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1 to address.

2 One, in the clinical area, the statistical

3 analysis indicated that a case for effectiveness had been

4 made, but the panel seems to feel that that has not been

5 done. We would be grateful if the panel could expound on

6 the issue, particularly in light of yesterday's

7 presentations where effectiveness was considered proved.

8 Secondly, in terms of the expectation of the, for

9 example, 25 years of data, while the device has been in use

10 for 35 years, over 35 years, the company itself is 10 years

11 old, so we would not be able to have or provide 25 years of

12 data.

13 Also, relative to PMMA, we certainly have heard

14 your concerns in the discussions. We do want to note that

15 there has been no clinically confirmed reaction to PMMA from

16 our devices.

17 It also seems that there might be some concern

18 relative to MDRs, and we would like to clarify that we take

19 an approach towards the MDR regulation that results in our

20 filing MDRs if even there is some question as to whether or

21 not it might be filed. Well, that is what we would consider

22 a conservative approach in terms of filing as opposed to not

23 filing.

24 Secondly, we are a major supplier and have been a

25 major supplier of these devices through the period

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1 considered for MDRs. It is not unexpected, then, that we
2 would have a large number of MDRs reported to the FDA as a
3 percentage of total reported to the FDA.
4 However, when you look at the number of MDRs
5 reported as a percentage of our devices in the marketplace,
6 the percentage, as Mr. Albrecht pointed out, is very small,
7 less than or about 1 percent total.
8 [Slide.]
9 Finally, relative to indications, currently, our
10 labeling for the fossa-eminence prosthesis, and you can see
11 it on the overhead, we state where conservative therapies
12 and treatment plans are not or are no longer indicated.
13 If the panel feels that there should be some
14 expansion of that, certainly, we would consider it, but we
15 do believe that, for the clinician, that captures the
16 essence of the indications for use for the fossa-eminence.
17 Once again, thank you very much for your time.
18 DR. JANOSKY: Dr. Floyd, as the Industry
19 Representative, do you have some comments for us?
20 DR. FLOYD: This has been a very interesting
21 presentation. There are a couple of comments I would like
22 to make.
23 Firstoff, having been associated with device
24 companies for some time, we have to be aware that device
25 companies and the medical device industry do not general

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1 market directly to the consumer, i.e., the patient. The
2 consumer in this case is the medical professional,
3 practitioners of medicine, and in many cases, companies
4 cannot really control the way a device is used.
5 They certainly have the labeling, and that is
6 prescribed by the regulations and the approval of the
7 device, and if those regulations aren't obeyed, the FDA does
8 have something to say about that.
9 On the other hand, we all know that we have
10 colleagues who may or may not use a device as prescribed in
11 the labeling of that device. So, that is something we all
12 have to be concerned about at all times.
13 The other issues that come about and that are
14 going to become increasingly important, and it is not a
15 matter to be addressed by this panel today, but I think it
16 is something we all have to put in the back of our minds and
17 start considering, is that the amount of information that is
18 available to the consuming public, the potential patient
19 population these days is increasing at a rapid rate.
20 The access to information is now worldwide and
21 instantaneous. All of the information that is available is
22 not necessarily accurate in all cases, and how we address
23 that and how both manufacturers and regulatory bodies and
24 scientific bodies and advocate groups, how we all address
25 those issues and work together to ensure that the

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1 information flow is as accurate as possible and is directed
2 as possible to the real issues is certainly a matter of
3 concern.
4 Thank you.
5 DR. JANOSKY: Before calling for a motion, Ms.
6 Scott has some guidelines that she would like to read to the
7 panel.
8 MS. SCOTT: Before the vote I would like to remind
9 the panel of the options that they have. If you would like
10 for me to read through the whole option document again I can
11 or I can just briefly read through it. Okay.
12 As you know, a PMA must stand on its own merits
13 and you recommendation must be supported safety and
14 effectiveness data in the application or by applicable
15 publicly available information.
16 I will reiterate the definition of safety provided
17 in the Act, which is the reasonable assurance based on valid
18 scientific evidence that the probable benefits to health
19 under conditions of use outweigh any probable risk.
20 Effectiveness is defined as reasonable assurance
21 that in a significant portion of the population, the use of
22 the device for its intended uses and conditions of use,
23 where labeled, will provide clinically significant results.
24 Your recommendation options for the vote are as
25 follows:

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1. Approval with no conditions attached.

2. Approvable with conditions.

3. Not approvable.

Of the five reasons that the Act specifies for denial of approval, the following three reasons are applicable to panel deliberations: (a) the data do not provide reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling; (b) reasonable assurance has not been given that the device is effective under the conditions of use prescribed, recommended, or suggested in the labeling; and (c) based on a fair evaluation of all the material facts and your discussions you believe the proposed the proposed labeling to be false or misleading.

We also ask that if you recommend the application not approvable for any other above stated reasons, that you identify the measures that you think are necessary for the application to be placed in an approvable form.

Lastly, in rare instances, the panel has decided to table an application, although we request that the panel not take this option if possible.

One other thing that I just wanted to clarify, there was discussion as it relates to the fact that there are several different prosthetic options contained within this PMA, but as submitted, the PMA needs to be voted on as

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1 submitted, it needs to be voted on as a whole, as a
2 submission, as an application. So, the vote has to be on
3 the PMA.
4 Now, if you have specific recommendations to the
5 agency regarding any specific portions or any specific
6 prosthetic options or devices included within the PMA, you
7 may provide those recommendations or statements to the
8 agency after the vote.
9 DR. JANOSKY: At this time I would like to call
10 for a motion.
11 DR. BERTRAND: I need a clarification. We are
12 voting on all of the aspects of the PMA and all their
13 indications as one unit?
14 MS. SCOTT: Yes.
15 DR. HEFFEZ: One further clarification. We are
16 voting the PMA as a unit, but not the indications, is that
17 correct? The indications can be modified with conditions,
18 is that correct?
19 MS. SCOTT: Yes. I believe that the panel can
20 state the specific indications for which you make your final
21 recommendation regarding.
22 DR. JANOSKY: Dr. Skinner.
23 DR. SKINNER: You want a motion I assume.
24 DR. JANOSKY: Yes.
25 DR. SKINNER: I move that the PMA be approved with

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1 the condition that a controlled clinical study be performed
2 and the indications be modified as will come out in the
3 discussion.
4 DR. BURTON: Second.
5 DR. JANOSKY: We have a motion and a second.
6 Discussion of the motion?
7 DR. LI: Excuse me. Can we amend by adding
8 conditions at this point?
9 DR. SKINNER: That was the intention.
10 DR. LI: I would like to see justification of the
11 continued use of the PMMA version of the device given that
12 there is a metal-on-metal alternative and their own data
13 also see that the methylmethacrylate wear is higher and then
14 the backup fail/safe of the methylmethacrylate, if the
15 methylmethacrylate fails, they end up with the metal-on-
16 metal. With all that together, it is unclear, at least I
17 believe the sponsor should justify why the PMMA option
18 should be continued other than that somebody wants to buy
19 that version.
20 DR. JANOSKY: Can I get a clarification? Are you
21 asking for a justification in terms of providing safety and
22 effectiveness data or a --
23 DR. LI: I would like them to provide some data to
24 justify the continued use of the PMMA version.
25 DR. JANOSKY: And what form would that data take?

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1 DR. LI: I would like that form to take clinical
2 trials as a specific option and Dr. Skinner's, and I would
3 like to see the appropriate laboratory tests accompany that,
4 specifically, basic property data on the PMMA including
5 fracture toughness data.
6 I would like to see fatigue testing aimed at the
7 known weakest engineering points of that device. I would
8 like to see the appropriate wear test, a validated wear test
9 and that it generates the appropriate size wear particles
10 for that device, and I would like to see a collection of
11 retrieved devices, however they get them, for whatever
12 reason they were retrieved to serve as a further validation
13 of the laboratory tests.
14 DR. HEFFEZ: For point of discussion, it would be
15 very difficult to develop a controlled study on these
16 patients because the population is so heterogeneous, the
17 reasons for performing the procedure are so heterogeneous
18 that even the same particular patient, a patient who has had
19 a mutilated joint from Proplast Teflon implant, the goals
20 for each individual patient are different. I think it would
21 be difficult to develop a controlled study.
22 DR. SKINNER: Dr. Heffez, are you saying that a
23 physician or surgeon couldn't ethically use another
24 treatment for such a patient, because if there is another
25 treatment, they could ethically be used in a controlled

1 study.

2 DR. HEFFEZ: I am saying that the numbers of

3 patients that would fall in specific categories to make that

4 a statistically valid study would be small. I am not saying

5 that a control can't be found. I am saying that the

6 population breaks into such small groups that you won't have

7 enough cases to make it statistically valid.

8 DR. SKINNER: I think that a good statistician

9 could take care of that problem. I have one in mind

10 actually, not me, but I think a good statistician could take

11 care of small numbers in a heterogeneous group, having

12 served on other panels with a statistician, but I see what

13 you mean.

14 I think, though, that if there is an ethically

15 valid treatment, no matter how small the numbers are, you

16 could form a controlled study. If there is no treatment

17 that is ethically an alternative, then, I think that the

18 prospective study as they have planned with appropriate

19 means of evaluating the patient, which I think are marginal

20 in the present study that is ongoing, things like the SF36,

21 for instance, would be a reasonable alternative.

22 DR. JANOSKY: Dr. Patters.

23 DR. PATTERS: I believe that a controlled study

24 can be done in this situation. Many patients are unable to

25 accept treatment, and it is not unethical to continue to

1 monitor those patients who, given the treatment option,
2 could not accept it and are accepting another treatment.
3 What I am most concerned about is that I think the
4 onus is on the sponsors to assure that long-term data is
5 gathered by supporting the patient, and obviously, an 80
6 percent dropout rate suggests that the patient was not
7 supported and the patient may not have returned for future
8 data collection because the costs were too high for the
9 patient to bear, et cetera.
10 So, I think that gathering the long-term data to
11 me is a critical issue, and that has to be designed in the
12 protocol to begin with.
13 I also would like to see--as I understand it, they
14 did break out some of the data into the different implant
15 types as they presented it today, but the PMA really needs
16 to be rewritten to have that data available for scrutiny by
17 the FDA staff. So, I would recommend that as a condition,
18 as well, that that data be provided to FDA in writing, so it
19 can be investigated.
20 DR. BURTON: I also think it needs to maintain the
21 patient registry and also that we should have some specific
22 engineering studies that deal at least in the lab bench
23 model with the patient-specific model. It didn't appear
24 that there was much discussion on that, but from what I
25 could see in looking through the materials, there didn't

1 seem to be much of an engineering validation to that. You
2 admit that it is a different design, but there is not much
3 other than the fact that it is different.
4 DR. JANOSKY: Dr. Bertrand.
5 DR. BERTRAND: I do not think that these implants
6 should be approved as a primary surgical intervention for
7 internal derangements. I am suspicious of whether they
8 should be approved as a primary intervention for meniscal
9 tears or perforations and also adhesions, and I have real
10 concerns about approving the delivery of these implants
11 unless those things are excluded from primary interventions.
12 DR. JANOSKY: Are you proposing a limit to the
13 indication for use?
14 DR. BERTRAND: Yes.
15 MR. ULATOWSKI: One comment concerning the
16 recommendation. I am detecting a little bit of difference
17 perhaps, and maybe you can clarify this for me.
18 When one makes a recommendation for approval or
19 approval with conditions, one is saying that given the data
20 in hand that has been presented to you, you made a baseline,
21 a fundamental decision that you have sufficient data,
22 sufficient valid scientific evidence upon which to make a
23 recommendation to FDA that the product should be approved
24 irregardless of the conditions for the moment.
25 So, we have data which supports the safety and

1 effectiveness, but we have some concerns now, you should do
2 this, you should do that, to support that fundamental
3 decision.
4 So, when you make recommendations, and I hear,
5 well, we need a prospective study to evaluate safety and
6 effectiveness, there is a disconnect there.
7 So, I am asking the panel in your discussion here,
8 have you made that baseline decision individually that you
9 have seen sufficient data to get over the initial threshold,
10 and the follow-up and the additional data is supporting data
11 in terms of longer term follow-up or some aspect of patients
12 or subpopulations that were inadequately studied to support
13 that baseline recommendation.
14 DR. SKINNER: Can I address that?
15 DR. JANOSKY: Yes, you may address it. Refresh my
16 memory, was it Dr. Heffez who put forth the motion?
17 DR. SKINNER: No, I did.
18 DR. JANOSKY: Thank you. There, you go.
19 DR. SKINNER: The normal situation from the time I
20 have served on panels in the past is that the company
21 presents with a PMA that has had 100 patients in the control
22 group and 100 patients in the study group or some number
23 that appears to be the appropriate number to provide a
24 statistically significant result that there is safety and
25 efficacy.

1 Frequently, those studies were designed without
2 the aid of the FDA, and there are flaws in the study which
3 raise questions. In that situation, the panel frequently
4 recommended a postmarket surveillance, but the data that
5 have been provided was data that was much cleaner than the
6 data here.
7 This is a much different situation with a
8 prosthesis that has been on the market for a number of
9 years, has demonstrated by its mere repetitive use by
10 surgeons like Dr. Curry that it has some efficacy and
11 safety, but it doesn't have all the i's dotted and the t's
12 crossed that would normally be found in a PMA.
13 I think that is what I, as the maker of the
14 motion, and I think the rest of the panel, feels would be
15 appropriate to cover the bases.
16 DR. JANOSKY: Dr. Stephens.
17 DR. STEPHENS: I have a question to Dr. Bertrand
18 about your motion. Is your concern that the device doesn't
19 work for this indication or is your concern regarding the
20 patient indications for which it has been used in the past?
21 I will tell you the reason that I ask.
22 This particular device, as someone who does a lot
23 of temporomandibular joint surgery, I don't do this
24 procedure, however, I know that the re-op rate for every
25 other procedure that is used for that indication is very

1 high, and my question is would you consider some study
2 mechanism to look at the device.
3 DR. BERTRAND: What I base what I said on is that
4 there is 30-year follow-up on people with internal
5 derangements in Holland who had nothing done and did very
6 well after a couple of years. It seems to me that with
7 people who have primary internal derangements, to place
8 something as an alloplast in, when we have that longitudinal
9 data on patients, I think it is a first surgery and a step
10 that might otherwise be avoided.
11 Now, if there is a way that you are going to
12 divide those groups of patients into two groups of 100, and
13 one is going to get a fossa implant, and the other group is
14 going to be followed, I might be convinced otherwise.
15 DR. STEPHENS: I think the question is whether
16 those patients are going to get this treatment or some other
17 surgery is probably the fairer question.
18 DR. BERTRAND: Or is surgery even necessarily
19 indicated and maybe just other treatments to support them.
20 DR. STEPHENS: The trouble I have is that it seems
21 like we are making treatment decisions rather than decisions
22 about the device, and it is hard to read the surgeons' minds
23 in decisionmaking process to go forward with any type of
24 surgical procedure. I understand your concern, but I also
25 wonder if we are making treatment decisions rather than

1 decisions related to the device.

2 DR. BERTRAND: Well, as Dr. Skinner said, an

3 ethical treatment doesn't necessarily mean another surgical

4 treatment. In the time course of this supposed disease, is

5 seems to burn out in most of the population

6 epidemiologically at age 45 or 50, whether treatment is done

7 or not.

8 DR. HEFFEZ: I believe the difficulty we are all

9 having is that the implants have been around for many years,

10 so the longevity is again their strongest suit. The problem

11 is that the data is muddled because it involves patients who

12 seem to have had a more aggressive approach using -- I take

13 that back -- patients have had a device placed when, in the

14 minds of many clinicians, other alternative treatments could

15 have been performed, and therefore it is hard to interpret

16 the data as presented. That is the difficulty, and I am

17 just airing it.

18 DR. JANOSKY: Dr. Patters.

19 DR. PATTERS: Getting back to the issue that Mr.

20 Ulatowski raised, I personally am convinced that the data

21 presented by the sponsor shows safety and efficacy short

22 term, but there were enough patients in my mind to validate

23 the data at the six-month interval and perhaps at the one-

24 year interval, but beyond that the dropout rate was so high,

25 I feel now that to answer the question is this device safe

1 and effective long term, which I believe is what the public
2 wants to know, is it safe for long-term use, I believe that
3 additional, well-designed, prospective studies need to be
4 done, but I am quite happy that the data, as presented,
5 makes the device approvable for at least the short-term use
6 that the data support.
7 DR. JANOSKY: Dr. Gonzales.
8 DR. GONZALES: I have one other difficulty, and
9 that is that others have tried to express or add to those
10 other difficulties, and that is, the indications that are
11 listed by the manufacturer are not the indications
12 necessarily of the surgeon. Dr. Curry, has indicated that,
13 in fact, one of his goals, the first goal listed on his
14 slide, in his summary, of pain reduction.
15 We have also heard that from the patient advocates
16 and others, that it keeps coming back to this issue that
17 pain is one of the indications, whether it is indicated or
18 not by the company, that is being used for the placement of
19 this device.
20 So, I think that a condition on the motion or a
21 couple of conditions on the motion would potentially expand
22 the indications of the company, first, that a prospective
23 study, that they are doing, be expanded and improved to
24 include measures of pain type at one point in time, that is
25 measurable, that is fixed, such as postprandial, for

1 instance, as well as pain relief, and the medications used
2 to modify pain, because this is not in a vacuum, these
3 patients are undergoing other treatments for their pain.
4 So, in addition to the pain studies that you are
5 doing presently, that this be expanded and improved. The
6 second is that the patients should be told that the studies
7 do not yet reveal that pain is significantly modified by the
8 device, until these studies show that, if, in fact, they
9 show that.
10 So, that would also modify the indication that the
11 company presently places on the device potentially. So,
12 that is a modification or a condition to the motion, the two
13 that I have just stated.
14 DR. LI: If the notion is that you need a
15 prospective clinical trial, if that is what you want, are
16 you saying that you should vote not approved?
17 MR. ULATOWSKI: I think Dr. Patters put it very
18 well, that in his instance, he has made a determination
19 based upon the data in front of him that he is comfortable
20 with the determination of safety and effectiveness, that
21 there is sufficient valid scientific evidence for the
22 indications for use albeit all the data is not there, but
23 there is sufficient information for him to base a clearance
24 decision.
25 If you don't believe that to be the case, if you

1 believe that the data fundamentally are insufficient upon
2 which to render a decision that it is safe and effective,
3 that is quite another thing.
4 The conditions of approval in terms of clinical
5 data usually follow the path of we need longer term data on
6 a certain set of patients, we need certain data on types of
7 patients or types of indications that weren't studied
8 sufficiently perhaps, so those are the sorts of conditions
9 that come into play with clinical data.
10 DR. LI: So, those would be approval with
11 conditions.
12 MR. ULATOWSKI: That would be the typical form of
13 conditions for clinical studies, but let me also, if I may
14 just for a moment, I think the point is well taken by Dr.
15 Skinner that--and Dr. Skinner I think missed my presentation
16 the first day, early in the morning, where I spoke about the
17 devices that come forward in 515(b) applications and that
18 they typically are the longer, the older devices that have
19 been around for quite some time, and the data is a mixed set
20 of data, and it is more difficult for the panel often to
21 come to grips with that information, but again, threshold is
22 not an absolute threshold on safety and effectiveness. It
23 is a reasonable assurance, not an absolute assurance, of
24 safety and effectiveness which gives you a lot of leeway as
25 a panel to consider within that context the sufficiency of

1 the data.

2 DR. JANOSKY: Dr. Heffez.

3 DR. HEFFEZ: I believe any studies that are

4 undertaken have to actually break up the population into

5 specific rubrics, and the rubrics have to be

6 indication/diagnostic categories, not categories such as

7 persistent pain or failed prosthesis.

8 I think that in order to really understand if

9 these devices are effective, we have to more accurately look

10 at the indications/diagnosis.

11 DR. JANOSKY: As I understand the motion presented

12 from Dr. Skinner and seconded, is that the motion is for

13 approvable with conditions, and the conditions that were

14 outlined by the panel. Is it my understanding, Dr. Runner,

15 that you were able to keep track of them a little better

16 than I was?

17 MR. ULATOWSKI: Madam Chairman, may I make a

18 comment?

19 DR. JANOSKY: Yes.

20 MR. ULATOWSKI: I think one condition that was

21 discussed yesterday and today in regard to this compensation

22 of patients--support for patients in some way, shape, or

23 form, I think there is no question it is well taken to

24 encourage follow-up and motivate subjects in a study to

25 return for follow-up is certainly laudable.

1 As far as FDA's ability to mandate certain
2 requirements of that sort of thing is extremely limited, but
3 it is certainly appropriate for the panel to make
4 recommendations of that sort for the benefit of the
5 sponsors, so that they can build in these sorts of concerns
6 into their studies and perhaps get the sort of follow-up
7 that is necessary because even though we are not mandating
8 certain compensations or whatnot to subjects, we have a high
9 expectation for follow-up, which goes for every study, that
10 is an aid to us, and when you have a lot of dropouts, and
11 you have the sorts of concerns expressed here the last
12 couple of days, so whatever the sponsors can do to improve
13 follow-up, these points are well taken.
14 DR. JANOSKY: So, the motion outlined is
15 approvable with conditions was presented by Dr. Skinner,
16 seconded by Dr. Burton, and the conditions are --
17 DR. RUNNER: That there will be a patient
18 registry, that there be a prospective study for safety and
19 effectiveness, that engineering and materials property data
20 be presented -- I have on the patient-specific implant, on
21 other implants, as well, is that correct?
22 DR. LI: In particular, the
23 polymethylmethacrylate.
24 DR. RUNNER: And the PMMA -- that it have limited
25 indications specifically the fossa-alone element should be

1 removed, is that correct?

2 DR. BERTRAND: As a primary measure for first-time

3 surgery for internal derangements.

4 DR. RUNNER: -- that measures of pain should be

5 made at one point in time, and the study should include pain

6 medications and other factors that are entering into the

7 pain management of the patient; that the use of the PMMA

8 device itself should be justified by the sponsor, and that

9 in any study, the population should be broken up such that

10 indications and diagnosis of the patient groups are clearly

11 specified.

12 DR. JANOSKY: Dr. Runner, I also have long-term

13 follow-up data.

14 DR. RUNNER: Could you be more specific as to what

15 long term is?

16 DR. JANOSKY: I thought I had heard three years or

17 longer -- three to five years.

18 DR. HEFFEZ: I would like to add one condition

19 which was raised by some of the patient advocate groups,

20 that a consumer hot line be available to answer questions,

21 and then I have one question, is that the PMA presented, as

22 the PMA stands, the eminence-fossa prosthesis was utilized,

23 the indications were as stated by the sponsor. Can we

24 indicate that as a labeling issue that we are, as Dr.

25 Bertrand brought up, that it wouldn't be used as a primary

1 surgical procedure? Are we permitted to do that or is that
2 splitting up the PMA as it was presented?
3 MR. ULATOWSKI: I think labeling recommendations
4 are appropriate.
5 DR. RUNNER: So, you are saying that the fossa-
6 alone would not be used as a primary surgical intervention?
7 DR. HEFFEZ: That is what Dr. Bertrand --
8 specifically for internal derangements. I concur, that is
9 what Dr. Bertrand said.
10 DR. BERTRAND: What about meniscal perforations?
11 DR. HEFFEZ: I consider that internal derangement.
12 DR. PATTERS: I think there was another condition,
13 that the data be broken up into the various implant types
14 and resubmitted to FDA for their evaluation, because the
15 data in the PMA was presented as group data, and that was in
16 the staff's recommendation.
17 DR. REKOW: I think there needs to be heavier
18 loads in the fatigue and wear, the recommendations that were
19 made before, and the wear debris reanalyzed.
20 DR. LI: To add the presentation of the analysis
21 of all retrieved devices that are available.
22 DR. REKOW: And confirmation that the wear data
23 from the laboratory reproduces the retrieved wear patterns,
24 wear patterns on the retrieved devices.
25 MR. ULATOWSKI: Just to bring the point back

1 again, there is two conditions here concerning clinical
2 studies. One states a prospective study to evaluate safety
3 and effectiveness. The other condition is longer term
4 follow-up. If you could fold those into something and
5 restate it in the context that Dr. Patters characterized it,
6 I think that would be more appealing as a condition to FDA.
7 DR. PATTERS: I didn't intend to make a separate
8 recommendation for a separate study.
9 MR. ULATOWSKI: So, the two in fact are one?
10 DR. PATTERS: Indeed.
11 DR. RUNNER: Could I also ask for a clarification?
12 There was the recommendation to justify the use of the PMMA.
13 What would you consider as a justification process for using
14 the PMMA device?
15 DR. LI: I am not quite sure how to put it in
16 terms of the FDA, but it seems to me the PMMA product is one
17 that demonstrably has higher wear, and demonstrably has more
18 engineering structural weaknesses than the metal-on-metal.
19 So, given the fact that the metal-on-metal is
20 available, and they don't seem to be able to present a
21 clinical reason why you would pick one over the other, my
22 question is why would you offer a device that is weaker and
23 has higher wear.
24 So, the question is how would you justify, why, in
25 a justification selling a higher wear product? I am not

1 sure I put that in terms of a condition.

2 DR. RUNNER: Do you feel that the company should

3 offer a justification if they continue to offer this portion

4 of their line?

5 DR. LI: I would say absolutely.

6 DR. BURTON: I would agree with that. I think

7 that if they want to continue to offer that particular

8 product, I think they have to justify the fact that it

9 continues to be offered in light of some of the engineering

10 things, and the fact that it may wear through the material,

11 obviously, then, you have something. We keep saying that

12 these don't have a life span. The point at which it wears

13 through the PMMA, you have altered the product to the point

14 that I think that it does have a life span, and then if it

15 continues to be offered, then, the patient needs to be

16 informed that that particular version has a life span of

17 whatever, which can be determined from adequate wear

18 studies.

19 DR. HEFFEZ: I believe that if a prospective study

20 is done where the proper diagnostic categories are

21 developed, it is possible to address something that Dr.

22 Skinner brought up, it is possible that the numbers may

23 reflect an ability to establish a control.

24 So, I would prefer to say that is my preference, I

25 ask for the panel's input, prospective studies with clinical

1 controls where possible, and I would suggest amending the
2 original proposal to remove the word "controls" and place
3 the control into the condition.
4 DR. REKOW: Tim, can I ask you a practical
5 question? We have come up with a pretty long list. Are we
6 talking ourselves into a different recommendation?
7 MR. ULATOWSKI: I have seen some long lists in
8 terms of conditions in the past. I think when we look at
9 it, we will try and make some sense out of it, what is
10 appropriate to do before we clear it if we can't see our way
11 through to a clearance without certain data, but I have seen
12 a mix of information from engineering to clinical under
13 conditions. So, I don't think you have changed the scenario
14 yet, in my mind. I had the fundamental, to me a pivotal
15 point, which was answered by Dr. Patters and others, so that
16 was my primary concern.
17 DR. JANOSKY: As I understand the motion, it is
18 approvable with conditions, and the conditions that were
19 just outlined--shall we redo those conditions again or are
20 they clear in everyone's mind--read the conditions is
21 necessary? Dr. Runner, please.
22 DR. RUNNER: I think I have separated them up into
23 three sections. One is the prospective study with controls
24 where possible, to gather long-term data, i.e., three to
25 five years, with the measurement of pain at one point in

1 time with an indication of the pain medications and other
2 interventions that are associated with this patient
3 population. The study should also break up the population
4 into indication and diagnosis for use, and should also have
5 the data broken off into separate implant types.
6 The company should also resubmit the data in the
7 present PMA, separating the data out into separate implant
8 types. The sponsor should also justify the use of the PMMA
9 data with either literature or engineering testing to
10 indicate why this device with its increased wear should
11 continue to be marketed.
12 Labeling should indicate that a decrease in pain
13 has not been found in long-term studies with this device.
14 Engineering data should include more testing on materials
15 property and specifically on the PMMA device, the patient-
16 specific device, and the fossa-alone.
17 There should be a consumer hot line set up, and in
18 the engineering data, heavier loads should be used in the
19 fatigue and wear data with debris analysis, and there should
20 be an analysis of any and all retrievals with wear data
21 correlated with lab data.
22 DR. HEFFEZ: I would clarify the consumer hot line
23 so that the patient actually has their questions answered.
24 It is easy to say a hot line is established. So, I would
25 say a consumer hot line should be established in order to

1 respond directly to patients' concerns and offer avenues for
2 resolution of their complaints.
3 DR. JANOSKY: Dr. Runner, did you have the item of
4 patient registry? I might have just missed it when you read
5 it.
6 DR. RUNNER: I may have missed it. There was a
7 patient registry.
8 DR. GONZALES: Can I add one other thing? Where
9 you stated that patients should be told that studies do not
10 reveal that pain is significantly modified, that really
11 should read patients should told that the studies do not yet
12 reveal that pain is significantly modified. I don't think
13 that the studies disprove or prove the impact on pain, and I
14 wouldn't want the other condition that patients get the
15 impression that this device will not help their pain,
16 because the studies have not been done, so I would add the
17 "do not yet reveal."
18 DR. JANOSKY: So, the motion is for approvable
19 with the conditions, the conditions outlined as read to us
20 by Dr. Runner.
21 At this time I would like to call for a vote. I
22 will start with Dr. Patters.
23 DR. PATTERS: I vote in favor of the motion
24 because I believe that the company presented sufficient data
25 to determine safety and effectiveness of their device short

1 term.

2 DR. JANOSKY: Dr. Li.

3 DR. LI: I vote to approve with the conditions

4 read. I think the thing that saves the device is that it

5 has been out for 30 years. I think it is unfortunate that

6 after 30 years, the data isn't tight enough to demonstrate

7 everything that it ought to demonstrate, and the performance

8 is in some ways a mismatch with other laboratory data, and I

9 think that gap needs to be closed.

10 DR. JANOSKY: Dr. Gonzales.

11 DR. GONZALES: I vote for approval of the device

12 with the conditions that have been stated. I think that the

13 indications, that there is a mismatch between the

14 indications as stated by the manufacturer and the way the

15 device may be used in a lot of cases, and I hope that these

16 studies will help to clarify that.

17 DR. JANOSKY: Dr. Rekow.

18 DR. REKOW: I vote to approve it as stated with

19 the conditions and the justification is essentially a repeat

20 of what Dr. Li has said.

21 DR. JANOSKY: Dr. Burton.

22 DR. BURTON: I vote for approval with conditions

23 as read. I concur with the fact that the longevity of the

24 device as shown safety and efficacy within the standards

25 that are necessary, however, its laboratory data and its

1 long term data collection is insufficient to promote long
2 term support.
3 DR. JANOSKY: Dr. Heffez.
4 DR. HEFFEZ: I vote in favor, and to reiterate,
5 the longevity of the data is the strongest suit for the
6 sponsor. I feel that the conditions that have been outlined
7 will greatly improve consumer awareness and lend greater
8 confidence to the data presented.
9 DR. JANOSKY: Dr. Skinner.
10 DR. SKINNER: I vote for approval with the
11 conditions as read.
12 DR. JANOSKY: Dr. Stephens.
13 DR. STEPHENS: I vote for approval with
14 conditions, and would hope that the conditions will help to
15 improve the confidence in this device, which is without
16 question very much needed in the clinical community.
17 DR. JANOSKY: Dr. Bertrand.
18 DR. BERTRAND: I vote for approval with
19 conditions, since the conditions will help us understand the
20 restrictions by which these implants should be used, and
21 will help collect data that will better define the long term
22 effectiveness or lack of effectiveness in specific
23 situations.
24 DR. JANOSKY: So, the motion carries.
25 The rationale for the votes. Dr. Skinner, did you

1 provide a rationale for your vote?

2 DR. SKINNER: I agree with Dr. Patters. I think

3 that the short term efficacy is demonstrated, and the long

4 term efficacy needs to be demonstrated through further

5 investigations.

6 Am I correct that everyone else provided a

7 rationale for their vote? Yes. Okay.

8 One more item of business in terms of the motion.

9 The conditions, to see whether they are met or not, would

10 you want it to come back to panel or to go back to FDA?

11 I hear a panel response. Dr. Patters, you are

12 saying panel? Any dissenting? Dr. Heffez?

13 DR. HEFFEZ: I agree.

14 DR. JANOSKY: Dr. Bertrand?

15 DR. BERTRAND: Panel.

16 DR. JANOSKY: I see a lot of head nods. It is

17 unanimous in terms of coming back to panel.

18 We have some closing comments from Ms. Scott.

19 MS. SCOTT: I just would like to remind all of the

20 attendees to the meeting today that if you would like

21 transcripts or summary minutes from the meeting, there is a

22 small sheet of paper on the registration table indicating

23 the numbers that you can call or the addresses that you can

24 write to, to request that information.

25 Also, I would just like to remind all the

1 attendees that you may call the FDA Advisory Committee
2 Information Line for future information regarding upcoming
3 Dental Products Panel meetings as the information becomes
4 available. For long-distance callers, you may call 1-800-
5 741-8138, and for local callers, you may call 301-443-0572.
6 The code number for the Dental Products Panel is 12518.
7 There is also a sheet of paper on the registration table
8 that has this information on it, also.
9 Lastly, we have one of our former panel members--
10 and when I say panel members, meaning a voting member to the
11 panel--who recently came off as a voting member, but has
12 continued on as a consultant to the panel, and that is Dr.
13 Willie Stephens. We have a plaque of appreciation to
14 present to him at this time.
15 [Applause.]
16 This plaque is from the Center for Devices and
17 Radiological Health, U.S. Food and Drug Administration.
18 Certificate of Appreciation presented to Dr. Willie Stephens
19 in recognition of distinguished service for the Dental
20 Products Panel of the Medical Devices Advisory Committee,
21 term from February 24th, 1995, to October 31st, 1998.
22 Signed by Dr. Burlington, our former Center
23 Director, and also our former Acting Commissioner, Dr.
24 Friedman.
25 [Applause.]

1 DR. JANOSKY: The meeting is ended.

2 [Whereupon, at 3:40 p.m., the meeting was

3 adjourned.]

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CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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