

1 description of your fatigue test results. In other
2 words, to help me close that gap between your fatigue
3 test and what happens clinically, perhaps a
4 description of what and where and how your devices
5 fail and fatigue.

6 For instance, if you're generating giant
7 holes in your fatigue test when it blows out that look
8 nothing like your retrievables, then that test is far
9 less meaningful than it is if you're actually
10 generating similar types of behavior as found in
11 retrieved devices.

12 I would encourage further analysis of
13 retrievables, and then the closer you can mimic your
14 laboratory test to what you actually find, the more
15 comfortable, much more comfortable I would be, but I
16 think it behooves you to find some cases or some tests
17 where your implants actually do, in fact, leak and
18 fail because they, in fact, do that clinically, and
19 they do so even more under the reconstructive
20 environment.

**

21 So I think it would behoove you if you
22 wanted people to make your tests more believable that

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1 you actually run tests that actually fail in a
2 reasonable amount of time, that somewhat mimics what
3 happens clinically rather than some of the more
4 extreme tests that you've provided so far.

5 CHAIRMAN WHALEN: Thank you, Dr. Li.

6 As to the first condition --

7 DR. DUBLER: Excuse me.

8 CHAIRMAN WHALEN: Okay.

9 DR. DUBLER: I just don't understand if we
10 stipulate that number and specificity of conditions
11 which are such at odds with the data that's been
12 presented. Can that still be considered under the FDA
13 rules for conditions of approval or does that have to
14 go into the explanation for why the data have not been
15 adequate and don't show safety?

16 CHAIRMAN WHALEN: Anyone, including of
17 course FDA, correct me if I'm wrong, but what we're
18 discussing and what we will shortly vote upon is that
19 there be a condition that there be in vitro
20 engineering testing.

21 Dr. Li has amplified for us some potential
22 examples of what form that testing may take, but at

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1 the point in time when we come to vote upon that being
2 a condition, we are being rather generic in what we
3 are voting upon with only the specificity of the field
4 of testing that would need to be done.

5 Dr. Blumenstein.

6 DR. BLUMENSTEIN: I have a question.
7 There were conditions specified here, but I have
8 additional conditions, but I have additional
9 conditions that I would like to add.

10 CHAIRMAN WHALEN: And we will, indeed, get
11 -- we're going to discuss each of the ones that have
12 been stipulated as conditions, enlist further
13 conditions, then vote upon each of those conditions,
14 then vote upon the motion of approvable with those
15 conditions that we have then approved.

16 Dr. Morykwas.

17 DR. MORYKWAS: Well, I'd like to add to
18 that that a potential testing condition could be done.
19 Instead of just 37 degrees saline, do it in serum or
20 some other biological fluid in case you do get lipid
21 incorporation. You get minor swelling of the device
22 which may potentially alter some of the mechanical

1 effects and just try and mimic the in vivo environment
2 a little more in your testing.

3 CHAIRMAN WHALEN: And we can do that. The
4 only response I would say to that is, as I just
5 alluded to, we're going to be voting upon that there
6 be further in vitro testing. If it's the pleasure of
7 this committee that we get very specific in what that
8 testing is, then by all means we'll do that.

9 But as first stipulated, we're being
10 rather generic in specifying that there be further
11 testing.

12 As regards the first potential condition
13 of in vitro engineering testing, is there further
14 discussion before we go to discuss any other
15 conditions?

16 MS. DOMECUS: Yeah, I just wanted to
17 clarify. I heard Dr. Li said it's pre-approval and
18 Dr. Burkhardt say it's post approval. So I'm not sure
19 what the condition is.

20 CHAIRMAN WHALEN: Dr. Burkhardt, since you
21 had proposed that condition, did you propose it as
22 post approval or pre-approval?

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1 DR. BURKHARDT: I proposed it as post
2 approval.

3 CHAIRMAN WHALEN: Dr. Li, do you agree
4 with its being post approval or do you feel that this
5 needs to be done before we can approve, which I would
6 -- which I believe means we would not be then saying
7 it's approvable with conditions if we're saying it's
8 pre-approval.

9 DR. LI: Oh, I misunderstood. I thought
10 approvable with conditions means we would approve it
11 so long as they met the conditions.

12 MS. DOMECUS: Right.

13 DR. LI: And if they don't meet the
14 conditions, then it's not approved. That's how I was
15 interpreting. Is that --

16 CHAIRMAN WHALEN: Dr. Witten?

17 DR. WITTEN: Well, I think that's up to
18 you to clarify in your recommendations because you can
19 make the approval. You can make your recommendation
20 about approval with conditions, that it's approval
21 that some things be done before we go ahead and
22 approve it or you can recommend that something be

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1 approved and recommend some post approval additional
2 testing.

3 DR. BURKHARDT: The intent of the motion
4 was to approve now and proceed with post approval
5 studies.

6 CHAIRMAN WHALEN: With that actually
7 having been what was proposed, do you wish to speak
8 against that, Dr. Li, or are you agreeable to that?

9 DR. LI: If it's post approval, I withdraw
10 my second.

11 CHAIRMAN WHALEN: Into the microphone.

12 DR. LI: Sorry. I misunderstood you to
13 mean pre-approval in the sense that you would approve
14 it before we would move on. So all of my conditions
15 are that I would vote for approval so long as the
16 conditions of testing are met, but not otherwise.

17 CHAIRMAN WHALEN: But would you --

18 DR. LI: So I would not approve it without
19 those tests. Is that what you mean?

20 CHAIRMAN WHALEN: As Dr. Burkhardt has
21 phrased it, we would recommend that the FDA find this
22 approvable and then subsequently do these studies.

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1 DR. LI: Can I ask, I guess, a procedural
2 question? If we go that route and say it's approved
3 first, and they do some subsequent testing, whatever
4 that may be, and at the end of it, whatever time
5 period, they go, "Oh, my gosh, this isn't what we
6 should be doing," what is our course of action?

7 DR. WITTEN: Well, usually if you're
8 recommending something post approval, it's to answer
9 some focused questions. So I guess we'd have to see
10 what that data showed, but in general it would be to
11 answer a focused question.

12 DR. LI: In that case I would disagree
13 then with Dr. Burkhardt's motion.

14 CHAIRMAN WHALEN: Very well. And withdraw
15 your second?

16 DR. LI: And I withdraw my second.

17 CHAIRMAN WHALEN: Well, you withdraw the
18 second of the motion as approvable with conditions?

19 DR. LI: No, his that it's approvable --

20 CHAIRMAN WHALEN: Yeah, we don't have to
21 move and second each individual condition.

22 DR. LI: Okay, fine.

1 CHAIRMAN WHALEN: So the motion is still
2 on the floor, and we're discussing this first
3 condition.

4 MS. DOMECUS: I think there may be a
5 semantics issue. Post approval means post FDA
6 approval of the PMA application. It doesn't mean post
7 panel approval today.

8 CHAIRMAN WHALEN: Correct. We don't
9 approve anything. We only recommend.

10 MS. DOMECUS: Right, but I mean if you say
11 approvable with conditions, those conditions can be
12 met after today's panel approval, but before FDA
13 approval of the PMA.

14 DR. BURKHARDT: May I comment?

15 CHAIRMAN WHALEN: Dr. Burkhardt.

16 DR. BURKHARDT: What I'm saying is I don't
17 think we ought to take these things off the market
18 pending these things, pending the new studies. I
19 think we should leave them on the market at the
20 present time and go ahead and proceed with the studies
21 and reconsider if the studies do not turn out
22 satisfactory.

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1 MS. DOMECUS: But approval with conditions
2 wouldn't take them off the market, would they? Would
3 it?

4 DR. WITTEN: Well, I'm not sure. You all
5 make a recommendation of approval with conditions, but
6 then our action would be either to have them -- would
7 be -- our action isn't approval with conditions. Our
8 action is either approving it, possibly with some post
9 approval conditions, or not approving it. So I guess,
10 you know, it's sort of a difference between what you
11 recommend and, you know, what we end up doing.

12 But we would either approve it with post
13 approval conditions or we wouldn't approve it or we
14 would try to do everything, you know, that you
15 recommended within the allowed time. So, you know,
16 that would be another option depending on how
17 involved, you know, some of these things were.

18 CHAIRMAN WHALEN: Ms. Brinkman.

19 MS. BRINKMAN: I have a question that I
20 don't understand. So how do you provide
21 accountability then if you say we'll approve this with
22 post approval conditions and the conditions are not

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1 met? So then what does the FDA do?

2 I don't understand. How then is the
3 manufacturer accountable and what happens?

4 DR. WITTEN: Well, we work very hard with
5 the sponsors, with them on their post approval
6 studies. So I'd say, you know, there's accountability
7 both on our end and on the sponsor's.

8 And I'll say that also I don't want to
9 suggest to the panel what you do, but you may look at
10 some of those specifics in the mechanical testing, and
11 maybe differentiate those that really are pre-approval
12 versus post approval.

13 I mean perhaps, you know, retrieval
14 versus, you know, approving the ones that are tested
15 or in other words, it may not be an all or nothing
16 thing, some of what you're recommending. So you might
17 look at it and say, "What do you think is really a
18 post approval condition of what needs to be done pre-
19 approval?"

20 I mean you might want to -- I don't want
21 to tell the panel what to do, but you might want to
22 look at the specifics of the suggestions.

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1 CHAIRMAN WHALEN: Dr. Blumenstein and then
2 Dr. Li.

3 DR. BLUMENSTEIN: I was just wondering if
4 we could make it unspecified as to whether it's pre-
5 approval or post approval and let that be the FDA's
6 discretion.

7 DR. LI: I guess I don't mean to over
8 complicate this, but I guess I was thinking the last
9 panel I was on was a completely different device
10 family, that there was a lot of additional testing we
11 required of the sponsor, but the sponsor was not taken
12 off the market during that time.

13 In other words, the FDA and the sponsor
14 agreed on a set of tests and a time frame for which
15 those tests should be completed, and during that time
16 frame the company or the sponsor will still able to
17 sell their device.

18 So I'm not saying you should stop selling
19 their device until all of these tests are met was my
20 intention.

21 DR. BURKHARDT: ^{**} Would you like to
22 reinstate your second?

1 CHAIRMAN WHALEN: Well, since we're
2 dealing with an FDA issue, Dr. Witten.

3 DR. WITTEN: Yeah, I think we'd prefer to
4 hear, you know, your recommendations about what needs
5 to be done for approval of these products versus
6 getting into a regular -- you know, have the panel get
7 into a regulatory discussion about what the different
8 terminology means.

9 I will just say in this case, as I
10 mentioned in my background, we have a 180 day total
11 time frame for review from the date on which the call
12 for PMAs was issued, which was in August. So that by
13 the end of that time, we will need to take a final
14 action.

15 Having said that, I might say that, you
16 know, you could perhaps want to tell us approval with
17 conditions that some issues be addressed if you don't
18 want to get specific and into some of the regulatory
19 issues versus how we would handle some types of
20 recommendations versus others.

21 Because I think what we really want to
22 know from you is what you think needs to be addressed

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1 by this application, you know, rather than your
2 regulatory assessment.

3 CHAIRMAN WHALEN: So if I may then, in
4 line with what Dr. Blumenstein raised, we are now
5 discussing the motion of approvable with conditions,
6 the first condition of which we are now specifically
7 discussion is that there be in vitro engineering
8 testing.

9 Does anyone wish to speak further about
10 that condition?

11 (No response.)

12 CHAIRMAN WHALEN: Seeing no one, Dr.
13 Burkhardt, your second condition was, please?

14 DR. BURKHARDT: The second condition was
15 that the comment regarding the shaped implant in the
16 promotional material or the informational material,
17 which technically is labeling, be revised. There is
18 a strong implication that these implants will offer a
19 more anatomical shape. Those are the words used, and
20 there has been no evidence presented to support that.

21 CHAIRMAN WHALEN: Does anyone wish to
22 speak to that condition?

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1 (No response.)

2 CHAIRMAN WHALEN: Dr. Burkhardt, were
3 there other conditions that you had raised?

4 DR. BURKHARDT: The third condition was
5 that the company labeling, the sponsor labeling
6 discourage periumbilical insertion.

7 CHAIRMAN WHALEN: Does anyone wish to
8 speak further to that condition?

9 Ms. Dubler.

10 MS. DUBLER: I'm just distressed that if
11 we get that particular that there might be other
12 instructions for surgeons that would be equally
13 important, and if we stipulate one particular one and
14 don't do a total review of the other possible negative
15 practices, that we will look like we have just merely
16 identified one and approved all the others.

17 So that strategically makes me a bit
18 uncomfortable.

19 DR. BURKHARDT: I am reluctant to put
20 constraints on the surgeon as a rule, but here we have
21 clear evidence that the ^{**}deflation rate of these
22 implants is increased by compression and by insertion

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1 through a small incision, and I think this is a
2 reasonable restriction to recommend from the
3 manufacturer.

4 If the surgeon wants to do it that way,
5 they're going to do it anyway.

6 CHAIRMAN WHALEN: Further comment on that
7 particular condition?

8 (No response.)

9 CHAIRMAN WHALEN: Dr. Burkhardt, were
10 there any further conditions that you had?

11 DR. BURKHARDT: No.

12 CHAIRMAN WHALEN: Thank you.

13 Now, I'm sorry. Dr. Morykwas, did you
14 have anything further?

15 DR. MORYKWAS: No.

16 CHAIRMAN WHALEN: Are there any of the
17 panel members -- Dr. Chang.

18 DR. CHANG: In the data, one of the
19 factors that also increased rate of rupture and
20 failure of the implant was an incision smaller than
21 three centimeters. **

22 So I would offer a friendly amendment that

1 if you stipulate a recommendation that the incision of
2 insertion be greater than three centimeters, would
3 that not take care of the practice of putting this
4 through endoscopically or through a long tube?

5 CHAIRMAN WHALEN: Dr. Burkhardt?

6 DR. BURKHARDT: It would, but it would
7 also preclude axillary and periareolar insertion,
8 which are very commonly used, and I don't think we
9 should do that.

10 CHAIRMAN WHALEN: Any further discussion
11 as to that particular condition?

12 (No response.)

13 CHAIRMAN WHALEN: Are there any other
14 conditions that any members of the panel wish to
15 suggest?

16 Dr. Blumenstein.

17 DR. BLUMENSTEIN: I think we discussed
18 collecting revision data before the indication of the
19 revision data would be approved, although now that I'm
20 reading this, I don't think that was -- I think just
21 collect additional revision data.

22 CHAIRMAN WHALEN: Dr. Burkhardt?

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1 DR. BLUMENSTEIN: Do we want to go one at
2 a time?

3 CHAIRMAN WHALEN: In terms of additional
4 conditions?

5 DR. BLUMENSTEIN: Yes.

6 CHAIRMAN WHALEN: If anyone wishes to
7 address collection of revision data as an additional
8 condition.

9 DR. BURKHARDT: I don't understand what
10 you mean.

11 DR. BLUMENSTEIN: We talked about how the
12 sample size for data on revision was small and that
13 additional revision data would be helpful.

14 DR. BURKHARDT: I would accept that
15 amendment.

16 CHAIRMAN WHALEN: Anyone else wish to
17 address that condition, imposition of the necessity of
18 the collection for revision or, quote, indication
19 data?

20 (No response.)

21 CHAIRMAN WHALEN: Do you have something
22 further, Dr. Blumenstein?

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1 DR. BLUMENSTEIN: Yes. That the risk
2 estimates either be done using true cumulative
3 incidence methodology or that the risk estimates be
4 appropriately labeled as to their conditional nature,
5 as conditional probability estimates.

6 DR. BURKHARDT: I would accept that.

7 CHAIRMAN WHALEN: Does anyone wish to
8 discuss that condition further?

9 (No response.)

10 CHAIRMAN WHALEN: Are there any further
11 conditions?

12 DR. BLUMENSTEIN: Redo the analyses
13 showing a demonstration of the potential for
14 informative censoring of missing data related to
15 dropouts affecting biasing the results.

16 CHAIRMAN WHALEN: I'm sorry. Can you
17 elucidate that a little further for me again?

18 DR. BLUMENSTEIN: That analyses be done in
19 which the characteristics of the patients dropping out
20 be documented.

21 CHAIRMAN WHALEN: Does anyone wish to
22 discuss that?

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1 DR. BURKHARDT: I don't understand how
2 you'd do that.

3 DR. BLUMENSTEIN: You can take the
4 baseline data, for example, age, and compare the age
5 of the women who have follow-up data with the age of
6 women who do not have follow-up data. This is a very
7 simple example, and then you can do that for almost
8 all of the baseline characteristics that one has.

9 DR. BURKHARDT: I understand that for age.
10 I don't understand how you're going to collect
11 complication data on people who don't return for
12 follow-up.

13 DR. BLUMENSTEIN: No, we're not collecting
14 complication data. We're collecting for patients who
15 have an assessment at 12 months for a particular
16 complication, and for the patients who do not have an
17 assessment at 12 months for a particular complication.
18 then you can compare their characteristics at
19 baseline.

20 DR. BURKHARDT: I will accept that,
21 assuming that the other statisticians understand it.

22 (Laughter.)

1 DR. BLUMENSTEIN: the other statistician
2 is nodding yes.

3 (Laughter.)

4 CHAIRMAN WHALEN: The question has been
5 raised on this last point that you raise do you wish
6 this for the labeling.

7 DR. BLUMENSTEIN: Yes.

8 CHAIRMAN WHALEN: Okay.

9 DR. BLUMENSTEIN: In other words, that the
10 labeling data be published in a way that would be
11 consistent with publication in a peer reviewed
12 journal. That's certainly what I'm getting to.

13 CHAIRMAN WHALEN: Okay. Any further
14 conditions?

15 (No response.)

16 CHAIRMAN WHALEN: You still have the
17 floor, Dr. Blumenstein. Is that all of yours?

18 DR. BLUMENSTEIN: I think I know what
19 she's going to say.

20 (Laughter.)

21 DR. BLUMENSTEIN: I think that we also
22 mentioned about long term follow-up data with specific

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1 attention to those patients, again, who are part of an
2 informative -- potentially part of an informative
3 censoring pattern.

4 CHAIRMAN WHALEN: Any discussion of that?

5 Dr. Blumenstein, would you like to take
6 the next one? Why don't you complete whatever you
7 need to do?

8 DR. BLUMENSTEIN: Well, I was going to --
9 this was a point that Karen raised earlier about the
10 analyses of particularly the quality of life data
11 being labeled in such a way that it's clear that
12 patients who have had a revision prior to the time
13 point in which the analysis is being done are not
14 included in that analysis.

15 CHAIRMAN WHALEN: Any further discussion
16 of that?

17 (No response.)

18 DR. BLUMENSTEIN: I'm done.

19 CHAIRMAN WHALEN: Karen.

20 DR. BANDEEN-ROCHE: I don't know how
21 appropriate this is, but I wonder whether we could
22 state as a formal condition that the sponsor and FDA

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1 work on a specific protocol to guarantee reasonable
2 assurance that patients are accurately and fully
3 informed.

4 And I do this meaning this in more than
5 sort of the generic you write out a label and people
6 have the opportunity to see the label. You know, it's
7 not enough to leave a procure on a table. It's not
8 reasonable to track people down and interview them in
9 their homes, but there's got to be something in
10 between that meets a standard of reasonable assurance
11 of accurate and complete information.

12 CHAIRMAN WHALEN: Any discussion as to
13 that condition?

14 (No response.)

15 CHAIRMAN WHALEN: Are there any other
16 conditions?

17 (No response.)

18 CHAIRMAN WHALEN: Seeing none, we are here
19 listed with ten potential conditions, and we will vote
20 on each of the ten individually before we then vote on
21 the motion. I will try to key word these conditions
22 so that we can each vote on them.

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1 I would remind that there are two non-
2 voting members of the panel. So please don't vote.

3 Ms. Brinkman?

4 MS. BRINKMAN: I got a bit lost on the
5 discussion. Did you ask for long term study to be
6 included in the --

7 CHAIRMAN WHALEN: That was number eight.

8 MS. BRINKMAN: Thank you.

9 DR. BURKHARDT: Mr. Chairman, in regard to
10 the ten conditions, would it be reasonable to ask
11 first if anyone objects to any one of those conditions
12 and then maybe vote on the whole bunch at one?

13 DR. WITTEN: That's up to you.

14 CHAIRMAN WHALEN: There are vigorous nods
15 from the FDA contingent.

16 (Laughter.)

17 CHAIRMAN WHALEN: So thank you for that
18 excellent suggestion.

19 Among these ten conditions, is there
20 anyone who is going to be voting negatively against on
21 any of them?

22 (No response.)

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1 CHAIRMAN WHALEN: Seeing none, just to
2 make it formal, as regards these ten conditions, all
3 those who are voting members who are in favor, please
4 signify approval by raising your hand.

5 (Show of hands.)

6 CHAIRMAN WHALEN: And all ten conditions
7 are, indeed, unanimously approved.

8 Thank you.

9 We now go to the motion, which is that we
10 recommend to FDA that the PMA be approvable with the
11 ten conditions we have just approved. Would all those
12 who are in favor of that motion signify by raising
13 their hand?

14 (Show of hands.)

15 CHAIRMAN WHALEN: All those that are
16 opposed?

17 (Show of hands.)

18 CHAIRMAN WHALEN: For the record then,
19 since it is not a unanimous vote, opposed to that
20 motion is Ms. Dubler, and therefore, approving that
21 motion are Dr. Li, Dr. Blumenstein, Dr. Boykin, Dr.
22 Bandeen-Roche, Dr. Burkhardt, Dr. Chang, Dr. --

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1 DR. MORYKWAS: Morykwas.

2 CHAIRMAN WHALEN: It's been a long day.

3 -- and Dr. Robinson, and the two non-
4 voting members have not voted.

5 DR. WITTEN: Dr. Whalen, you know you're
6 going to have to go around and ask everybody --

7 CHAIRMAN WHALEN: I know, but I had to
8 first read that in for the record.

9 DR. WITTEN: Okay.

10 CHAIRMAN WHALEN: Well, I've just been
11 requested something to do that I can't do, and that is
12 to read each of those conditions again into the record
13 because all I did was write down key words. So if
14 that's an obstruction, I'm sorry, but I can't fulfill
15 it.

16 DR. WITTEN: Just read the key words. Can
17 you read the key words?

18 CHAIRMAN WHALEN: The key -- I'll be happy
19 to read the key words.

20 DR. WITTEN: Read the key words. We can
21 get the rest from the transcript.

22 CHAIRMAN WHALEN: The key words of each of

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1 those ten conditions are:

2 In vitro engineering testing;

3 That the shape of the implant in the
4 present labeling be revised from its present labeling
5 as "more anatomic";

6 That the sponsor labeling discourage the
7 use of the umbilical distant incision;

8 That there be accumulation of revision
9 data;

10 That there be risk estimates;

11 That the present data be reanalyzed as to
12 the characteristics of those patients dropping out as
13 it pertains to labeling;

14 That there be accumulation of long term
15 follow-up data;

16 That there be labeling which concerns
17 itself upon those findings regarding quality of life
18 data that has been accumulated;

19 And that the sponsor and the FDA work
20 together to attempt to maximize the benefit of an
21 accurate and fully informed consent process.

22 DR. WITTEN: Well, now, that's nine

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1 conditions.

2 CHAIRMAN WHALEN: That's because when I
3 went to page 2 I dropped off seven. There were nine
4 conditions.

5 DR. WITTEN: Okay.

6 CHAIRMAN WHALEN: Now, we're not done. As
7 is our directive, we must go around the table and ask
8 that each of the members comment upon why they voted
9 as they did, and we will start with Dr. Li.

10 DR. LI: It seems quite redundant somehow,
11 but one more time, the instruction?

12 CHAIRMAN WHALEN: The instruction is that
13 you indicate to us why you voted as you did, and that
14 is to vote for approval, approvable with the
15 conditions as stipulated.

16 DR. LI: Okay. I think we have the usual
17 case of a device which has been around a long time and
18 has been quite effective to a large number of patient
19 populations and has been, at least for the majority of
20 cases, been beneficial.

21 I think the approval should be with
22 conditions, however, because I think unfortunately the

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1 mechanical in vitro characterization and testing lags
2 quite a bit behind the clinical experience, and that
3 the testing is incomplete versus the current product
4 line, both in terms of materials and manufacturing
5 methods, and there is a rather large -- actually it's
6 a disconnect between the data generated and the
7 ability to use that data to predict or assure a
8 certain level of clinical performance.

9 But I believe that gap could be at least
10 closed or made much smaller with more complete testing
11 and perhaps modifications of their current testing.

12 CHAIRMAN WHALEN: Thank you.

13 Dr. Blumenstein.

14 DR. BLUMENSTEIN: I voted yes because i
15 feel like that there is efficacy here, and that with
16 the conditions, there will be a movement towards a
17 nearly adequate characterization of risk that the
18 potential patient would be able to understand.

19 CHAIRMAN WHALEN: Thank you.

20 Dr. Boykin.

21 DR. BOYKIN: " I agree that we have a
22 significant level of comfort about the efficacy of the

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1 product and its reasonable safety, and that the
2 conditions of approval, I think, reasonably reflect
3 the deficiencies which I think can be worked through
4 quite easily.

5 CHAIRMAN WHALEN: Thank you.

6 Dr. Bandeen-Roche.

7 DR. BANDEEN-ROCHE: I found the whole
8 issue of safety and effectiveness and risk and benefit
9 very complicated per my previous comments. I voted
10 for approvable with conditions because I came to the
11 conclusion that at this point the best resolution is
12 not for me to decide on risk and benefit.

13 But to leave the device on the market and
14 leave the adjudication of risk and benefit up to the
15 individual patient, the condition being that the
16 patient be very, very fully informed.

17 And I would also state that I believe that
18 FDA has maybe more than the usual responsibility here
19 to very vigilantly keep up with ongoing developments,
20 as indeed we all do as scientists, and to investigate
21 opportunities to target people with particular risk
22 for adverse outcomes.

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1 CHAIRMAN WHALEN: Thank you.

2 Dr. Burkhardt.

3 DR. BURKHARDT: I think the evidence
4 clearly supports maintaining the availability of these
5 devices; that it would be wrong to take them off the
6 market at this time; but there are some additional
7 housekeeping items that need to be attended to and
8 approvable conditions was the best way to handle this.

9 CHAIRMAN WHALEN: Thank you.

10 Dr. Chang.

11 DR. CHANG: I think the information
12 provided by the PMA shows that there is relative
13 safety. There's a more clear demonstration of
14 efficacy, and I believe the previous discussions that
15 we have and approval conditions can be met and worked
16 between the FDA and the sponsor.

17 CHAIRMAN WHALEN: Thank you.

18 Dr. Morykwas.

19 DR. MORYKWAS: Also be that the efficacy
20 has been met and reasonable safety has been approved
21 or has been proven, with the conditions that we have
22 stipulated.

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1 CHAIRMAN WHALEN: Thank you.

2 The anticipation is killing us. Ms.
3 Dubler.

4 MS. DUBLER: It always makes me anxious to
5 find myself odd person out, but I think, in fact, that
6 the analysis of the data, especially as provided by
7 Drs. Li and Blumenstein, seem to indicate that the
8 tests that had been done that would permit patient to
9 assess risk and benefit, the data are not there.

10 My question earlier went to the issue of
11 whether there was some way to leave these on the
12 market pending the gathering of adequate data, and the
13 answer appeared to be no.

14 I don't know how to make this choice
15 because if there were other alternatives that women
16 could use, I would be extremely comfortable with my
17 vote.

18 However, I think that given the deflation
19 rate and the leakage rate and the very clear
20 explanations of why the test did not, in fact, gather
21 the sorts of data that would permit us to understand
22 these variables, I felt I couldn't vote for the

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1 reasonable safety.

2 CHAIRMAN WHALEN: Thank you.

3 Dr. Robinson.

4 DR. ROBINSON: Continued access to these
5 devices are very important for a lot of patients, and
6 I think the PMA shows me they're effective and they're
7 reasonably safe, and I supported the conditions,
8 although the first one I like warmly because I strongly
9 believe that expansive ex vivo new testing probably
10 will not provide additional significant information,
11 but I suppose we can try one more time.

12 CHAIRMAN WHALEN: Thank you.

13 The recommendation of the panel is that
14 the pre-market approval application for saline filled
15 breast prostheses from Mentor Corporation be
16 recommended as approvable with the stipulated
17 conditions.

18 We have, therefore, completed the first
19 day's activities, and I feel very much like Bill
20 Murray in the movie Groundhog Day when I say, "We will
21 meet here again tomorrow morning at 8:00 a.m."

22 DR. WITTEN: I'd like to thank our hungry

1 panel for bearing with us and the sponsor and the
2 public today, as well.

3 (Whereupon, at 9:21 p.m., the meeting was
4 adjourned, to reconvene at 8:00 a.m., Thursday, March
5 2, 2000.)
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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: MEETING

Before: GENERAL AND PLASTIC SURGERY
 DEVICES PANEL

Date: MARCH 1, 2000

Place: GAITHERSBURG, MARYLAND

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

Rebecca Davis