might comment that
7 Dr. Wright has already pointed out that an
8 orthopedic surgeon can read the x-rays as well
9 as any radiologist. So, you know --

10 CHAIR KIRKPATRICK: Well, to
11 clarify, it is not independent radiologist.
12 It is an independent reviewer of experience
13 within the ankles.

14 DR. SKINNER: Exactly. But
15 presumably the doctor doing the surgery is an
16 experienced orthopedic surgeon and would be
17 able to read those x-rays adequately.

18 CHAIR KIRKPATRICK: So you are
19 willing to have each separate surgeon
20 interpret their own radiographs and report
21 then to the manufacturer?

22 DR. SKINNER: Sure.

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1 CHAIR KIRKPATRICK: Is that a
2 concurrence? Would you consider that a
3 friendly amendment?

4 MEMBER GOODMAN: I'm not happy with
5 that.

6 CHAIR KIRKPATRICK: Okay. So the
7 motion person would not agree to that as a
8 friendly amendment.

9 So any further discussion on the
10 conditions as reflected?

11 DR. PFEFFER: This one condition?
12 We may have others.

13 CHAIR KIRKPATRICK: This individual
14 condition. We are only talking about the one
15 condition. So as I understand it, we pass
16 each condition independently.

17 Seeing no additional comment, then
18 we will start the voting with Dr. Mayor
19 please. Are you in favor of the current
20 motion of approval with the condition of
21 adding a post-approval study as outlined? Do
22 you need to hear all the details again?

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1 DR. MAYOR: Are you asking me to
2 approve the condition? Or the motion itself
3 to rule this PMA approvable?

4 DR. PFEFFER: How could we approve
5 the ankle unless we know which conditions
6 would be approved. I wouldn't be able to make
7 that vote.

8 CHAIR KIRKPATRICK: It is
9 specifically just the condition that was
10 proposed.

11 DR. MAYOR: On the basis of that
12 clarification, I'm going to abstain from a
13 vote related to this condition for reasons I
14 will explain later.

15 DR. PFEFFER: Yes.

16 CHAIR KIRKPATRICK: We are going
17 around.

18 Thank you, Dr. Pfeffer, who voted
19 yes.

20 Dr. Propert?

21 DR. PROPERT: Yes.

22 CHAIR KIRKPATRICK: Thank you.

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1 Dr. Skinner:

2 DR. SKINNER: No.

3 CHAIR KIRKPATRICK: Dr. Goodman?

4 MEMBER GOODMAN: Yes.

5 CHAIR KIRKPATRICK: Dr. Wright?

6 DR. WRIGHT: Yes.

7 CHAIR KIRKPATRICK: Okay, there is
8 four in favor, one abstention, and one no. If
9 I'm not mistaken, we need to have an
10 explanation for their reasons. Is that
11 procedurally what we need to do? Mark? Ron?
12 Oh, that will be at the end? Thank you.

13 Okay, is there another condition to
14 consider?

15 Dr. Pfeffer?

16 DR. PFEFFER: Yes, we already have
17 proposed by Link a weight restriction. I
18 would propose a weight restriction to be
19 placed on the implant that is directly
20 supported, as best possible, by ongoing
21 biomechanical wear studies that we discussed
22 earlier.

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1 CHAIR KIRKPATRICK: So is that a
2 pre-approval study or a post-approval study?
3 And if it is post approval, in what time span
4 would you like that completed?

5 DR. PFEFFER: What was our
6 decision, if you could remind me, regarding
7 the wear studies that we recommended -- which
8 we considered at a higher load?

9 CHAIR KIRKPATRICK: It was
10 suggested that the load should be doubled to
11 represent a worst case or 250-pound person.

12 DR. PFEFFER: As pre-approval? Or
13 is it post approval?

14 CHAIR KIRKPATRICK: That was just a
15 matter of discussion that we wish we had seen
16 that.

17 DR. PFEFFER: So I would propose a
18 pre-approval study which could happen -- but
19 then we have to delay approval -- is that --
20 help me clarify the administration.

21 CHAIR KIRKPATRICK: Okay, from a
22 procedure standpoint, we are voting on

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1 approvable. So if you ask for a pre-approval
2 study, it is kind of getting out of sequence
3 and out of order.

4 If you want to do a post-approval
5 study and suggest it be done within a certain
6 time, that can be done.

7 DR. PFEFFER: Fine.

8 CHAIR KIRKPATRICK: And I don't
9 know if there is another procedure we can do.
10 Maybe Mark can help me with that.

11 MR. MELKERSON: No, I as going to
12 actually say if you are asking for something
13 pre-approval, then your recommendation would
14 not be approval with conditions at this point.

15 DR. PFEFFER: Fine. Then I would
16 suggest that there be an upper weight
17 restriction placed on this ankle that is
18 opposed to being what seems to somewhat
19 arbitrary now, 250 pounds, is directly related
20 to post-approval wear testing that is
21 performed that as best possible given science
22 in 2007 can support that weight justification.

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1 CHAIR KIRKPATRICK: May I suggest
2 that within a 12-month time span might be a
3 reasonable --

4 DR. PFEFFER: Well, a wear study
5 like that, as Dr. Skinner mentioned, could be
6 done very quickly. I would say a two-month
7 time frame.

8 CHAIR KIRKPATRICK: I would argue
9 that very quickly from an engineering wear
10 standpoint is different than very quickly from
11 a surgeon's standpoint.

12 DR. PFEFFER: I would defer to the
13 FDA and to Link regarding that issue then.

14 CHAIR KIRKPATRICK: Okay. So it
15 have been moved that we have a post-approval
16 study looking at the wear testing at a
17 proposed weight of 250, which would be
18 approximately 600 Newtons -- 6,000, thank you,
19 thank you for clarifying.

20 Is there a second to that motion?

21 MEMBER GOODMAN: I'll second that
22 motion.

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1 CHAIR KIRKPATRICK: It has been
2 moved and seconded. Is there discussion on
3 this motion?

4 Dr. Skinner?

5 DR. SKINNER: I would like to
6 suggest a friendly amendment to that to state
7 that the weight restriction would be
8 reevaluated after the wear studies rather than
9 changed.

10 CHAIR KIRKPATRICK: Dr. Pfeffer,
11 would you consider a friendly amendment to
12 basically do a post-approval wear study at
13 6,000 Newtons to determine if a 250-pound
14 weight restriction is appropriate?

15 DR. PFEFFER: Yes, that was my
16 intention. So I would agree to that.

17 CHAIR KIRKPATRICK: Dr. Goodman, do
18 you agree with that?

19 MEMBER GOODMAN: Yes.

20 CHAIR KIRKPATRICK: Okay. So I
21 think we have that nailed down. Is there
22 further discussion on that motion?

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1 Dr. Wright? Microphone please.

2 DR. WRIGHT: I'm concerned about
3 taking the decision out of the surgeon's
4 hands, discriminating against very fat people,
5 very obese people who have a limited life
6 expectancy. I'm concerned about putting
7 abnormal constraints on this whole thing. So
8 would you read the proposal? And I would be
9 in favor of keeping it more open ended, as Dr.
10 Skinner suggest.

11 CHAIR KIRKPATRICK: Yes, he
12 accepted an open-ended basically --

13 DR. WRIGHT: Weight restriction?

14 CHAIR KIRKPATRICK: -- what was
15 recommended and accepted was a post-approval
16 wear study at 6,000 Newtons to determine
17 whether a 250-pound patient would be subject
18 to early failure or major problems. And then
19 that implies with the discussion that has gone
20 on that the FDA will then negotiate with the
21 sponsor on what the most appropriate weight
22 limit is.

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1 Is that a correct assumption, Mr.
2 Melkerson?

3 MR. MELKERSON: We will take your
4 discussion into consideration when speaking
5 with the company.

6 CHAIR KIRKPATRICK: Thank you.

7 Further discussion on Condition No.
8 2, which is wear testing at 6,000 Newtons to
9 determine whether 250 pounds is an appropriate
10 weight restriction? And if not, to make
11 further attempts at identifying the
12 appropriate weight restriction to the
13 implants.

14 (No response.)

15 CHAIR KIRKPATRICK: Seeing none, we
16 will vote starting with Dr. Pfeffer.

17 DR. PFEFFER: Yes.

18 CHAIR KIRKPATRICK: Dr. Propert?

19 DR. PROPERT: Yes.

20 CHAIR KIRKPATRICK: Dr. Skinner?

21 DR. SKINNER: Yes.

22 CHAIR KIRKPATRICK: Dr. Goodman?

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1 MEMBER GOODMAN: Yes.

2 CHAIR KIRKPATRICK: Dr. Wright?

3 DR. WRIGHT: yes.

4 CHAIR KIRKPATRICK: And Dr. Mayor?

5 DR. MAYOR: Abstain for the same
6 reasons as stated earlier.

7 CHAIR KIRKPATRICK: Which you said
8 you would discuss later.

9 DR. MAYOR: Later when the
10 approvability issue comes to vote.

11 CHAIR KIRKPATRICK: Thank you.

12 All right. Are there further
13 conditions to apply? We'll go to Dr. Goodman.

14 MEMBER GOODMAN: Okay. I would
15 like to see the surgical manual updated to
16 reflect more appropriately what the company
17 wants the participating surgeons to follow in
18 the future.

19 CHAIR KIRKPATRICK: Is there a
20 second for updating the surgical manual prior
21 to marketing? I'll second that. To specify,
22 in the FDA materials there was -- behind the

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1 tab that talked about the surgical technique
2 guide, there is a one-page with approximately
3 eight to ten bullets talking about changes in
4 technique.

5 We would like that incorporated
6 into the technique manual prior to marketing.

7 Is that specific enough for the FDA?

8 Dr. Jean, would that be specific
9 enough? Or do we need to defer to Mr.
10 Melkerson?

11 MR. MELKERSON: I was just checking
12 to see if the Chair could second. And we
13 don't know of any rule against it.

14 CHAIR KIRKPATRICK: I can vote if
15 there is another vote. So, you know, I had to
16 make that assumption. I appreciate you
17 confirming my suspicion, however.

18 So is the detail sufficient for
19 that motion?

20 MR. MELKERSON: Yes.

21 CHAIR KIRKPATRICK: Thank you.

22 We will begin with Dr. Propert.

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1 DR. PROPERT: Yes.

2 CHAIR KIRKPATRICK: Dr. Skinner?

3 DR. SKINNER: Yes.

4 CHAIR KIRKPATRICK: Dr. Goodman?

5 MEMBER GOODMAN: Yes.

6 CHAIR KIRKPATRICK: Dr. Wright?

7 DR. WRIGHT: Yes.

8 CHAIR KIRKPATRICK: Dr. Mayor?

9 DR. MAYOR: Abstaining for the
10 reasons cited earlier.

11 CHAIR KIRKPATRICK: Thank you.

12 Dr. Pfeffer?

13 DR. PFEFFER: Yes.

14 CHAIR KIRKPATRICK: Are there
15 further conditions? Dr. Pfeffer?

16 DR. PFEFFER: Yes. The most
17 important condition that we, as a Panel, I
18 believe, place on this is appropriate patient
19 and surgeon education. The company goes a
20 long way to doing that with its courses but
21 I'd like to formalize the education of the
22 surgeon by a statement in writing about the

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1 failures and appropriate patient selection of
2 this total implant.

3 What the group of esteemed
4 orthopedic surgeons in the front row here
5 understand now is the appropriate selection.
6 And the tyro surgeon may not -- the novice
7 surgeon may not or will not. And certainly
8 won't just by going through a course.

9 So I think that is one very
10 important issue. I don't know how to -- that
11 could be negotiated, perhaps, with the FDA and
12 the company.

13 CHAIR KIRKPATRICK: If I might ask,
14 do you not feel it is adequately described in
15 the indications and contraindications as
16 currently stated?

17 DR. PFEFFER: No. I think as Dr.
18 Mann put it, and we could read back the
19 record, he said we have learned a lot about
20 who to put these ankles into now which is why
21 we had better results in the continued access
22 study than we did in the pivotal study.

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1 And that information just needs to
2 be summarized, perhaps in as little as one
3 page by Link and these surgeons, to be given
4 to orthopedic surgeons or whoever is putting
5 these ankles in. A simple list is not
6 sufficient -- a list may be sufficient but it
7 is not in the best interest of the patient.
8 And that is what we should be after, the best
9 interest of the patient.

10 MS. WHITTINGTON: Can I comment?

11 CHAIR KIRKPATRICK: Yes.

12 MS. WHITTINGTON: I would agree. I
13 think so many times I have seen surgeons put
14 in a corner because a patient demands to have
15 a device implanted because there is no clear
16 information for the patient that they truly
17 are in a contraindicated population.

18 And I think that having that in the
19 patient piece would be helpful. And that
20 would automatically, I think, put it in the
21 surgeon's piece of information as well to
22 indicate both the indications and

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1 contraindications.

2 And have it in the patient side at
3 a sixth-grade level which is nationally what
4 is recognized as the reading level so that
5 they understand.

6 And that way it doesn't compromise
7 that relationship with the surgeon.

8 CHAIR KIRKPATRICK: I apologize. I
9 let us get out of order to having discussion
10 before we had a second on the motion. So may
11 I assume that your comments are seconding his
12 motion?

13 MS. WHITTINGTON: I'm not allowed
14 to do it.

15 CHAIR KIRKPATRICK: You are not
16 allowed to do it. You are not a voting
17 member. I'm sorry.

18 DR. PFEFFER: The motion has to do,
19 at this point though, with specific surgeon-
20 directed education in print based upon the
21 cumulative knowledge of the study group on
22 appropriate patient selection.

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1 CHAIR KIRKPATRICK: May I ask how
2 the particular concerns you have are not
3 addressed in their surgical technique brochure
4 if they update it with the items listed?

5 DR. PFEFFER: It could be in the
6 surgical technique brochure. I just want to
7 make sure that it is there.

8 Could you refer to a specific page
9 on what you are referring to?

10 CHAIR KIRKPATRICK: There is not a
11 page number. It is behind the tab which is
12 labeled proposed surgical technique.

13 MS. ADAMS: Dr. Kirkpatrick? It's
14 also in the training course outline where they
15 say that their plan is how to avoid the
16 managed adverse events, questions and answers,
17 indications and contraindications, how to
18 select the right patient. I think there is
19 just not the backup detail here that you are
20 suggesting you would like to see because we
21 have got an outline.

22 CHAIR KIRKPATRICK: Thank you for

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1 helping us with that, Ms. Adams.

2 Dr. Pfeffer, may I ask you to look
3 at that for a few more minutes and determine
4 if there is a motion to make that is clear and
5 specific?

6 DR. PFEFFER: Yes, I could. But I
7 could defer my concern to the FDA. My concern
8 is something we all have in common. And if it
9 can be included -- I would withdraw my motion
10 if they could be included effectively in this
11 manual.

12 CHAIR KIRKPATRICK: Okay. So there
13 is a comment that we'd like to make sure that
14 the contemporary optimal use is contained
15 within the surgical technique manual.

16 And I will entertain if there is a
17 second on that motion. Or if anybody doesn't
18 feel that is necessary, that's fine.

19 Is there a second for that motion?

20 Yes, Mark?

21 MR. MELKERSON: Just a
22 clarification. I thought you had identified

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1 that in your Condition No. 3, where you wanted
2 the surgical manual updated, that it could
3 just include this information. And if that is
4 what you are saying, that can be --

5 CHAIR KIRKPATRICK: That is why I
6 was asking him to clarify what exactly he
7 wanted --

8 DR. PFEFFER: That's fine.

9 CHAIR KIRKPATRICK: -- because I
10 thought it was already included in the manual.

11 DR. PFEFFER: Fine. Then I can
12 withdraw that motion.

13 CHAIR KIRKPATRICK: Okay, thank
14 you.

15 DR. PFEFFER: That wasn't clear
16 that all that detail would be in the manual.

17 CHAIR KIRKPATRICK: Thank you.

18 Are there additional conditions to
19 raise? Dr. Skinner?

20 DR. SKINNER: Just to clarify for
21 me, Dr. Kirkpatrick, have we put on a
22 condition that there be a training course for

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1 the physicians?

2 CHAIR KIRKPATRICK: That is a
3 question I need to defer to the FDA. Was that
4 part of the initial proposal? Or do we need
5 to add that as a condition? If it is in the
6 post-approval as described, do we need to
7 specify the training? Because we excluded it
8 when we took that vote.

9 MR. MELKERSON: I believe the
10 sponsor, and correct me if I'm wrong, sponsor,
11 you had actually proposed some formal training
12 already in the PMA.

13 CHAIR KIRKPATRICK: If that is
14 already in the PMA, we don't need to add it as
15 a condition.

16 MR. MELKERSON: Right.

17 CHAIR KIRKPATRICK: Okay. Are
18 there other conditions that people wish to
19 propose? Dr. Pfeffer?

20 DR. PFEFFER: Yes. I would just
21 second what Ms. Whittington had to say. The
22 surgeons are covered by the manual but the

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1 patients are not. And the patients must be
2 provided with educational material based upon
3 the best available, you know, evidence-based
4 outcomes of total ankle arthroplasty in
5 general.

6 We have complications with the STAR
7 group but the complications that occur with
8 total ankles in general are also reasonable
9 information to patients.

10 And that package insert should be
11 made available somehow to patients
12 preoperatively.

13 CHAIR KIRKPATRICK: If I may, you
14 can't second something from a non-voting
15 member procedurally. So if you would like to
16 make a motion that patient education materials
17 be made available through easy communication
18 means but not through television advertising,
19 that would probably be a better way to phrase
20 that.

21 DR. PFEFFER: I would thank you
22 very much for that guidance. I would propose

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1 that patient education material be available
2 that reflects the warnings that are placed in
3 the package insert, couched in terms
4 understandable to the average patient.

5 It would particularly address
6 outcomes of total ankle, risks and benefits of
7 total ankle arthroplasty in general or
8 specifically the STAR.

9 CHAIR KIRKPATRICK: Thank you.

10 Is there a second? Dr. Skinner?

11 DR. SKINNER: Yes, I'd second that.

12 And I'd like to ask them if we could state
13 that that be included on the Link website.

14 CHAIR KIRKPATRICK: That would be a
15 friendly amendment is that patient education
16 materials be included on the Link website for
17 patients.

18 DR. PFEFFER: An excellent idea as
19 always.

20 CHAIR KIRKPATRICK: All right. Is
21 there further discussion on the patient
22 education materials?

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1 (No response.)

2 CHAIR KIRKPATRICK: And we will
3 allow the FDA to make sure it is at the sixth-
4 grade level as would be appropriate. Thank
5 you.

6 We'll go ahead and vote on that
7 now. Let's see, let's start with Dr. Skinner.

8 DR. SKINNER: Yes.

9 CHAIR KIRKPATRICK: Dr. Goodman?

10 MEMBER GOODMAN: Yes.

11 CHAIR KIRKPATRICK: Dr. Wright?

12 DR. WRIGHT: Yes.

13 CHAIR KIRKPATRICK: Dr. Mayor?

14 DR. MAYOR: Abstaining for the
15 reasons as cited before.

16 CHAIR KIRKPATRICK: Thank you very
17 much, sir.

18 Dr. Pfeffer?

19 DR. PFEFFER: Yes.

20 CHAIR KIRKPATRICK: And Dr.
21 Propert?

22 DR. PROPERT: Yes.

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1 CHAIR KIRKPATRICK: Thank you.

2 Are there any other conditions that
3 members of the Panel wish to add?

4 May I add one procedurally? I have
5 a question since it same up can I second
6 something, can I also propose a condition as
7 the Chair? If you don't know, I can propose
8 it and then we will see how it goes.

9 (Laughter.)

10 MR. MELKERSON: I would say if you
11 can second it, you could propose it.

12 CHAIR KIRKPATRICK: Thank you.

13 In all of the materials that I read
14 on indications, each time it talked about an
15 indication being -- I'm sorry I'm having to
16 flip through that -- "painful arthritic and/or
17 severely deformed ankle" -- those words both
18 me considerably because in the
19 contraindications you have severe deformity.

20 I would suggest that my condition
21 would be that deformity be eliminated from the
22 indications.

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1 DR. PFEFFER: Second.

2 CHAIR KIRKPATRICK: Thank you.

3 Any further discussion on that?

4 DR. PFEFFER: Well, I'm assuming
5 that that will all be straightened out because
6 now the contraindications are greater than 35
7 degrees, which very few people would accept
8 any longer. So that there is an assumption of
9 intent here that Link will update all this
10 information based on our discussion.

11 CHAIR KIRKPATRICK: If I may go
12 back to junior high school when somebody wrote
13 assume on the blackboard and said what it
14 really makes if you divide it up, we need to
15 be careful and be specific. So I would prefer
16 to make sure that we eliminate that as an
17 indication at this forum.

18 Any other comments or discussion?
19 Mark?

20 MR. MELKERSON: Just a point of
21 clarification, I thought I heard in previous
22 parts of the discussion there was concern with

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1 the primary arthritis. Was that -- so if you
2 are talking about a limitation or change in
3 the indications, should that be brought into
4 the discussion? And that is just a point of
5 discussion.

6 CHAIR KIRKPATRICK: I would
7 certainly entertain it as a friendly amendment
8 as the definition of primary arthrosis is
9 always under question. I know your sentiment
10 on abstaining but if you would like to suggest
11 that as a friendly amendment, Dr. Mayor --

12 DR. MAYOR: I'd be happy to do so.

13 DR. PFEFFER: Did we vote on yours
14 yet?

15 CHAIR KIRKPATRICK: No, we haven't
16 voted on it because we've been offered a
17 friendly amendment to include the elimination
18 of the term primary arthrosis and instead put
19 idiopathic or some other acceptable phrase.

20 MEMBER GOODMAN: Why not just put
21 degenerative arthritis? That covers
22 everything.

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1 DR. MAYOR: I would be happy with
2 that, too.

3 CHAIR KIRKPATRICK: That would be
4 fine with me. So the motion would now read
5 that we eliminate the indication of severely
6 deformed ankle. And that we list rheumatoid
7 arthritis, degenerative arthritis, or post-
8 traumatic arthritis. Any further discussion?

9 (No response.)

10 CHAIR KIRKPATRICK: Thank you.
11 We will begin the voting with Dr.
12 Goodman.

13 MEMBER GOODMAN: Yes.

14 DR. WRIGHT: Yes, sir.

15 CHAIR KIRKPATRICK: Sorry, that was
16 Dr. Wright.

17 Dr. Mayor?

18 DR. MAYOR: Abstaining for the
19 reasons cited before.

20 CHAIR KIRKPATRICK: Thank you.
21 Dr. Pfeffer?

22 DR. PFEFFER: Yes.

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1 CHAIR KIRKPATRICK: Dr. Propert?

2 DR. PROPERT: Abstaining. Outside
3 my expertise.

4 CHAIR KIRKPATRICK: Thank you.
5 Dr. Skinner?

6 DR. SKINNER: Yes.

7 CHAIR KIRKPATRICK: Okay. So they
8 have all carried so far.

9 Any additional conditions of
10 approval?

11 DR. PFEFFER: Simple clarification.

12 CHAIR KIRKPATRICK: Yes.

13 DR. PFEFFER: The patient
14 information that we discussed and voted on
15 before will be worked out with both Link and
16 FDA approval. Is that correct?

17 CHAIR KIRKPATRICK: Correct as well
18 as with different venues as heard in the
19 discussion.

20 DR. PFEFFER: Thank you.

21 CHAIR KIRKPATRICK: Is that
22 adequate, Mr. Melkerson?

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1 (No response.)

2 CHAIR KIRKPATRICK: Thank you.

3 Any further conditions of approval?

4 (No response.)

5 CHAIR KIRKPATRICK: Now I just have
6 to flip through the pages. Okay. So it has
7 been moved and seconded that the Link PMA
8 Application P050050 for the STAR Ankle be
9 approved with the conditions the Panel just
10 voted in favor of.

11 We will now vote on the main motion
12 of approval with these following conditions.
13 As you vote, please state your name for the
14 record, your vote of yes or no, and indicate
15 if you are abstaining from the vote.

16 We will start with Dr. Mayor.

17 DR. MAYOR: Michael Mayor.
18 Arthroplasty in many joints has proven to be
19 the most cost effective and beneficial
20 intervention that almost any surgical
21 specialty can offer the patient cadre.

22 Modes of failure of arthrodesis

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1 involve patients getting slowly better and
2 then getting slowly worse if the subtalar
3 joint has been properly invoked as a reason
4 for a decline in the long-term result.

5 Arthroplasty of the ankle is likely
6 to be early better and then later and possibly
7 suddenly catastrophically worse.

8 I am unreconstructably disappointed
9 with the sponsor's approach to the assessment
10 of polyethylene as a bearing surface in this
11 architecture. There is ample material science
12 available which could have provided guidance
13 on how to manage the polyethylene and how to
14 assure me that the polyethylene, as managed by
15 the sponsor, could identify whether or not the
16 polyethylene was vulnerable to catastrophic
17 failure at some late stage.

18 And there has been no indication
19 from the sponsor either in regard to their own
20 willingness to commit to a careful study of
21 the polyethylene's mechanical properties
22 subsequent to its sterilization and

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1 implantation nor any items of evidence brought
2 from the European experience to answer the
3 same question from that base of data.

4 And on the basis of all of that, my
5 vote would be in relationship to approvability
6 with conditions previously described, no.

7 CHAIR KIRKPATRICK: Thank you, Dr.
8 Mayor.

9 Dr. Pfeffer?

10 DR. PFEFFER: Glenn Pfeffer. I
11 think Dr. Mayor's comments are important but I
12 think with the wear studies that we are
13 mandating and the broader world knowledge that
14 we have of this implant, that patients will
15 benefit more than they could potentially be
16 harmed. And I vote in favor of the STAR
17 ankle.

18 CHAIR KIRKPATRICK: Thank you, Dr.
19 Pfeffer.

20 I will remind the Panel that we
21 will have an opportunity to go around and
22 explain our votes once we are through. Thank

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1 you.

2 So, Dr. Pfeffer, if I recall, you
3 voted yes? Thank you.

4 Again, the motion is approvable
5 with conditions. And the conditions are
6 already specified. Thank you.

7 Dr. Propert?

8 DR. PROPERT: Kathleen Propert. I
9 vote no.

10 CHAIR KIRKPATRICK: Thank you.

11 Dr. Skinner?

12 DR. SKINNER: Harry Skinner. I
13 vote yes.

14 CHAIR KIRKPATRICK: Thank you.

15 Dr. Goodman?

16 MEMBER GOODMAN: Stuart Goodman. I
17 vote yes.

18 CHAIR KIRKPATRICK: Thank you.

19 Dr. Wright?

20 DR. WRIGHT: Douglas Wright. I
21 vote yes.

22 CHAIR KIRKPATRICK: Thank you.

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1 That's four votes in favor and two
2 votes no. I will now revisit those that did
3 not have an opportunity to explain their vote.

4 And ask for them to do so.

5 Dr. Pfeffer, did you complete your
6 explanation?

7 DR. PFEFFER: Yes, sir.

8 CHAIR KIRKPATRICK: Thank you.

9 And Dr. Mayor, did you complete
10 your explanation?

11 DR. MAYOR: Yes, I have explained
12 my vote. And I wonder if there might be an
13 appropriate -- an occasion for me to explore
14 some of the other issues that appear to be
15 related to an approved or an application that
16 has been voted approvable in the long run?

17 Despite my vote against it, I
18 recognize the thrust of the Panel in that
19 direction. And with that recognition, I
20 wonder if I might at some point be permitted
21 to offer some additional suggestions about
22 wording details?

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1 CHAIR KIRKPATRICK: I would also
2 ask Mr. Melkerson if procedurally I may
3 revisit the conditions because through the
4 conditions naming, he was always considering a
5 non-approvable vote. And as such, he wouldn't
6 have suggested a conditions because he was
7 thinking not approvable.

8 Is there any potential for that?

9 MR. MELKERSON: In terms of
10 revisiting? No. You basically approved with
11 the conditions as specified.

12 CHAIR KIRKPATRICK: So he can't add
13 another condition?

14 MR. MELKERSON: But you do have the
15 ability to listen to his points of discussion.

16 CHAIR KIRKPATRICK: Correct. Well
17 understanding now that we cannot add a
18 condition, I will be all means ask you right
19 now, Dr. Mayor, to please elucidate your
20 concerns so that the FDA is aware of them and
21 we all are aware of them. Thank you.

22 DR. MAYOR: Thank you, Dr.

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1 Kirkpatrick.

2 They are not major issues but they
3 include the observation that the extra small
4 sized tibial implant is not tapered from front
5 to back. And it is just sort of a curious
6 issue as to why that one is rectangular and
7 the others are trapezoidal.

8 A note was brought from the
9 warnings and precautions section to quote,
10 although the implant may appear undamaged, it
11 may have small defects and internal stress
12 patterns that may lead to premature failure of
13 the device. What? That sounds like a COA
14 clause that you might want to consider
15 expunging.

16 And following in the same area of
17 warnings and precautions, there is the clear
18 statement that says do not use implants or
19 components if the package is opened which
20 suggests that you have got to put the whole
21 package in. You've got to open the package to
22 put the implant in.

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1 So you might want to consider
2 expunging that particular caveat because you
3 can't put it in if you don't open the package.

4 A minor point, the surgical
5 technique guide, pages 11, 13, 14, 15, 16, and
6 21 all depict the ankle in the lateral
7 recumbent position, left side down. And I
8 wonder if that might be revisited to put the
9 ankle illustration in the position that might
10 be more meaningful for the surgeon addressing
11 the surgical field.

12 Beyond that, I think I have already
13 expressed my concerns regarding the issue of
14 the polyethylene. There is one small thing
15 that comes to mind in relationship to my
16 experience with amputations. And the loss of
17 ankle motion that attends an amputee's
18 activities in a lot of the activity areas that
19 your clinicians have cited.

20 And I'm sort of startled to realize
21 that I can't climb hills or stairs with my AK
22 limb or get around the woods with any kind of

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1 grace or collect the four cords of wood that I
2 bring in every year from those forests that I
3 wander around in.

4 So I'm suspicious that the
5 assertion which appears also in some of the
6 things that the patient may be apprized of in
7 promoting the idea of an ankle arthroplasty
8 instead of an arthrodesis might want to be
9 revisited as being perhaps a little bit over
10 the top.

11 Saying to patients that if they
12 don't have ankle motion, they will be unable
13 to perform those activities which my
14 experience suggests certainly for a BK amputee
15 with a good prosthetic ankle applied to that
16 lower extremity prosthetic limb, they actually
17 do almost imperceptibly related to a patient
18 in otherwise normal circumstances.

19 Finally, I would suggest in looking
20 at the draft proposal for the post-approval
21 study, a mention is made that at least six
22 months of conservative treatment for severe

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1 ankle conditions be -- and confirmed by the
2 patient's medical history, radiographic
3 studies, and medication record, and so forth,
4 I have a particular aversion to applying the
5 term conservative when what you really mean is
6 non-operative. Because in certain situations
7 a non-operative approach may not be
8 conservative at all. And I think it is a
9 little more clear if you use the term non-
10 operative instead.

11 I'll stop there.

12 CHAIR KIRKPATRICK: Thank you, Dr.
13 Mayor.

14 I will interject that I got one
15 stop out of order. And after announcing what
16 the vote was, I was supposed to read a further
17 statement.

18 It is the recommendation of the
19 Panel to the FDA that the Link PMA Application
20 P050050 for the STAR Ankle be approved with
21 the previous conditions voted in favor of.

22 And with that I will now continue

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1 to make sure that the Panel members all have
2 an opportunity to explain their vote.

3 Dr. Pfeffer?

4 DR. PFEFFER: I have nothing more
5 to add.

6 CHAIR KIRKPATRICK: Thank you.

7 Dr. Propert?

8 DR. PROPERT: I certainly struggled
9 with this vote. And I do not have the insight
10 of some of my clinical colleagues on the Panel
11 of know what else is out there. So a lot of
12 my decision-making was based entirely on what
13 I saw here today.

14 My reasons I have already outlined.

15 I am reasonably assured that this device is
16 effective. I am not reasonably assured that
17 it is safe.

18 And I want to make it very clear
19 that it is not that I think it is unsafe. It
20 is just that I did not see valid scientific
21 evidence to convince me that it meets the
22 safety standards.

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1 And although I am empathetic with
2 the issues that the sponsor and the FDA had to
3 deal with here, that was why I voted that way.

4 CHAIR KIRKPATRICK: Thank you.

5 Dr. Skinner?

6 DR. SKINNER: Well, I voted for
7 this proposal, this total ankle arthroplasty
8 because I felt that it demonstrated efficacy,
9 that it was effective in taking care of ankle
10 pain and the changes from arthritis. And I
11 felt also -- I was reasonably assured that it
12 was not inferior to an arthrodesis. And based
13 on that, I thought that it would be of benefit
14 to the patient population.

15 CHAIR KIRKPATRICK: Thank you, Dr.
16 Skinner.

17 Dr. Goodman?

18 MEMBER GOODMAN: I would just like
19 to make a point with regards to Dr. Mayor's
20 comments. And I know that you spoke with Mr.
21 Melkerson about adding any conditions after
22 the fact.

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1 But I am a little disturbed at how
2 this all transpired because had we heard a few
3 other points that might have been conditions,
4 because of the language Dr. Mayor decided to
5 choose, we didn't hear perhaps something
6 important about polyethylene and his vast
7 experience in that area.

8 And I am a little disturbed at the
9 rigidity of the process here insofar as we
10 couldn't somehow incorporate some of his
11 suggestions into our conditions. And I would
12 -- before I make any further comments, I would
13 like to inquire as to why that point can't be
14 revisited at this moment.

15 CHAIR KIRKPATRICK: I can answer
16 part of that real quickly in that the FDA
17 considers everything said in making their
18 decisions. We are an Advisory Panel. And the
19 strength of Dr. Mayor's recommendations will
20 certainly be incorporated into any future
21 studies or modification of materials or, you
22 know, preapproval requirements.

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1 Mark, does that summarize things?

2 MR. MELKERSON: That summarizes
3 things exactly.

4 CHAIR KIRKPATRICK: Thank you.

5 Dr. Goodman, would you like to
6 explain your vote?

7 MEMBER GOODMAN: I don't think I
8 have any more to say. I think the data, as in
9 any clinical study, is never perfect. And you
10 have to make a decision based on what is
11 presented.

12 We don't know the long-term safety
13 of such devices. And, in general, ankle
14 replacement for long periods of time has not
15 enjoyed the clinical success that hip or knee
16 replacement has.

17 And I would encourage the sponsor
18 to have their investigators follow their
19 patients very, very closely. And notify the
20 appropriate agencies if they see things are
21 developing that are untoward.

22 CHAIR KIRKPATRICK: Thank you.

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1 Dr. Wright?

2 DR. WRIGHT: I'm not going to tell
3 you how many times I changed my mind on my
4 vote. But I think that the biggest complaints
5 I had about today were the design study. I
6 thought from the start we were really
7 comparing two different things -- arthrodesis
8 to joint replacements.

9 I think it is unfortunate that we
10 did that. I think it is unfortunate that we
11 didn't compare this implant to another type of
12 implant. And I think that probably that was
13 the thing that swayed me is that I don't think
14 this implant is any worse than anything on the
15 market right.

16 I haven't been convinced that it is
17 better. I think it is comparable. But I
18 think that the study design was flawed. And
19 I'll leave it at that.

20 CHAIR KIRKPATRICK: Thank you.

21 Ms. Whittington, would you like to
22 comment?

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1 MS. WHITTINGTON: I echo some of
2 the concerns about the outcome data that was
3 presented. And the comparative body. I'm
4 puzzled at the beginning at why it wasn't
5 compared to another total ankle. But you
6 experts know more about that than I do.

7 I appreciate the process and the
8 transparency that I think the Panel worked in
9 today.

10 CHAIR KIRKPATRICK: Thank you.

11 Ms. Adams, would you like to
12 comment?

13 MS. ADAMS: Yes, thank you.

14 I think Dr. Wright's comments are
15 really important and really interesting. I'm
16 reminded of the resurfacing panels that many
17 of us sat on where the same challenge exists
18 when you talk about what is the appropriate
19 control. It is always a challenge.

20 And I think that the sponsor did a
21 good job, although not a great job or perfect
22 job, in trying to deal with that issue. So

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1 I'd like to acknowledge the work that the FDA
2 and the sponsor did together to try and cross
3 the bridge when you are talking about a new
4 technology and have to design a study to
5 address it.

6 I'd also like to acknowledge you,
7 Dr. Kirkpatrick, because you did a good job
8 keeping us on track and moving in a process
9 that sometimes can be fuzzy. So thank you.

10 CHAIR KIRKPATRICK: Thank you.

11 I would like to thank the sponsor
12 and the FDA for all your excellent work in
13 making the Panel's job relatively easy.

14 I would like to thank all of the
15 Panel members for dedicating their time to
16 this, both ahead of time and here, to be able
17 to serve in this capacity.

18 I would especially like to thank
19 the Panel members for not making it a split
20 decision that I had to cast a deciding vote.

21 (Laughter.)

22 CHAIR KIRKPATRICK: And I would

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1 also like to make sure Dr. Mayor doesn't have
2 another comment.

3 DR. MAYOR: Just very briefly. I
4 wanted to acknowledge Stuart Goodman's very
5 kind observations and concerns and to reflect
6 my confidence that FDA has heard what I am
7 concerned about as has the sponsor. And that
8 my experience with the system suggests that
9 those concerns will not go unheard.

10 CHAIR KIRKPATRICK: I would further
11 like to recognize that there are very few
12 places in this world that can have this kind
13 of open discussion as ordained by our
14 government. And once again, if you see a
15 member of our military on your way home,
16 please thank them for defending our liberty to
17 do this.

18 And with that, I'd like to see if
19 Mr. Melkerson has further comment.

20 MR. MELKERSON: Well, I'd just like
21 to thank the Panel for, again, putting up with
22 our idiosyncracies and our procedures as well

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1 as doing an excellent job of discussing the
2 points and bringing them to our attention.

3 I would also like to thank the
4 sponsor and the review team for their efforts.

5 CHAIR KIRKPATRICK: Thank you, one
6 and all, and we are now adjourned.

7 Oh, by the way, if you want to
8 applaud the servicemen, I heard that starting.

9 Go ahead.

10 (Applause.)

11 (Whereupon, the above-entitled
12 meeting was concluded at 4:33 p.m.)

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