

1 all have normal endometrium? Were there patients
2 included who had simple hyperplasia? I don't believe
3 so. So I think it really should read that the
4 indication is a patient with normal endometrium, put
5 that under the indications rather than -- and then we
6 can list it again under contraindications. But a
7 stronger statement is that the indication is the
8 treatment of abnormal bleeding in patients with normal
9 endometrium.

10 DR. BLANCO: Okay. Any other comments on
11 any of the ones up there? Okay.

12 Next. And I guess I'd bring it up to the
13 Panel to see what the members thoughts are on D, how
14 much investigation should be done to make sure those
15 are not occurring before the patient is included in
16 the study?

17 DR. LEVY: I think that's a clinical
18 thing. It just says it would be with an endometrial
19 biopsy or anything else. I don't think we need to get
20 more specific than that.

21 DR. BLANCO: Okay. All right. Any other
22 comments?

23 DR. LEVY: In terms of size limit, clearly
24 ten is our -- ten centimeters is our upper limit,
25 because that's the upper limit of the study. I would

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1 say for the lower limit we need to think about --
2 these are all in pre-menopausal women. So if we had
3 pre-menopausal, nulliparous women, you know, you could
4 have a uterus that's six centimeters or seven
5 centimeters in length.

6 DR. JANIK: Especially if they're Lupron
7 pre-treated.

8 DR. LEVY: Especially if they're Lupron
9 pre-treated, right.

10 DR. BLANCO: Well, but it's a tough
11 question to go both ways on, because on the one hand
12 you can say, well, there may be some damage if you get
13 the lower end of the cervix. But what damage is that
14 going to be if you're not going -- you're not
15 supposedly going to become pregnant again. And at the
16 same time, the study did not have a lower number so
17 that the data may have some patients that were small
18 and they really didn't have any complications.

19 DR. JANIK: Well, you're risking cervical
20 stenosis.

21 DR. LEVY: Right. And hematometra.

22 DR. JANIK: Right. And there were a
23 couple of cases reported.

24 DR. LEVY: With hematometra.

25 DR. JANIK: Yes. But you could do post-

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1 operative surgical dilatation as part of your --

2 DR. LEVY: I think what I would ask, just
3 to forestall this conversation because we don't really
4 know, is to ask Company Sponsor and FDA to go back and
5 look at your data, look at the sizes of uteri. I
6 assume that you collected something about what the
7 uterus actually sounded to and take a look to see if
8 there were -- were the perforation issues issues in
9 small uteri? Were the hematometra issues issues in
10 small uteri? Did you have any uteri that sounded less
11 than seven centimeters? I mean we just need to -- we
12 don't have that data, and we need it to be able to ,
13 give you a good answer.

14 DR. JANIK: Or you could put as a warning
15 of potential problems in small uteri.

16 DR. LEVY: Well, they need to look at
17 their data. Maybe they have good data on those things
18 and it isn't a problem. We just don't have the data.

19 DR. BLANCO: Okay. All right. Anything
20 else on the training program? I mean I think we've
21 addressed a lot of issues already about training in
22 terms of the ultrasound skills, physician skills --

23 DR. LEVY: Just one more thing, Jorge.

24 DR. BLANCO: Go ahead.

25 DR. LEVY: We've talked about entry

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1 uterine pathology as an exclusion criteria, but
2 clearly in their protocol, patients with intramural
3 myomas were acceptable. And I think that something in
4 the training, something in the comments needs to talk
5 about the shape of the uterus, not with respect to
6 congenital anomalies but with respect to the position
7 and placement of myomas that could make visualization
8 difficult with ultrasound.

9 I mean it's just one of those things when
10 you get out there into general usage people are going
11 to push the envelope, and the way they're going to
12 push the envelope is to have some very large
13 intramural submucous myoma that may indeed distort and
14 make ultrasound guidance very difficult. So probably
15 we need to have some comment about pathology that's
16 outside the cavity but could compromise the procedure.

17 DR. BLANCO: Okay. Yes. And the other
18 thing along those lines that we ought to -- with prior
19 devices of this type, one of the concerns has been the
20 perforation issue. And I think in the training with
21 the ultrasound and in the labeling for the physicians,
22 that needs to be addressed, because if it's in the
23 uterus, it's probably not going to create any problem.
24 But if you do perforate and turn it on, there's the
25 potential for a lot of complications and problems. So

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1 we need to seriously deal with that.

2 Any other issues on training that we might
3 not have touched on? Nope?

4 All right. Then let's go to question
5 number eight, post-market study. Under FDA guidance,
6 patients from the pivotal study are scheduled to be
7 followed for a total of three years after the
8 procedure -- one year pre-market, two years post-
9 market. Is the proposed follow-up plan adequate to
10 address issues of long-term safety and effectiveness?

11 DR. LEVY: Yes.

12 DR. BLANCO: Okay. That's a very
13 definite. Dr. Diamond?

14 DR. DIAMOND: I would probably say I would
15 like to see an additional group of patients with the
16 device having corrected all 18 root problems involved
17 for this length of time, in addition to the patients
18 who participated in this study being followed up.

19 DR. BLANCO: In post-market?

20 DR. DIAMOND: Post-market.

21 DR. BLANCO: Okay. Your rationale for
22 that? I mean I'm not sure I clarified -- I'm sure
23 what you want.

24 DR. DIAMOND: Well, we talked about
25 earlier about the fact that the device that has been

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1 utilized for the clinical trial is not the one that
2 will ultimately be utilized if this device were to be
3 approved. I think that in addition to longer-term
4 follow up on the patients that participated in this
5 study, we also want longer-term follow up with
6 patients with the device, as it will be out in
7 commercial use.

8 DR. LEVY: But, Mike, what -- do you want
9 long-term follow up with those patients or do you just
10 want success or failure of the procedure? That's a
11 very short look at the next --

12 DR. DIAMOND: Oh, I may want the former as
13 part of the approval process, but I still would like
14 them to go through the process we envisioned
15 originally for a three-year follow up.

16 DR. BLANCO: No, I know. But I guess my
17 question, Mike, would be what do you think would be
18 different about a new subset of patients that have
19 this procedure that is different from the subset
20 already in the study that they're going to follow for
21 three years?

22 DR. DIAMOND: I don't know. That's what
23 we'd find out.

24 DR. JANIK: Maybe the skill level of the
25 people doing is different, so it will be a lower

1 success.

2 DR. BLANCO: Well, you know, we've
3 addressed kind of this issue before also in terms of
4 how long to have follow up, because it really put a
5 large onus on industry to try to keep up this follow
6 up. so I think we need to be specific as to what it
7 is we're looking for, we're concerned about. And I'm
8 not sure we place that onus on other devices. Now I
9 don't know that necessarily means we shouldn't place
10 it on this one, but at least I guess I would feel more
11 comfortable hearing what we think is different about
12 this one long-term. I totally agree with you -- short
13 and with a new machine -- but is it that we expect
14 differently?

15 DR. DIAMOND: Well, the difference between
16 this device and other ones along this line that we've
17 looked at is in the other times we've had the final
18 device, and we haven't had a 25 percent or higher
19 failure rate with a device as part of the clinical
20 trial, which we do have here.

21 DR. BLANCO: Right. But that's all a
22 short-term -- those are all short-term failures.

23 DR. LEVY: I mean we can say failure or
24 success at the time of the procedure. That doesn't
25 require a three-year follow up.

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1 DR. BLANCO: Yes. See, I think -- I mean
2 I don't know, and maybe somebody may want to address
3 this, but the idea of the long-term follow up was we
4 don't know what this may do, all these ablations may
5 do in terms of development of endometrial hyperplasia,
6 endometrial cancer, subsequent pregnancy, and how
7 those go on, rather than device specific.

8 Anybody else -- what's the feeling of the
9 other Panel members? Somebody besides me say
10 something. Dr. Janik, what do you think?

11 DR. JANIK: Well, I think my concern area
12 is the variability amongst the different trial sites.
13 That's a little unusual compared to other devices,
14 that wide range. So that would be the one thing to me
15 that would warrant maybe looking at a second subset of
16 study group, but it is a heavy burden. So I don't
17 know in the weighing of things if it's worth it.

18 DR. O'SULLIVAN: The only thing that I
19 think we might see is going to -- may well be an
20 increase incidence of hematometra. That I think is a
21 definite possibility because of the freezing and the
22 possible damage of the internal loss.

23 DR. BLANCO: so would you recommend
24 another set of patients to follow for another three
25 years?

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1 DR. O'SULLIVAN: No. I'd just follow the
2 ones that are here.

3 DR. BLANCO: Okay. Anybody else want to
4 make some comment? I'd like to hear some comments
5 from the other folks about this. It got quiet all of
6 a sudden. How about you, Gerry? You're not usually
7 quiet.

8 DR. SHIRK: Well, I guess I'm not so
9 concerned about problems after three years. I mean
10 I'm certainly concerned about the short-term problems
11 that have been identified, and I think that follow ups
12 over three years that most of those are going to be
13 identified with. I think putting a longer time frame
14 than three years becomes an onerous process for the
15 company. So I think that the short-term -- you know,
16 there's some things that need to be carefully looked
17 at. Over the long-term, I think, you know, I don't
18 think it's probably any different than any other
19 device.

20 DR. DIAMOND: I was not advocating follow
21 up for longer than three years. Maybe I didn't make
22 my point clear. I was advocating that the additional
23 patients be evaluated for three years, not more than
24 a total of --

25 DR. O'SULLIVAN: You're talking about the

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1 ones that get tested with the device as it's going to
2 be or has been commercially released.

3 DR. DIAMOND: Right.

4 DR. JANIK: The 400 patients, or whatever,
5 that are done are upcoming patients you're talking
6 about.

7 DR. BLANCO: Well, I think Dr. Diamond's
8 assumption -- because what we suggested is that the
9 Company needs to provide some data to confirm that the
10 new machine has corrected the high malfunction rate in
11 clinical settings. And I guess if there's an
12 assumption that they may do another small set of
13 patients, to demonstrate that acutely, okay. And what
14 you're saying is in that group of patients that that
15 is done. Because there's this other 400 out there
16 that were mentioned, but if the machine just got
17 changed, I'm not sure how they got 400 patients on
18 there, but that's another issue.

19 you would like to see those followed for
20 three years as well. Is that what you're saying?

21 DR. DIAMOND: Right.

22 DR. JANIK: There is some logic to that,
23 because we did put the question out there, why is
24 there this variability? And, to go back and look
25 internally within their data, they may not be able to

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1 answer that question without looking at more patients.

2 DR. SHARTS-HOPKO: Well, I agree that it
3 makes some sense in terms of logic, but I think that
4 it's excessively burdensome to prescribe another
5 three-year study at this point.

6 DR. O'SULLIVAN: Don't worry about
7 burdensome. They can afford it.

8 (Laughter.)

9 DR. BLANCO: Any other comments? Well, at
10 least we had one controversial issue anyway.

11 DR. SHIRK: Jorge, I think we're looking
12 at two issues here. Basically, one is a regular post-
13 market study, and I think that needs to go on. But,
14 two, we've already addressed the other issues that I
15 think that they need to be secondary studies, not
16 necessarily included in a post-market study but
17 basically I thought that we already addressed the fact
18 that we're going to ask the Company to address these
19 other issues. And is that part of the post-market
20 study or is that -- are those separate issues?

21 DR. BLANCO: No, I think --

22 DR. SHIRK: Do we make sure we divide them
23 into two different issues?.

24 DR. BLANCO: Well, it is an issue. I
25 think everybody agrees that the Company needs to

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1 provide data showing that the machine has a lower
2 malfunction rate out in the field. I don't think
3 there's anybody that has a problem with that. Well,
4 we'll see what the vote -- the question whispered in
5 my ear before approval, when we come to a vote we'll
6 see how the Panel feels on that. But I think the
7 issue that Dr. Diamond brings up is that that set of
8 patients also needs to be followed for three years,
9 right?

10 DR. DIAMOND: Correct.

11 DR. BLANCO: Okay.

12 DR. DIAMOND: Because if we have a more
13 efficient cryo process, who knows whether they'll be
1 4 -- whether it's hematometra or elsewhere.

15 DR. BLANCO: Well, but the malfunctions I
16 don't believe were in the efficient -- well, no, there
17 were, because there were some temperatures reported
18 there. Okay.

19 DR. DIAMOND: And there were some place
20 where there were more than two freezes.

21 DR. BLANCO: I stand corrected; you're
22 right.

23 DR. JANIK: I think those were three
24 issues. One, you want to see that the machine
25 actually works, so that data probably is already

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1 available. you want your three-year data to see if
2 there's some untoward effect we haven't figured out.
3 And then you really want some intermediate data to try.
4 to explain the site variations. So there's three
5 different questions that we really need clarification
6 on. And the last question I mentioned doesn't really
7 require a three-year study. It just requires some
8 further site explanation or more patients.

9 DR. BLANCO: Okay. Why don't we bring it
10 up to a vote. We'll bring that up. That seems to be
11 a controversial issue. We'll see how it falls.

12 I'd like to now address FDA and see if any
13 other issues that we need to bring up? Have we
14 answered the questions that you have in mind? Okay.
15 Anybody else wants to say anything? If not, we're
16 only three minutes over our time table, so let's go
17 ahead and take -- no, actually, we're ahead of our
18 time table. Oh, all right.

19 Well, then we're going to skip the break,
20 and we're going to move right on to the next step.
21 And the next step is another open public hearing. So
22 if there are some folks who would like to come forward
23 and address some of the issues that we may have
24 brought up.

25 DR. SCHULTZ: Dr. Blanco?

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1 DR. BLANCO: Yes, sir?

2 DR. SCHULTZ: With all due respect, I'm
3 seeing a lot of restlessness in the audience. Could
4 we do maybe a five-minute break?

5 DR. BLANCO: Okay.

6 DR. SCHULTZ: Would that be a fair
7 compromise?

8 DR. BLANCO: Five-minute potty break. But
9 we'll start on time.

10 (Whereupon, the foregoing matter went off
11 the record at 3:07 p.m. and went back on
12 the record at 3:15 p.m.)

13 DR. BLANCO: All right. Let's go ahead
14 and get started. And what we'll do now is we have
15 some time to go ahead and hear back from you folks.
16 You've heard us talk about some of the issues and some
17 of the discussion, so this is your turn to make some
18 comments on some of the issues that we've addressed.

19 So is there anyone who would like to
20 speak? Mr. Murray, go ahead.

21 MR. MURRAY: Thank you, and thanks for the
22 opportunity to address the Panel again. I'm Dave
23 Murray.

24 First, I guess I want to say -- start out
25 by saying that all the physicians in the study were

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1 directed to use a procedural technique of four and six
2 minutes, and that when you consider the patients, only
3 those patients who got four- and six-minute freezes
4 during the study, we achieved the equivalence, as
5 identified in our IDE. And it is our intent now to
6 label the device for physicians in the direction for
7 use to do four- and six-minute freezes. So we're on
8 board with you there.

9 We also wanted to mention the site-to-site
10 issue that you mentioned. We were interested in that
11 as well, as you might imagine. We interviewed
12 investigators. We had our statisticians look at the
13 data. But keep in mind that the sites that had poor
14 results had low enrollment numbers. So there was no
15 statistical issue that came up, other than some of the
16 refinements of technique, like traction on the
17 tenaculum that we learned as we talked to
18 investigators. We will continue to work with the FDA
19 on that but thus far have been unable to find that.

20 We also, I guess, would mention that we
21 will work with FDA to modify the labeling to ensure
22 that we give physicians good, early instruction on how
23 to start using this device,. But we agree with those
24 of the Panel who advised some flexibility in the case
25 of smaller uteri, for instance, or just anatomical

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1 variability. We hope that that flexibility can at
2 least remain at the physician's discretion at some
3 point.

4 And then finally, regarding reliability,
5 we agree with Dr. Neuman's suggestion on validation of
6 changes. I just want to make sure and clarify for the
7 Panel, the 16 root causes that we identified, that we
8 corrected, and that we did validation on, those 16
9 root causes have all been implemented in the devices
10 that have been sold since commercial launch. And we
11 do have data on those 16 issues in our commercial
12 complaint database and will work with FDA to provide
13 that data to them. We think the fact that there have
14 been zero complaints on those 16 issues speaks to the
15 effectiveness of the validation technique, that those
16 that got changed and validated got put in the field.
17 Four hundred procedures have been done, zero
18 complaints.

19 So we think that speaks for why validation
20 ought to work for these last two issues that we're in
21 the process of validating right now and suggest that
22 we get on with that and come back to the FDA with that
23 data to show that those two issues have been totally
24 resolved.

25 So, again, I thank you. I hope the

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1 clarification of the implementation of the changes for
2 the 16 helps everyone to understand the device. And
3 I guess one other final point is that the device in
4 commercial use is not a changed device from the device
5 that was used in the clinical study. We did change
6 some material so there would be a lower level of
7 contamination. We made some other minor process
8 changes to reduce contamination. But engineering-
9 wise, it's substantially the same device as was used
10 in the clinical study and has exactly the same
11 performance specifications and criteria as the device
12 used in the clinical study. Thank you.

13 DR. BLANCO: Thank you. Anyone else that
14 would like to address the Panel from the audience or
15 the sponsor? Any of the physicians? No? I think FDA
16 would -- anyone from FDA like to make some final
17 comments at this point?

18 DR. SCHULTZ: Well, no. I think the
19 discussion has been extremely complete and extremely
20 helpful, and I think we have a clear direction in
21 certain key specific areas like the issue of the
22 validation of the changes that were made and like some
23 of the labeling changes that you've recommended. And
24 I think that we can work with the Company to resolve
25 those issues. And, clearly, if there are questions

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1 that come up during that process, we know where to
2 find you guys.

3 DR. BLANCO: All right. Thank you. All
4 right, having no other comments, I'll turn it over to
5 Dr. Harvey to go over the definitions and the method
6 of voting.

7 DR. HARVEY: I just wanted to review our
8 definitions of safety, effectiveness, and valid
9 scientific -evidence. There's reasonable assurance
10 that a device is safe when it can be determined, based
11 on valid scientific evidence, that the probable
12 benefits to health from the use of the device for its
13 intended uses and conditions of use, when accompanied
14 by adequate directions and warnings against unsafe
15 use, outweigh any probable risks.

16 Effectiveness, There's reasonable
17 assurance that a device is effective when it can be
18 determined, based on valid scientific evidence, that
19 in a significant portion of the target population the
20 use of the device for its intended uses and conditions
21 of use, when accompanied by adequate directions for
22 use and warnings against unsafe use, will provide
23 clinically significant results.

24 I'm not going to read that whole thing.

25 (Laughter.)

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1 Just to review what we mean by valid
2 scientific evidence, we're talking about primarily
3 well-controlled investigations, partially controlled
4 studies, studies and objective. trials without match
5 controls, well-documented case histories conducted by
6 qualified experts, and reports of significant human
7 experience.

8 Do we have voting procedures up there?
9 For the Panel, the recommendation options for the PMA
10 are either approval. That would mean that there will
11 be no attached conditions. Approval with conditions.
12 That would mean that specific conditions would be
13 discussed by the Panel and listed by the Panel Chair
14 before the vote. And your third choice would be not
15 approvable, and you can do that for one or more of the
16 following reasons. Basically, it would be that there
17 would be a lack of showing of reasonable assurance
18 that the device is safe under the conditions of use
19 prescribed, recommended or suggested in the labeling;
20 there is a lack of showing of reasonable assurance
21 that the device is effective under the conditions of
22 use prescribed, recommended or suggested in the
23 proposed labeling, or based on a fair evaluation of
24 all material facts, that the proposed labeling is
25 false or misleading.

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1 The voting procedures will be for a voting
2 member to make a motion recommending an action,
3 including any conditions pertaining to the
4 recommendation. The Chair will request a second on
5 the motion and entertain any discussion. And then the
6 Chair will call for a vote on the motion. If there is
7 more than one condition, this is always the confusing
8 part, each condition will be voted on separately, and
9 then the entire amended motion will be voted on. And
10 voting can be accomplished by a show of hands or
11 polling. And as part of the vote, the Chair may query
12 each Panel member to state for the record their
13 rationale for their vote.

14 And you should keep in mind that PMA
15 review is independent of the following considerations:
16 cost, previous regulatory difficulties, clinical data
17 submitted in any other PMAs for similar devices by
18 competing companies or the medical/legal climate and
19 its effect on the standard of care.

20 DR. BLANCO: Okay. I'm also going to take
21 the Chair's prerogative, just because we've done this
22 a couple more times and it makes it easier, that the
23 way I'd like for the motions to be made is that if we
24 can first get out of the way whether we want total
25 approval with no attached conditions or not approvable

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1 so that if the wish of the Panel turns out to be
2 approvable with conditions, then we can talk about the
3 individual conditions and get the other two issues out
4 of the way.

5 So, as the Panel Chair, I will now
6 entertain a motion. If anyone would like to make a
7 motion for full approval with no attached conditions
8 or for non-approval for one of those reasons. And
9 then if not, I will entertain motions on the other
10 one. Anyone care to make a motion?. I don't hear a
11 motion on approvable or not approvable.

12 All right. Would anyone care to make a
13 motion on approvable with conditions, and we can then
14 begin to list conditions?

15 DR. JANIK: I'll motion.

16 DR. LEVY: So moved.

17 DR. BLANCO: Okay. How about you motion
18 and you second? Okay? So we have a motion and a
19 second with approvable with conditions. So now let's
20 start sitting down and going over some of the
21 conditions. And I'd just tell you ahead of time, they
22 don't like to say everything we discussed before. So
23 let's point out some of the conditions, and I'd try to
24 write a few, but you guys go ahead and bring them on.

25 DR. JANIK: One is documentation that

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1 device failures have been corrected.

2 DR. BLANCO: You're talking malfunction --

3 DR. JANIK: Malfunction.

4 DR. BLANCO: -- or device failures? Okay.

5 So that the malfunction rate has been corrected. Do
6 you want to be anymore specific than that or just
7 leaving it as documentation and leaving it up to the
8 FDA and the Company to determine the level of need of
9 documentation?

10 DR. JANIK: I'd leave it open.

11 DR. BLANCO: Okay. Any comments on this
12 particular item? Let's just take them item by item,
13 I guess.

14 DR. LEVY: I guess I'd like to leave it up
15 to FDA up to point but to say that I do think an
16 additional study is required of the current marketed
17 device with all 18 of 18 corrected, just to document.
18 And a study just means that I don't think looking
19 backwards at 400 marketed devices where comments that
20 were not solicited by the Company have not been
21 received. I think that's different than actually
22 looking at it and soliciting comments.

23 So my recommendation is that it doesn't
24 have to be an in-depth, randomized, complex deal, but
25 that the currently marketed device be studied

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1 prospectively from this point on to assure --

2 DR. BLANCO: And your interest is the
3 malfunction, so it would be an acute, short-term study.

4 DR. LEVY: Correct.

5 DR. BLANCO: Okay. Any comments on that?

6 DR. KATZ: Well, I think we -- the way
7 it's worded it's still open ended, and I think that if
8 we're going to say that, I think we have to leave that
9 to the discretion of FDA regarding what will be
10 sufficient in such a smaller prospective study.

11 DR. BLANCO: Okay. Any other comments?
12 Dr. Janik?

13 DR. JANIK: I'm not sure that it needs to
14 be prospective. I think it could be retrospective
15 review, but --

16 DR. LEVY: And that's what I'm saying I'm
17 uncomfortable with.

8 DR. JANIK: Okay.

19 DR. LEVY: Because when something's
20 already on the market and you're relying on medical
21 device reports, I know in my hospital if I don't
22 demand that they get done, they don't get done. And
23 I may whine and scream and carry on about something
24 that didn't work, but it may not get reported. so I
25 think we need to be looking for problems with this

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1 device rather than relying upon reports that may or
2 may not have been solicited.

3 MS. DOMECUS: But maybe there's a middle
4 ground. Maybe we don't have to just rely on the
5 passive MDR system or do a prospective study. Maybe
6 we could just have -- if it's feasible, and I don't
7 know if it is -- if it's a manageable number of sites,
8 go back with standardized case report forms, and if
9 the hospital records are detailed enough to -- or the
10 physician records are detailed enough to transpose it
11 onto the case report forms. And I think that should
12 be available as an option. It may not be a legitimate .
13 option once they try to implement it.

14 DR. LEVY: Well, one thing, though, is
15 that only 16 of the 18 have been corrected, as I
16 understand it, in the things that are on the market
17 right now. Is that correct?

18 DR. BLANCO: Yes.

19 DR. LEVY: So my issue is I'd like 18 out
20 of 18 to be corrected.

21 DR. BLANCO: Okay.

22 DR. LEVY: And then we take a look at it.

23 DR. BLANCO: All right. Let's go, because
24 we need to go over this with very specifics. So the
25 other issue that you need to put into there, Dr. Levy,

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1 is do you want this as pre-market or a post-market
2 study?

3 DR. LEVY: Pre-market.

4 DR. BLANCO: Okay, pre-market. so go
5 ahead, Dr. Diamond.

6 DR. DIAMOND: Yes. I would like to see
7 post-market for three years followed up with a pre-
8 market study, number one. Number two, I'd like --

9 DR. BLANCO: Wait a minute, because we're
10 now going into a different amendment. So we're going
11 to different issues. All right. Go ahead. So a
12 three-year study pre-market or post-market?

13 DR. DIAMOND: No, no, no. The pre-market
14 study that's done, that those patients be followed for
15 a total of three years, which would then include a
16 post-market component.

17 DR. BLANCO: All right. So make sure we
18 clarify. The motion of Dr. Levy includes a condition
19 that they develop a pre-market study to ensure that
20 the malfunctions of the machine have been corrected,
21 and then you would add to that as a post-market you
22 would like to see those patients followed for three
23 years, correct?

24 DR. DIAMOND: As we've done with similar
25 devices, yes. I also would like to see that the

1 indication talk specifically about the fact that this
2 group -- this device will reduce vaginal bleeding.
3 Because the way the indication is now labeled --

4 DR. BLANCO: Well, let's take one of the
5 conditions at a time. That's kind of another
6 condition.

7 DR. DIAMOND: That is.

8 DR. BLANCO: So let's take one. So, so
9 far, what I've got is that a condition needs to be
10 documentation of correction of malfunction rate, and
11 the motion on the floor is for that to be through a
12 pre-market prospective study and, Dr. Levy, do you
13 accept Dr. Diamond's amendment to add a three-year
14 post-market study?

15 DR. LEVY: I don't feel that it's
16 necessary.

17 DR. BLANCO: Okay. So then we've got to
18 vote on each of them separate. So let's vote, first,
19 on the three-year post-market follow up of these
20 patients. Does everyone know who's a voting member
21 and who is not? Okay. All right.

22 So may I see a show of hands --

23 DR. O'SULLIVAN.: May I ask a question?

24 DR. BLANCO: Certainly.

25 DR. O'SULLIVAN: Are we voting on the

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1 three-year post-market study of the ones that have
2 already been done?

3 DR. LEVY: No.

4 DR. BLANCO: No. We're taking it a step
5 at a time. So what we're voting is if we pass -- a
6 condition of approval is that they do another study
7 looking at the malfunction rate that is corrected,
8 that they follow those patients for three years. So
9 we're just voting right now on the three-year post-
10 market condition if that study is done, if we approve
11 that study. We're trying to take it one step at a
12 time.

13 All right. Maybe I've got the wrong
14 order. Maybe we should vote on the pre-market
15 prospective study first. So any discussion? So right
16 now the issue is we think a condition needs to be the
17 device malfunction evaluation and the suggestion is a
18 pre-market prospective study. Any comments before we
19 vote, or discussion? All right, fine.

20 May I see a show of hands. Those in favor
21 of having a pre-market prospective study to
22 demonstrate this? Please hold your hands so I can
23 count. Nine in favor.

24 All those opposed? Zero opposed. So
25 that's part of the condition.

1 Now, Dr. Diamonds adds an amendment to
2 have a three-year post-market follow up of these
3 particular groups of patients. Any comments on that
4 before we vote.

5 DR. DIAMOND: For a total of three years.

6 DR. BLANCO: For a total of three years,
7 I'm sorry. Okay. Any comments?

8 DR. KATZ: I think that they confuse the
9 issue of what's an adequate post-market evaluation,
10 because the standards for what is essentially a
11 technological evaluation of a device may not be the
12 same standards for a biological evaluation of the
13 consequences of the application of the device. I
14 think that our issues of post-market evaluation should
15 be separated from evaluation of the technological
16 performance of the device.

17 DR. BLANCO: So you would vote no on this.

18 DR. KATZ: I would vote no.

19 DR. BLANCO: Okay. All right. Any other
20 comments? Dr. Levy, I think you were leaning forward
21 to make a comment? No? All right.

22 All those in favor of studying those
23 patients three years post-market, raise your hand,
24 please. One.

25 All those opposed? Seven opposed. Does

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1 not carry and one abstention.

2 Okay. So right now one of the conditions
3 that we have is documentation of correction of
4 malfunction rates through a pre-market prospective
5 study. And we would leave it up to the Company and
6 FDA to work out numbers and length of time, et cetera.
7 But the thrust was acutely looking at malfunctions,
8 short, quick. Okay? All right.

9 Are we ready to move on to a separate
10 condition? Dr. Shirk?

11 DR. SHIRK: I would move that there be a
12 study evaluating the cause of the user variability,
13 not only within the original study but also if there's
14 a problem with user variability, it could be tied to
15 this post-market thing so that we get some idea as why
16 there was a site variation.

17 DR. BLANCO: All right. So you are -- let
18 me make sure I rephrase this correctly -- you are
19 proposing a motion that you have a pre-market new
20 study to look at inter-site variability and to try to
21 explain that. Is that what you're saying?

22 DR. JANIK: Or another way --

23 DR. BLANCO: Wait, wait a minute. Let me
24 make sure that that's what he's saying first.

25 DR. SHIRK: Correct. And that could be

1 included in the study that --

2 DR. BLANCO: All right. Is there a second
3 to that motion?

4 DR. KATZ: Are you talking about a new
5 clinical study with different sites or are you talking
6 about a reexamination of the current data?

7 DR. SHIRK: Well, I supposed both, but I
8 mean I think --

9 DR. BLANCO: Well, no, you made the motion
10 -- I'm sorry to interrupt, but you made the motion.
11 That's why I tried to clarify it. My understanding of
12 your motion was that you wanted a new study. Is that
13 not correct? Or you just want an analysis of the
14 current data?

15 DR. KATZ: That's my question. I'm not
16 quite sure what's being moved here.

17 DR. SHIRK: Well, I guess, basically, you
18 could do both, but I mean it's a sort of -- I mean but
19 the question basically is a user variability inherent
20 in the procedure and what things can be done in the
21 labeling or training process to minimize that.

22 DR. BLANCO: All right. So what you're
23 saying -- make sure I say it correctly -- you want a
24 pre-market analysis with analysis of the current
25 existing data plus a new study looking at inter-site

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1 variability; is that correct?

2 Okay. Now before we go into discussion,
3 does anybody want to second that motion?

4 DR. JANIK: I want to rephrase it.

5 DR. BLANCO: Okay. Well, that's okay.
6 We're going to do that in a minute. The motion dies
7 because of lack of a second. Okay? Now you want to
8 rephrase it, 'Dr. Shirk, or you want to let Dr. Janik
9 do a little rephrasing for you?

10 DR. SHIRK: Dr. Janik can do it better.

11 DR. BLANCO: Okay. Dr. Janik, roll with
12 it.

13 DR. JANIK: I think what maybe he's trying
14 to say is we want to have a standardization of the
15 technique, so looking at the inter-site variation to
16 come up with a standardization as far as ultrasound,
17 pulling back from the cornua, tenaculum, questions
18 that have come up, and then validation that corrects
19 the inter-site variability. So follow up of these
20 existing patients with standardization of technique so
21 it can be published as a user manual.

22 DR. LEVY: Following up, you mean
23 reanalysis of the data on existing patients.

24 DR. JANIK: No. Because I think if you
25 reanalyze the data, you're going to come up -- I don't

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1 think you'll be able to answer the question. So
2 you'll have to come up with what your theory is of why
3 --

4 DR. LEVY: But following these patients
5 longer isn't going to give you that information
6 either.

7 DR. JANIK: But it would in that you come
8 up with your theory of why. And then if you retest
9 and it removes the variability, you have answered it.

10 DR. LEVY: No, no. I think we either have
11 to take a look at the data that we have, analyze it,
12 and say, yes, we can come up with a series of things
13 like the tenaculum that are going to answer the
14 question for us, or we have to say we can't use these
15 data that we have. We've been unable to find
16 something. And then we need to have a second look at
17 it all, perhaps taking the pre-market trial that we've
18 just approved and following those patients perhaps for
19 six months.

20 DR. JANIK: I see what you're saying. If
21 you can answer the question with the old data, then
22 you don't need it.

23 DR. LEVY: Correct.

24 DR. JANIK: But I'm thinking you won't be
25 able to answer it.

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1 DR. LEVY: Well, so -- okay.

2 DR. BLANCO: And the point I was trying to
3 get at with Dr. Shirk is that's what -- you know,
4 there's a big difference between going back and
5 analyzing data or even looking during the pre-market
6 --

7 DR. LEVY: Right.

8 DR. BLANCO: -- study of the malfunction
9 and trying to see the failure, add that to it, which
10 should be relatively easy to do, and seeing whether
11 you see something, as opposed to a whole new study
12 which may take another two years or more to put
13 together. So that's why I want to be very specific
14 about what it is that we're suggesting needs to be
15 done. Okay? Dr. O'Sullivan?

16 DR. O'SULLIVAN: Jorge, didn't they
17 already say that they went back and looked at it, and
18 they couldn't see anything because the numbers were so
19 small that there was nothing that they could come up
20 with?

21 DR. BLANCO: They have mentioned that, I
22 believe. Okay. Can you try to restate your motion?

23 DR. JANIK: Here, you want to try it
24 again?

25 DR. BLANCO: Well, let me clarify it for

1 you. Let me try to do that, because there are two
2 issues. You want some documentation of
3 standardization of technique, and I think that's
4 great, and that can come up separate. So let me
5 narrow the issue down to I think what the point is.
6 Do you want to make a motion to require a new study,
7 pre- or post-market, however you think it should be,
8 that addresses the issue of inter-site variability?
9 Are you concerned enough about that inter-site
10 variability that you need to have new data in order to
11 be able to approve the device?

12 DR. JANIK: I'm concerned that there's too
13 much variability in the technique in the manual as it
14 is. If they can go back and rework the existing data
15 to document standardization of the technique, that
16 would be fine.

17 DR. BLANCO: Okay. What about a new
18 study, because you brought it up?

19 DR. JANIK: If it can't be answered, then
20 follow up with the existing patients, yes.

21 DR. LEVY: Following up with the existing
22 patients isn't going to solve the issue, because you
23 already have the discrepancies. If you want to look
24 at --

25 DR. JANIK: Of these patients.

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1 DR. LEVY: New ones?

2 DR. JANIK: New ones.

3 DR. LEVY: Then you're going to need
4 numbers that are big enough. I really think that
5 there are two issues here. The Company has
6 demonstrated to us statistically effectiveness. There
7 have been -- our concern is the fact that there seemed
8 to be some sites that were significantly less
9 effective than other sites, and we're all struggling
10 with that issue.

11 May I suggest that perhaps a better way to
12 deal with that is in a post-market analysis of a
13 certain number of patients, once it's in general use,
14 to assure FDA and us that indeed in general use post-
15 market -- not pre-market, because pre-market they've
16 already done what they needed to do -- but in a post-
17 market analysis that in general use, once the
18 training's been uniform and standardized, that we
19 indeed get results that are comparable to the pivotal
20 study.

21 DR. DIAMOND: It sounds like at least
22 three people are asking for some sort of post-market
23 analysis of these patients for Barbara's amendment,
24 which are going to be done in a more standardized
25 fashion, correcting for the tenaculum, pulling back

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1 from the cornua, and all the other things that we've
2 learned, which is the amendment I was trying to
3 propose and it got voted down.

4 (Laughter.)

5 It sounds like I might have finally three
6 converts.

7 DR. BLANCO: You want consistency there,
a Dr. Diamond?

9 DR. LEVY: Wait a minute. Michael, I
10 don't think we need three-year data on that.

11 DR. JANIK: That's the problem with three-
12 year data.

13 DR. LEVY: I'm very happy with six months.

14 DR. JANIK: I'm happy with six months a
15 year too. I'm fine with that. It's the three year
16 part of it.

17 DR. DIAMOND: Make it a year.

18 DR. BLANCO: All right. Make that motion.

19 DR. JANIK: Okay. It's two motions. One
20 is standardization of technique and modification of
21 the manual based on analysis of the inter-site
22 variability. The other motion is post-market analysis
23 of this new study to document that the modification of
24 technique actually is effective.

25 DR. BLANCO: Okay. Let's take the first

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1 one, the standardization of technique. First of all,
2 do I have a second for that?

3 DR. LEVY: Second.

4 DR. BLANCO: All right. Any discussion?
5 All right.

6 The motion on the floor, as a condition of
7 approval, is that there be standardization and
8 documentation of that standardization in the physician
9 manual and training of the technique required.

10 All those in favor raise your hand,
11 please. Okay.

12 All those opposed? Zero. Okay. Oh,
13 sorry. I thought you were a voting member, sorry.

14 All right. That motion passes.

15 Now, the second motion, and do I have a
16 second for that. It's to have a post-market analysis
17 study, and the recommendation was to do the evaluation
18 of device malfunction patients and follow them out for
19 either a six or a one-year period, and we need to --

20 DR. LEVY: Let's make it six.

21 DR. BLANCO: Make it six.

22 DR. JANIK: Months.

23 DR. BLANCO: Six months. Yes, not years.
24 Sorry, sorry. Six months period to try to address the
25 issue of inter-site variability. Have I restated that

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1 correctly?

2 DR. JANIK: That's good.

3 DR. KATZ: I have a question.

4 DR. BLANCO: Certainly. Go right ahead.

5 DR. KATZ: Okay. Michael, here is my
6 question: Is this group sufficient to get us that
7 information? In other words, if we're looking at
8 variability between sites and we have a -- it seems to
9 me we have a short-term technological goal that I
10 think can be dismissed very quickly. And maybe the
11 most -- and I think that that's a pre-market goal,
12 right?

13 DR. DIAMOND: Correct.

14 DR. KATZ: Right? Now the sample size to
15 achieve this pre-market goal may not be sufficient to
16 statistically answer the question of inter-site
17 variability.

18 DR. LEVY: I agree, and that's why I
19 didn't include that it should be the same group.

20 DR. JANIK: It doesn't have to be the same
21 group.

22 DR. BLANCO: Okay. So --

23 DR. LEVY: It's just a post-market
24 analysis.

25 DR. BLANCO: Okay. So both people that --

1 the person who put the motion in and the seconder
2 changed that. So now it's not tied to the other
3 study. so we're asking for some post-market evidence
4 of inter-study variability.

5 DR. LEVY: It's really of effectiveness
6 and general usage is what we're really looking at.

7 DR. KATZ: Yes. And how are we going to
8 define that? In other words, it is post-market, but
9 it means that there needs to be a rigorous way that
10 data are collected to give us this information that
11 are balanced enough that we can ferret out the
12 variability, right?

13 DR. LEVY: That's not our issue.

14 DR. BLANCO: Yes. I think that probably
15 we can leave that up to the Company and FDA to work
16 out.

17 DR. KATZ : Okay. That's fine, that's
18 fine. It we can pass that on to FDA, that's fine.

19 DR. BLANCO: Okay.

20 DR. KATZ: Fine with me.

21 DR. NEUMAN: Mr. Chairman, are we going to
22 require that the same sites be used as in the pre-
23 market study?

24 DR. LEVY: No.

25 DR. JANIK: No. We don't want them to be.

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1 DR. BLANCO: No. I think that's up to
2 them.

3 DR. JANIK: It's general usage.

4 DR. BLANCO: I think we'll leave it as
5 general as the motion currently is. I think FDA gets
6 the point of what we're saying if it passes. Cindy,
7 you had a comment.

8 MS. DOMECUS: I appreciate the issue we're
9 trying to address here, but I'm a little bit concerned
10 that the numbers -- and I think this is what you were
11 saying as well -- that the numbers to really get at
12 our issue and prove our issue are going to be
13 astronomical. And also if you look at the rollerball
14 group, which is the gold standard, the failure rate at
15 six months ranged from zero to 80 percent. And at 12
16 months, the failure rate ranged from zero to 75
17 percent. So I think there's going to be with anything
18 that's in the hands of a physician isn't just a --
19 there's technique involved. There's going to be some
20 variability. I don't know if we can ever eliminate
21 it, and to try to study it and all the potential
22 factors that go into the variability, I just think
23 it's going to be very difficult to prove.

24 DR. D'AGOSTINO: I think when we
25 originally started saying can you go back and

1 reanalyze the data, I'm sure the FDA is going to do
2 that. We don't have to really tell them to do that or
3 suggest it. The next study that you're talking about,
4 it's much harder than the study that the sponsor
5 already put forth in terms of trying to sort that out.

6 But I think the message is clear that
7 we're very uncomfortable with the variability and so
8 forth, and we're saying that we're not really -- the
9 way I'm interpreting it, we're not willing to let it
10 end, that we can nod to it. We're asking that another
11 study be put together and sort of leaving it quite
12 loose, I think, and quite appropriately on how that
13 actually gets implemented.

14 DR. BLANCO: Okay?

15 MS. DOMECUS: Maybe the goal is just to
16 reduce the variability based on recommendations that
17 come out of analysis of existing data.

18 DR. JANIK: What we want to know is the
19 technique as standardized in the manual is really
20 going to be able to be applied to all people. Are all
21 the elements in there?

22 DR. BLANCO: Any other comments? Okay.
23 Then this condition is up for a vote. Try to
24 summarize it in general. There would be a post-market
25 analysis of the standardized technique with a revised

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1 device to address the inter-site variability with as
2 short as a six-month follow up.

3 All those in favor raise your hand. Eight
4 in favor.

5 All those opposed? And one abstention.

6 Okay. Further conditions of approval.

7 Dr. Diamond?

8 DR. DIAMOND: That the indication
9 specifically state it is for the reduction of
10 bleeding.

11 DR. LEVY: Second.

12 DR. BLANCO: Any comment? All those in
13 favor?

14 All those opposed?

15 Passes. Dr. Levy?

16 DR. LEVY: Since all the patients were
17 pre-treated, I think we have to have in the labeling
18 the statement or the label for pre-treated uteri,
19 because I don't think we have any data on no
20 treatment.

21 DR. BLANCO: Unless you think that's more
22 important than all the others, can we make it more
23 general so we don't sit here and nit-pick this to
24 death? Anyway, can we just say the labeling, both
25 patient and physician --

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1 DR. LEVY: Absolutely.

2 DR. BLANCO: -- have a lot of work to do.

3 DR. LEVY: Yes.

4 DR. BLANCO: And that --

5 DR. LEVY: I love it.

6 DR. BLANCO: -- we have made throughout
7 our discussion lots of comments that would be good
8 suggestions?

9 DR. LEVY: Yes.

10 DR. BLANCO: Would everybody -- would the
11 Panel be agreeable to that, rather than go through
12 every single one?

13 DR. LEVY: I'll second your --

14 DR. BLANCO: No, I'm just --

15 DR. LEVY: No, I like it.

16 DR. BLANCO: Okay. Great. I don't think
17 I can make motions either. I don't vote. So, anyway,
18 does everybody understand the motion in front?

19 All those in favor for labeling
20 considerably revised?

21 All those opposed.

22 The motion passes. Any other items? Do
23 we want to make any specific statement or make issues
24 about the safety of the ten-minute freeze? We wanted
25 to leave it variable, wanted the machine to do that.

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1 We mentioned something about looking at some more data
2 from a few extirpated organs to ensure that if you
3 froze the organ for ten minutes, you still got the
4 same results as they have already provided at six
5 minutes. Anyone have any interest in pursuing that?

6 DR. O'SULLIVAN: I thought --

7 DR. BLANCO: I'm looking for a motion from
8 you guys.

9 DR. O'SULLIVAN: But I thought that they
10 said that they were going to label it as four-minute,
11 six-minute freeze. They just said that.

12 DR. BLANCO: Right. No, but the issue
13 that was brought up -- and that's true, and we want
14 the variability, and everybody agreed to that. What
15 we discussed, and just was as a safety issue for the
16 machine that it would shut itself off after a
17 continuous ten-minute freeze is what it does now. And
18 the issue was that is there some evidence that that's
19 safe, that ten minutes is safe to do? And if we don't
20 want it, we don't want it.

21 DR. JANIK: I don't think we need it,
22 because you can keep freezing it five times if you
23 want.

24 DR. BLANCO: Okay. Then it's gone.

25 DR. LEVY: I think the real issue is

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1 consistency in usage and getting those training
2 guidelines the way we need to have them. Clean that
3 up a lot, and I think it will be fine.

4 DR. BLANCO: Yes. I just wanted to bring
5 up the points that I had written down to bring back
6 for the documentation.

7 All right. Any other issues on any other
8 condition that the Panel would like to take a look at?
9 Okay. Is there anything -- we spoke also about
10 training. Any physician training? The issue of
11 ultrasound? I think we kind of thought that maybe
12 that was lumped under labeling.

13 DR. LEVY: Well, it's in the
14 standardization of the training guidelines. It's
15 under that, standardization and in labeling. It's in
16 both places.

17 DR. BLANCO: So everybody's comfortable
18 with this. Anything else? All right. Hearing no
19 other additions to conditions of approval, do I have
20 a motion to accept the product -- I forgot the exact
21 terminology; it's here somewhere.

22 DR. LEVY: With conditions.

23 DR. BLANCO: To approve the product with
24 the conditions listed?

25 DR. JANIK: So moved.

1 DR. LEVY: So moved.

2 DR. BLANCO: Moved and second? Any
3 discussion?

4 All those in favor? Okay.

5 All those opposed? All right.

6 The motion passes, and the device is
7 approved with those conditions. And now we go through
8 the fun thing of everyone explaining why they voted
9 the way they did. Dr. Levy, why don't you go first?

10 DR. LEVY: I think the Company proved
11 safety and effectiveness with the caveats that we had
12 some concerns about their consistency in the way the
13 device was used across sites. And I think that these
14 conditions will relieve my mind and resolve my issues.
15 I think all of us are concerned about the
16 effectiveness of this device in general use. And
17 although I understand that its burdensome to do a
18 post-market study, I think the only way we'll know for
19 sure that we don't get 25 percent overall is to
20 require that post-market study.

21 DR. BLANCO: Thank you, Dr. Levy. Dr.
22 Sharts-Hopko?

23 DR. SHARTS-HOPKO: I would only add -- I
24 agree with what Barbara had to say. I would only add
25 that I'm very concerned about how the product is

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1 presented to women. And so I believe that our
2 concerns about labeling will take care of that issue.

3 DR. BLANCO: Thank you. Dr. Diamond?

4 DR. DIAMOND: I think the data that was
5 presented showed the device used as it was in this
6 trial was safe, and although there was some variation
7 efficacy overall, it was within 20 percent of the
a control group, meeting the prescribed criteria.

9 DR. BLANCO: Okay. Before Dr. Neuman,
10 we'll do ladies first. Dr. Janik?

11 DR. JANIK: I voted this way because of
12 some concerns of use in actual clinical practice and
13 variability in ability of the standard gynecologist
14 versus the study site people. And I think the
15 standardization of protocol will help ensure that it's
16 both safe and effective.

17 DR. BLANCO: Thank you. Now Dr. Neuman?

18 DR. NEUMAN: I believe that the Company
19 followed the guidelines that this Committee had
20 prepared in an earlier meeting, and that although our
21 discussions today have brought up several issues that
22 need to be considered, I believe that these will be
23 adequately addressed by both the sponsor and the FDA.

24 DR. BLANCO: Thank you. Dr. Shirk?

25 DR. SHIRK: Well, I think I voted this way

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1 because I'm still uncomfortable with variability and
2 data and the final outcome as to how effective the
3 procedure really is. Obviously, I think it
4 demonstrated that in certain hands the procedure is
5 very effective, but in general hands how effective it
-6 really is is still to be determined.

7 DR. BLANCO: Thank you. Dr. O'Sullivan?

8 DR. O'SULLIVAN: You just said what I was
9 going to say. I voted for this because I really
10 believe that the Company did do exactly what they were
11 required to do to show that indeed it was of equal or
12 equivalence to the rollerball technique. There were
13 concerns regarding the differences in inter-site
14 variations, and I think that putting the caveats on
1 5 the approval are only an attempt to make it a better
16 device and more safe for women.

17 DR. BLANCO: Thank you. Dr. D'Agostino?

18 DR. D'AGOSTINO: I mean I think the
19 variability we saw actually is not unusual in clinical
20 settings. The trouble was the explanation, the
21 understanding why and so forth. And I think that some
22 of the recommendations will in fact try to grapple
23 with that. Is it a learning phenomenon that doesn't
24 look like the data really says that, and the data they
25 have right now is probably not sufficient. But with

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1 some standardization and some more activities,
2 hopefully they'll get a better handle at that. so I
3 think it was very sensible the way we voted.

4 DR. BLANCO: Thank you. Dr. Katz?

5 DR. KATZ: I don't have much to add. I
6 think that the Company did follow the guidelines of
7 FDA, and I think that we have covered the bases in
8 dealing with our concerns about the standardized use
9 of the device and our understanding of how to make it
10 the best possible product for women.

11 DR. BLANCO: And although you did not
12 vote, both Ms. Domecus and Ms. Young, I would like to
13 hear your comments. In no particular order, I'm
14 sorry. No comments? Okay.

15 MR. YOUNG : I'd like to speak to one
16 issue, which we didn't really discuss, and that was
17 informed consent. I'm concerned about always the
18 wording of the informed consent for the patient and
19 the information, of course, particularly with respect
20 to risks. In the documentation you provided, you gave
21 us a copy of the informed consent form for women who
22 were taking part in the study. You gave us the
23 informed consent form for the addendum on the
24 hysteroscopy procedure, but you didn't give us the
25 informed consent form, maybe because it hasn't been

1 developed yet, that will be used for women who are
2 given the treatment of your product, for the device.

3 so I just would like to state that that
4 informed consent form should be based on all of the
5 information that has been discussed relative to the
6 patient today. And I don't know whether there has
7 been -- whether you have that form, but it's important
8 that it be developed, I don't know, in conjunction
9 with the FDA or according to specific guidelines. But
10 I regret that we didn't have that in front of us to
11 look at so that we could see exactly what information
12 was provided in it.

13 DR. BLANCO: Thank you. Anything further?

14 DR. DIAMOND: In response to Diony's
15 comments, I would not have expected, and so I just
16 want to make sure, at least from my point of view, the
17 FDA is not going to produce a consent form for this
18 surgical procedure that is different than standard
19 ways that we consent patients for surgery for anything
20 that we're doing in our procedure rooms or our
21 operating rooms. I would not have thought that this
22 is something that would be done for this procedure.

23 DR. BLANCO: All right. I think a lot of
24 shaking heads yes, so I think we agree. Anyone from
25 the FDA would like to say anything in final statement?

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1 If not --

2 DR. SCHULTZ: Well, two things. One, with
3 regards to the issue of informed consent, once a
4 device goes to market there is no longer a requirement
5 for informed consent. However, I think the points you
6 make are well taken, and I think that what we will do
7 and what you've already discussed is the need to
8 develop a patient information brochure that covers all
9 of the points that the Company needs to address in
10 terms of trying to maximize the patient's
11 understanding of this product. So I think that we
12 will attempt to do that in the context of the patient
13 labeling.

14 The only other comment I have to make is,
15 if you could, we need to do a final vote count. In
16 addition to the comments, we just need to say how many
17 people voted for --

18 DR. BLANCO: Oh, I'm sorry, it was nine to
19 zero.

20 DR. SCHULTZ: Thank you.

21 DR. BLANCO: That was easy. I did count,
22 I just didn't make the statement.

23 DR. SCHULTZ: I understand.

24 DR. BLANCO: So I'll put it on the record.

25 All right.

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I would like to thank the sponsors for their work. Having done research myself, I know that it's hard and expensive. And appreciate their presentation. I want to thank the FDA and all of their reviewers for their presentations and all of their work and doing this. And as always, I'd like to thank the Panel members for all of their excellent comments and participation and help and hope that you enjoyed it as much as I do.

And having said that, the meeting is adjourned.

(Whereupon, at 3:58 p.m., the FDA Meeting was concluded.)

CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: Obstetrics and Gynecology Devices Panel

Before: **DHHS/PHS/FDA/CDRH**

Date: January 29, 2001

Place: Gaithersburg, MD

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



A handwritten signature in black ink, appearing to read "R. W. Jeffrey", is written over a solid horizontal line.