

1 counseled on this procedure need to sign some sort of  
2 a consent that indicates that they have received full  
3 counseling on what their options are, and that they  
4 understand that if this fails, then their other option  
5 is a stoma.

6 And they need to fully understand what  
7 that means when they are making that choice. I think  
8 that the antibiotic prophylactics regimen that was  
9 outlined as the protocol that went on and that so many  
10 infections were discovered.

11 And your infectious disease consultant  
12 recommended a certain regimen, and I think that needs  
13 to be included in the package labeling, and any other  
14 technique issues that have been discovered along the  
15 way that would make implantation of the device have a  
16 lower complication rate need to be included in there.

17 I think there should be a component in  
18 there about women who subsequently become pregnant  
19 would be advised to consider C-section deliveries so  
20 as not to traumatize the perineum any further.

21 I think those are my major concerns, with  
22 particular emphasis on properly giving us the

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1 information on failures in the labeling device, or in  
2 the labeling insert packages.

3 CHAIRMAN KALLOO: Dr. Steinbach.

4 DR. STEINBACH: There is going to be  
5 difficulty warning to the package that right now our  
6 best guess is that it is a 50-50 chance of success.  
7 This may change as doctors get better.

8 And as a minor point, there is a  
9 complication that is in the literature, but not in the  
10 patient labeling that several patients were unable to  
11 pass gas at normal times, and in order to operate the  
12 device, they had to go to a private area so they would  
13 not embarrass themselves. And there should be a  
14 reference to that on the label.

15 DR. KOLTUN: I just reviewed this labeling  
16 now, as I didn't see it before. Is this the labeling  
17 that the individuals are getting now as educational  
18 backup? It seems to me that it could be updated if  
19 you have additional data or if you have additional  
20 information.

21 I think that it is an upbeat form, and I  
22 can understand why it is placed in that kind of a

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1 context. I think there has to be a fair  
2 representation of what would happened, or what would  
3 take place if something deleterious occurred.

4 And I know that it is largely the doctor's  
5 responsibility to advise a patient in that regard, but  
6 we also know that what a patient hears in the doctor's  
7 office is about 92 percent of what is the document,  
8 and not adequately appreciated.

9 But we want to have something to hold in  
10 the hand that proves carefully in the home that this  
11 is what they will have as a memory or an expectation,  
12 and I think it has to be a little more objective in  
13 regards to the success rate, and it can be updated  
14 with the data that we have.

15 CHAIRMAN KALLOO: Ms. Newman.

16 MS. NEWMAN: I want to go through this.  
17 I think you need several changes. The beginning  
18 paragraph sounds like this is my option as compared to  
19 diet changes, pads, diapers, medications.

20 What I am hearing is that all these other  
21 things may have been tried, and then these are the  
22 final options. So you need to state -- because maybe

1 the patient will go to an individual center, or  
2 whatever, that they really have not offered them.

3 So once you put this out on the market, a  
4 lot of people are going to use it. So you need to  
5 state that this is kind of one of the last things.  
6 And on the next page, will it be replaced, and most  
7 patients do not need it.

8 What is most? Most could be 80 percent  
9 and you need to put the data in there on what is most.  
10 Risk and complications, I think you need to be up  
11 front. What is the complications and what is the risk  
12 to me.

13 You have on the next page as far as -- you  
14 know, the issues as far as erosion and infection, and  
15 that is some of it, but what are the other  
16 complications that may occur.

17 What kind of stool should they expect  
18 after this? I think that you should talk about that.  
19 You don't really talk a lot about stool. I would talk  
20 all about that, and what kind of stool are we talking  
21 about.

22 Now I have liquid, and I have this type of

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1 incontinence, and what should they expect. When you  
2 go down from manual dexterity, give them an example.  
3 Some manual dexterity. Well, I can read a book.

4           You really need to define manual dexterity  
5 so that they can utilize it, okay? You need to state  
6 that. It may be different for men and women. Some  
7 older women don't touch their perineum, and do they  
8 have a problem with that.

9           You state about migration. Do you expect  
10 them to look at their anal opening with a mirror? Is  
11 that what you are saying, or is someone going to look  
12 at it for them to see if something is happening. You  
13 need to state that. Should they look at it every day,  
14 and how do they care for them over time?

15           And then next page, but let me go on. I  
16 think you need more anatomical explanation on your  
17 pictures, especially since you seem to be going into  
18 the middle age population. They need to see it.

19           And under what to expect after surgical  
20 procedure, you need to state how long they are going  
21 to be in the hospital, and what number of days is  
22 normal. You know, what does it mean if I am going to

1 be off from work and what do I have to do about that.

2 And a couple of pages later, on page 8,  
3 you take extra care when walking on ice because of  
4 falling. Does that mean that if someone falls that  
5 something can happen? Falling is a big issue as you  
6 age. Is that a concern? What are the concerns?  
7 Riding a bike; does that mean that if I do a bike on  
8 my exercise equipment.

9 You know, you need to get into that a  
10 little bit more. You don't ever mention sexual  
11 intercourse. You mention anal intercourse, but I know  
12 what the urinary lists, and the pump being in the  
13 labia, that is an issue with women with sexual  
14 intercourse.

15 What happens with that, and should they do  
16 a different position. I am sure that you have data on  
17 that. And then with men, and those are the kinds of  
18 things that I think you need to explore more with the  
19 patient.

20 CHAIRMAN KALLOO: Mr. Banik.

21 MR. BANIK: There is one particular item  
22 that I have some concern about, and to summarize it,

1 it is will my prosthesis have to be replaced. In the  
2 labeling, it says basically that all mechanical  
3 devices fail with wear.

4 But it says that clinical experience has  
5 shown that most patients with an AMS implantable  
6 prostheses do not need to have their prosthesis  
7 removed or replaced for at least 5 years after the  
8 original implant.

9 I think that is probably a true statement  
10 relative if we are talking about the total, including  
11 the urinary device. I don't know that for sure, but  
12 all we have seen is data for one year.

13 And therefore I think that this whole  
14 section in this paragraph should be somewhat  
15 rewritten, and including a little bit of a discussion  
16 about the risk of having to go in and putting in  
17 another prosthesis in case of failure, because we saw  
18 high incidents of explants here, and also changes in  
19 the device.

20 CHAIRMAN KALLOO: Dr. Epstein.

21 DR. EPSTEIN: Yes, I agree with what has  
22 been said, and I also think that the labeling needs to

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1 be updated to reflect the data that is in the most  
2 recent study, and just updating the tables primarily  
3 to reflect the erosion and infection rate, and to be  
4 more specific about that.

5 DR. KOLTUN: Can I interrupt again? I  
6 didn't appreciate that before though. When you start  
7 on that page one, it is saying that Acticon  
8 Neosphincter, and then you work down the page and  
9 suddenly the Acticon Neosphincter becomes the AMS  
10 implantable prosthesis.

11 And doesn't that sort of imply to the  
12 reader that you are talking about the same thing, but  
13 in fact your AMS implantable prosthesis, that you are  
14 now referring to your urinary, as well as anal,  
15 sphincters, anal devices? That is a little  
16 misleading. That should be consistent throughout.  
17 You should be talking about one thing.

18 DR. GELLENS: I agree with what has been  
19 said so far. I think it should be clearly stated in  
20 the professional and in the patient labeling what the  
21 intention to treat analysis showed, that it is a 56  
22 percent, or 51 percent chance, of effective results

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1 from this procedure.

2 And also the erosion and the infection  
3 rates should be included in the professional and the  
4 patient labeling. As a physician who presented here  
5 said, she tells her patients right up front that there  
6 is a 50 percent chance that you are going to need a  
7 reoperation, and I think that should be written  
8 somewhere, too.

9 DR. MCCLANE: Yes, again, I think a lot of  
10 people are saying that you really have to tell a  
11 patient that half will be successful in 12 months, and  
12 half will need a revision, and just include all that  
13 data. Actually, that's the only thing I have to say.

14 CHAIRMAN KALLOO: Dr. Talamini, if you  
15 would summarize.

16 DR. TALAMINI: I would like to make four  
17 comments of my own before summarizing. I had four  
18 changes that I thought would be important in the  
19 labeling, and most of them have already been  
20 reflected.

21 But on page one, where it says, is an  
22 implantable fluid-filled solid silicon to treat severe

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1 fecal incontinence. I think that severe fecal  
2 incontinence should be defined according to the  
3 parameters of the study, which in this case was X-  
4 number of episodes of incontinence per week or  
5 whatever it is.

6 And then I think perhaps adding as an  
7 alternative to a stoma in that sentence, or in another  
8 sentence, would frame this more clearly. There are  
9 two other things that I think would be important,  
10 which are that as everybody has said, include the  
11 adverse events.

12 But even more importantly, I would propose  
13 potentially extending this study, since we only have  
14 12 months of data, and that is not very much for an  
15 implantable device, and continuing to update the  
16 labeling on some interval, or some defined period of  
17 time, so that the labeling keeps up with what we know  
18 about this device as we learn more about it.

19 Having said that, I think, Mr. Chairman,  
20 that the panel's opinion is that the labeling should  
21 really be, if approved, the primary vehicle for this  
22 device for clearly outlining the indications, and

1 outlining the appropriate use protocols for the  
2 surgeons putting this in, and framing who is qualified  
3 to put it in, and informing the patient regarding the  
4 realistic risks of infection, and having to have the  
5 implant revised or removed.

6 DR. SMITH: And I would like to just  
7 reiterate one point, and that is that it is important  
8 that this pamphlet is not given to the patient in the  
9 holding area just before he or she goes into the  
10 operating room.

11 I would like to see that the patient  
12 receives this several days beforehand, and stipulates  
13 that I have received and read this document at least  
14 72 hours prior to the procedure. So that way it gives  
15 them time to where they are actually reading it  
16 instead of another pamphlet that is simply being  
17 discarded.

18 DR. BROGDON: I would just like to comment  
19 on the recommendation that a couple of panel members  
20 made about an additional informed consent document, or  
21 some certification that is signed by the patient.

22 This is something that is very difficult

1 for FDA to require, because it is virtually  
2 unenforceable on our part. So if the panel ends up  
3 recommending changes to the patient labeling, I think  
4 that is easy for us to deal with. But some additional  
5 signed statement would be difficult for the FDA to  
6 require and then enforce.

7 CHAIRMAN KALLOO: All right. I think we  
8 will move on to the next question.

9 DR. KOLTUN: And this thing about what you  
10 said there. What is done with implantable heart  
11 devices? Aren't those followed perpetually after  
12 implant? Patients get cards, and those with devices  
13 are registered with the company, and if there are any  
14 defects subsequently, and batteries running out too  
15 soon, and things like that?

16 DR. BROGDON: Yes, there are tracking  
17 systems in place with many implantable devices. There  
18 may be implant cards given to patients, and implant  
19 cards returned to sponsors so that they can track the  
20 patients and so forth.

21 That is different from what I was  
22 addressing regarding a signed statement from a

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1 patient.

2 DR. KOLTUN: When those cards and implant  
3 device registration forms are created and maintained,  
4 have those been mandated by the FDA?

5 DR. WOODS: In a few cases, I believe they  
6 have been mandated by the agency. Generally those  
7 data though are not held by the agency, but are held  
8 by the companies themselves.

9 DR. KOLTUN: But then if there is  
10 identified a problem, and like I said if a battery  
11 runs out too soon, and all of a sudden you find that  
12 out that there is a lot of them, then the FDA inspects  
13 the company's records and says there is a pattern  
14 there. Is the FDA ever an overseer of that, the  
15 registration data that the company maintains?

16 DR. BROGDON: I believe that the agency  
17 can require in some cases that the sponsors notify  
18 specific patients, but --

19 DR. KOLTUN: Like a recall?

20 DR. BROGDON: Yes. We can require  
21 recalls, and it certainly is easier if the  
22 manufacturers have data on specific patients.

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1 CHAIRMAN KALLOO: Okay. Moving on to  
2 question Number 8. Please discuss whether the  
3 professional labeling as submitted is adequate to  
4 adequately inform the physician of the risks and  
5 benefits of using the device, and whether there are  
6 any additional contra-communications, warnings,  
7 precautions, or instructions for use that you believe  
8 would be appropriate.

9 So we are looking at the professional  
10 labeling to the physician. Dr. Smith.

11 DR. SMITH: I have not read it all, and I  
12 would like to look at it first.

13 CHAIRMAN KALLOO: Okay. Dr. Woods.

14 DR. WOODS: I apologize, but I think I  
15 addressed most of this in the last question, which  
16 actually was more with respect to patient labeling.  
17 So I don't really have much to add, except to say that  
18 if the package insert, or the professional labeling,  
19 is what is included here, I really don't see any data  
20 in here.

21 And perhaps I am not looking at the right  
22 thing, but I would encourage to include the data that

1 I already mentioned that I thought would be important.

2 CHAIRMAN KALLOO: Dr. Steinbach.

3 DR. STEINBACH: I think the professional  
4 labeling is adequate. I think that the professionals  
5 are going to have to follow the literature and see  
6 whether this 50-50 number changes.

7 CHAIRMAN KALLOO: Dr. Koltun.

8 DR. KOLTUN: I more or less agree with  
9 that. I think there is data available now that could  
10 be added. You know, a couple of tables summarizing  
11 the success rate and the demographics of the  
12 complication rates is appropriate, and possibly  
13 consideration in regards to individuals who are at  
14 higher risk, because there has been some reference  
15 made to the issue of radiation therapy, and the  
16 perineum immuno-suppressant patients and such, should  
17 be mentioned.

18 CHAIRMAN KALLOO: Ms. Newman.

19 MS. NEWMAN: I think that this is one  
20 piece to me that is part of training, and sometimes  
21 people don't always read the little inserts because  
22 the printing is so tiny.

1                   But I presume, along with what Dr. Epstein  
2 was saying, that this is part of a big training kind  
3 of an issue that will go forward. It should include  
4 the data.

5                   And I would also highly recommend that you  
6 include your references that have been done all over  
7 the world, because I think that is very helpful to the  
8 clinician and to the person who is doing this. And  
9 then also do some other types of presentations other  
10 than just print.

11                   CHAIRMAN KALLOO: Mr. Banik.

12                   MR. BANIK: I felt the physician related  
13 labeling was good and anticipated a lot of things that  
14 people don't anticipate, and in particular there was  
15 information on MRIs which I thought was good.

16                   I agree with the other comments that were  
17 made that relative to adding some of the performance  
18 of the device relative to the clinical performance  
19 would be helpful to add into that.

20                   CHAIRMAN KALLOO: Dr. Epstein.

21                   DR. EPSTEIN: Yes, I agree with that, and  
22 I also think there needs to be a training

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1 certification.

2 DR. GELLENS: I think the labeling is  
3 relatively adequate, except that I think the  
4 contraindications section should be expanded, and I  
5 just think that the current data that we have just  
6 seen should be included.

7 DR. MCCLANE: Yes, a couple of things. On  
8 page 6, again they mention the adverse events are  
9 based on 50 and we are up to 115, and that is  
10 obviously very old data.

11 And on pages 8 and 9, it is a little bit  
12 misleading. On the bottom, they talk about according  
13 to the PIF, 152 patients received the Acticon  
14 Neosphincter, and then on the next page, it only says  
15 9.8 percent of the implants were revised, removed, or  
16 replaced.

17 I mean, that is not even close to what we  
18 have been talking about today, and that might be a  
19 little misleading.

20 DR. KOLTUN: What section are you under?

21 DR. MCCLANE: The professional labeling  
22 section. Oh, the pink is different than the black

1 folders. I guess it has been revised from what we  
2 got.

3 And then they talk about the  
4 contraindications. The device is contraindicated in  
5 patients with fecal incontinence complicated by an  
6 irreversibly obstructive approximal segment of bowel.  
7 I am not sure what kind of patients they are referring  
8 to here.

9 Patients that come in with bowel  
10 obstructions I wouldn't think would be getting these  
11 devices. I am not sure if you need to include that.

12 DR. KOLTUN: Excuse me, but now I am  
13 really confused, because in the pink book there is  
14 something that is identified as labeling, the  
15 operating manual.

16 DR. MCCLANE: And then just one other  
17 comment. In warnings, they said that patients with  
18 urinary tract GI infections, diabetes, spinal cord  
19 injuries, open sores, have a increased risk of  
20 infection. But again the data says that there really  
21 aren't, and that there is not a significant risk of  
22 increased infection to some to these patients.

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1                   So there is an increase, but it is not  
2 significant based on the P value on some of these  
3 things that they talk about here. That's all I have  
4 to say.

5                   CHAIRMAN KALLOO: Dr. Talamini, please  
6 summarize.

7                   DR. TALAMINI: Mr. Chairman, it is the  
8 majority opinion of the committee that indeed there  
9 are additional contraindications, warnings,  
10 precautions, and instructions that most members  
11 believe would be appropriate specifically regarding  
12 indications, contraindications, and updated data.

13                   CHAIRMAN KALLOO: Thank you. And for  
14 Question 9 and the final question.

15                   DR. SMITH: Are we allowed to stipulate  
16 that there should be a training program, and that you  
17 should have a training certificate?

18                   CHAIRMAN KALLOO: Yes, and that is what  
19 you are saying.

20                   DR. BROGDON: If there is a training  
21 program that the panel recommends and that the FDA  
22 agrees with, we ask the sponsor to design their

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1 training program. And if they want to have a  
2 certification form that they keep on record, that is  
3 fine with us.

4 CHAIRMAN KALLOO: Question 9. In addition  
5 to the intent to treat analysis, please discuss  
6 whether the results of the valuable analysis should be  
7 included in the professional and patient labeling.

8 DR. TALAMINI: I think we already covered  
9 that and we agreed to that.

10 CHAIRMAN KALLOO: Yes. Well, let's have  
11 you summarize anyway just for the record.

12 DR. TALAMINI: Mr. Chairman, the answer is  
13 yes to Number 9.

14 CHAIRMAN KALLOO: Okay. Before we take a  
15 vote and actually take a break, I think, Dr. Talamini,  
16 that you need to summarize all the comments thus far.

17 DR. TALAMINI: Give me 30 seconds.

18 CHAIRMAN KALLOO: While Dr. Talamini is  
19 getting his thoughts together, does anyone from the  
20 public wish to address the panel, and if so, please  
21 raise your hand, and you may have an opportunity to  
22 speak.

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1 (No audible response.)

2 MS. NEWMAN: Can we take a break before we  
3 do that?

4 CHAIRMAN KALLOO: We could. If the panel  
5 feels strongly about that, how many people would like  
6 to take a break?

7 ( A show of hands.)

8 CHAIRMAN KALLOO: How many people would  
9 not like to take a break?

10 (A show of hands.)

11 CHAIRMAN KALLOO: So we will take a break  
12 for 10 minutes.

13 (Whereupon, at 2:47 p.m., the meeting was  
14 recessed, and was resumed at 3:01 p.m.)

15 CHAIRMAN KALLOO: Okay. Good afternoon.  
16 I would like to reconvene. I would like to start off  
17 this final session by asking the FDA if there were any  
18 comments, or does the FDA have any comments?

19 (No audible response.)

20 CHAIRMAN KALLOO:

21 If not, does the sponsor have any final  
22 comments?

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1 (No audible response.)

2 CHAIRMAN KALLOO: Okay. Before  
3 entertaining a motion recommending an action on this  
4 PMA, Dr. Cooper will remind the panel of our  
5 responsibilities in reviewing today the pre-market  
6 approval application, and of the voting options open  
7 to us. Jeff.

8 DR. COOPER: Okay. Before you vote on a  
9 recommendation, please remember that each PMA has to  
10 stand on its own merits. Your recommendation must be  
11 supported by data in the application, or by publicly  
12 available information.

13 You may not consider information from  
14 other PMAs in reaching a decision on this PMA. Next,  
15 I would like to remind the panel of some definitions.  
16 Safety is defined in the medical device amendments as  
17 reasonable assurance based on valid scientific  
18 evidence, that the probable benefits to health under  
19 conditions of intended use outweigh any probable  
20 risks.

21 Effectiveness is defined as reasonable  
22 assurance that for a significant portion of the

1 population that the use of the device for its intended  
2 uses and conditions of use when labeled will provide  
3 clinically significant results.

4 And valid scientific evidence consists of  
5 well-controlled investigations, partially controlled  
6 studies, studies and objective trials without matched  
7 controls, well-documented case histories conducted by  
8 qualified experts; and reports of significant human  
9 experience with a marketed device.

10 Your recommendation options for the vote  
11 are as follows. Approval. There are no conditions  
12 whatsoever attached.

13 For approvable with conditions. You may  
14 recommend that the PMA be found approvable, subject to  
15 specified conditions, such as resolution of clearly  
16 identified deficiencies which have been cited by you  
17 or by the FDA staff.

18 And prior to voting, all the conditions  
19 are discussed by the panel, and listed by the panel  
20 chair. The third is not approvable. If you recommend  
21 that the application is not approvable, we ask that  
22 you identify the measures that you think are necessary

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1 for the PMA to be placed in an approvable form.

2 The reasons for recommending not  
3 approvable would be safety; the data do not provide  
4 reasonable assurance that the device is safe under the  
5 conditions of use prescribed, recommended, or  
6 suggested in the proposed labeling.

7 For effectiveness, if there is reasonable  
8 assurances that have not been given that the device is  
9 effective under the conditions of use and the  
10 labeling.

11 And labeling, based on a fair evaluation  
12 of all the material facts and your discussions, that  
13 you believe that the proposed labeling to be false or  
14 misleading. Thank you.

15 CHAIRMAN KALLOO: Okay. Thank you. Dr.  
16 Talamini, will you summarize the panel discussion,  
17 please.

18 DR. TALAMINI: Mr. Chairman, the panel has  
19 discussed the questions in some detail, and I think in  
20 summary the majority opinion of the panel is that the  
21 device is effective as just defined, and with an  
22 understanding of the risks that it entails, that it

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1 also is safe within the definition just delineated.

2 So I would say or my summary would be that  
3 the panel does seem to believe in large part that it  
4 is safe and that it is effective.

5 Two major categories of issues appear to  
6 have arisen. One is regarding significant changes in  
7 the labeling, and the second regarding training  
8 programs for surgeons implanting this device.

9 CHAIRMAN KALLOO: I would like to thank  
10 Dr. Talamini for summarizing the questions. The panel  
11 will now prepare to vote. The recommendation of the  
12 panel may be approval; approval with conditions that  
13 are to be met by the applicant; or denial of approval.

14 DR. STEINBACH: Mr. Chairman, I move that  
15 the device be approved with conditions.

16 DR. WOODS: I second that.

17 DR. TALAMINI: I would agree. I was going  
18 to make a motion that it be approved with conditions,  
19 and give two specific conditions. Do we just discuss  
20 conditions, or do we add them to the motion?

21 CHAIRMAN KALLOO: We would need a second.

22 DR. TALAMINI: I second.

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1 CHAIRMAN KALLOO: The condition has been  
2 seconded, and I would like to ask for the  
3 recommendation of the panel, that is, approval, or  
4 approval of this condition that has been approved,  
5 with conditions. Those in favor of the motion please  
6 raise your hands.

7 DR. STEINBACH: We need to discuss it  
8 first.

9 DR. WOODS: What are we voting on?

10 CHAIRMAN KALLOO: We are voting on the  
11 approval of this PMA with conditions.

12 DR. WOODS: When do we discuss the  
13 conditions?

14 CHAIRMAN KALLOO: So you want to discuss  
15 the conditions?

16 DR. TALAMINI: Yes, I would like to add  
17 two conditions or discuss two conditions. One of them  
18 would be a training program to be developed by the  
19 company in conjunction with the FDA, along the lines  
20 that the panel has delineated and discussed.

21 The second would be modifications of the  
22 labeling by the company, again in conjunction with the

1 FDA, and again along the lines of the panel discussion  
2 this afternoon.

3 CHAIRMAN KALLOO: So now we are going  
4 forward on the conditions. The first condition is --

5 DR. KOLTUN: Are we going to vote or  
6 discuss?

7 CHAIRMAN KALLOO: We can discuss first and  
8 then vote. What is the first condition?

9 DR. TALAMINI: The first one was training.

10 CHAIRMAN KALLOO: Training, starting with  
11 Dr. Smith.

12 DR. SMITH: I would agree with that.

13 DR. WOODS: Agreed.

14 DR. STEINBACH: The studies were done with  
15 a proctor apparently for the first case. I would hope  
16 that this would continue as part of the training  
17 program.

18 CHAIRMAN KALLOO: Dr. Koltun.

19 DR. KOLTUN: I would agree. I think the  
20 question is what is going to constitute training, and  
21 I think who would decide that. You are saying or you  
22 are proposing that the FDA, in conjunction with the

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1 company?

2 DR. TALAMINI: My proposal would be that  
3 the FDA develop -- that the company develop that  
4 program in conjunction with the FDA, which is  
5 certainly a pattern that has been followed before, I  
6 believe.

7 DR. KOLTUN: I would only add to that,  
8 which may be the obvious addition, that individuals  
9 such as Dr. Wong and Dr. Congilosi be the people who  
10 would coordinate that.

11 CHAIRMAN KALLOO: Ms. Newman.

12 MS. NEWMAN: Yes, that's interesting,  
13 because with other things that come out, I guess it is  
14 whether the company is the trainer or the  
15 professionals in the field. I agree that it should be  
16 the professionals or the societies in there somewhere  
17 in the certification.

18 CHAIRMAN KALLOO: Mr. Banik, comments?

19 MR. BANIK: No comments.

20 DR. BROGDON: I would like to comment just  
21 briefly on who offers training. That really is up to  
22 the sponsor to decide whether they want to do the

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1 training or to contract it to someone else to do the  
2 training, a society, or private organization, or  
3 whatever.

4 The FDA tends to look at just what is  
5 included in the training program, and not who offers  
6 it, and how much is charged for the training. That is  
7 really up to the sponsor.

8 DR. EPSTEIN: Yes, and I agree with what  
9 has been said, and also would recommend that the  
10 device for under 18 remain in the human device  
11 exemption arena until such time as more data can be  
12 brought forth.

13 DR. TALAMINI: That would be a third  
14 condition.

15 DR. EPSTEIN: Yes.

16 CHAIRMAN KALLOO: Yes. We are talking  
17 specifically about training.

18 DR. EPSTEIN: Okay. Then I agree.

19 CHAIRMAN KALLOO: Okay.

20 DR. GELLENS: I don't think it should be  
21 approved with conditions. So I don't know what  
22 comments I am supposed to make.

1 CHAIRMAN KALLOO: If you don't, then  
2 that's fine.

3 DR. GELLENS: Okay.

4 DR. MCCLANE: I agree with the training  
5 program, and I think the decision has to be how many  
6 do you need to do, and it looks as though in the  
7 packet it was just one.

8 CHAIRMAN KALLOO: Any comments, Dr.  
9 Koltun?

10 DR. KOLTUN: I think most -- well, my  
11 experience in similar things like this is the FDA has  
12 been faithful in helping companies develop an  
13 effective training protocol for things such as this,  
14 which is why I am comfortable with this as a  
15 condition.

16 CHAIRMAN KALLOO: Okay. Those in favor of  
17 the condition of training as outlined by our  
18 discussion please raise their hand.

19 (A show of hands.)

20 CHAIRMAN KALLOO: Those against, please  
21 raise your hand.

22 (A show of hands.)

1 CHAIRMAN KALLOO: Okay. Six in favor, and  
2 one against. The second condition, Dr. Talamini, is?

3 DR. TALAMINI: The second condition that  
4 I proffered was modified labeling, and modified by the  
5 company again in conjunction with the FDA. I am not  
6 sure how fair that is, but there were so many comments  
7 regarding labeling that I think it would be difficult  
8 to delineate all of those conditions.

9 And I would feel more comfortable having  
10 gone through the discussion, leaving that in the  
11 perview of the FDA if that is fair.

12 DR. BROGDON: I think we could handle  
13 that, and if we had questions about the intent of  
14 various panel members, we could certainly contact you  
15 for clarifications.

16 CHAIRMAN KALLOO: And certainly we have  
17 listed multiple modifications, and some of which I  
18 thought were very excellent. So I will just ask for  
19 comments as we go around the panel. Is there any  
20 further discussions on this point, starting with Dr.  
21 Smith?

22 DR. SMITH: None.

1 DR. WOODS: One, and that is we brought up  
2 the issue previously about an informed consent, and we  
3 are told that they could not necessarily mandate that,  
4 but I would suggest then that we include in the  
5 labeling a recommendation that a patient receive some  
6 special informed consent.

7 And I would like to suggest that the  
8 company may even wish to provide users with a template  
9 informed consent that they might give to their  
10 patients, or patient information with consent  
11 information in it regarding the specific device.

12 And not consent for any kind of surgery,  
13 but with respect to the device information. A patient  
14 should know about their options and such.

15 DR. STEINBACH: We had previously voted to  
16 include the tables of success and failure as part of  
17 the label.

18 DR. KOLTUN: I agree with that, including  
19 the success and failure rate of this device, and not  
20 some other device, and not of the European data,  
21 because that is not being considered at today's  
22 meeting.

1           The European data is mentioned in some of  
2 the labeling documents that we have had today, and  
3 that data in no way mirrors what we have read here or  
4 seen here today.

5           My second point is that in regards to the  
6 patient, and even the physician, I think it should be  
7 clearly stated that this device is an alternative to  
8 a stoma. I think that sometimes gets lost as a  
9 surgeon managing this kind of a problem.

10           This device is an alternative to a stoma,  
11 and it is not for someone who leaks air, or who has  
12 difficulty with liquid now and then, and that needs to  
13 be clearly stipulated, because the patient's labeling  
14 here was not I think forceful enough in that regard.

15           I think there is some other issues as well  
16 in regards to potential risk factors that need to be  
17 addressed in the physician's labeling insert. And I  
18 think there that there is a distinct lack of data, and  
19 in some ways I think this goes to another condition,  
20 and I think it would be nice if we could generate  
21 added data in that regard. But those are the points  
22 that I would make with regard to that.

1 MS. NEWMAN: I agree.

2 MR. BANIK: I agree also.

3 CHAIRMAN KALLOO: Dr. Epstein.

4 DR. EPSTEIN: I agree.

5 CHAIRMAN KALLOO: Any comments or other  
6 comments? If not, we will now vote on the condition  
7 that there be significant modifications of the  
8 labeling for both the patient and the physicians.  
9 Those panel members who are in favor of making  
10 modifications to the labeling as we discussed, please  
11 raise your hands.

12 (A show of hands.)

13 CHAIRMAN KALLOO: And those against?

14 (A show of hands.)

15 DR. GELLENS: I am not only against the  
16 modifications, but I am just against it.

17 CHAIRMAN KALLOO: That's fine, and your  
18 disapproval is noted.

19 MS. NEWMAN: Did she say why she is  
20 disapproving it?

21 CHAIRMAN KALLOO: She just did. Any other  
22 conditions that anybody else would like to bring up?

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1 Dr. Epstein.

2 DR. EPSTEIN: We discussed that under age  
3 18. And I would like to know what the vote is on  
4 that.

5 CHAIRMAN KALLOO: So we would like to  
6 discuss the condition of approval with the condition  
7 that the patient should be over the age of 18. So I  
8 ask for discussion of this condition. Dr. Smith.

9 DR. TALAMINI: Actually, if I could just  
10 modify that. I think, Dr. Epstein, that you were  
11 saying that for use under 18 that it would remain a  
12 humanitarian exemption.

13 DR. EPSTEIN: Right.

14 DR. TALAMINI: And so that the disapproval  
15 only would cover over 18; is that a legitimate  
16 distinction to make?

17 DR. BROGDON: Those of us from the FDA who  
18 are in the room right now aren't a hundred percent  
19 sure. It seems logical on the face of it that the HDE  
20 should be able to remain in force for those younger  
21 patients, but we are not a hundred percent certain  
22 because there is not a lot of agency experience with

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1 HDEs.

2 But we are willing to look into it and to  
3 try to make it work if we can.

4 CHAIRMAN KALLOO: I think that we should  
5 discuss that. I mean, that is a point, and over 18  
6 approval, and under 18 for humanitarian.

7 DR. EPSTEIN: If applicable.

8 CHAIRMAN KALLOO: Yes, if applicable. Dr.  
9 Smith.

10 DR. SMITH: I think I would approve that  
11 it is for people under the age of 18, but that doesn't  
12 preclude that it could be put into a younger person if  
13 the surgeon sees it fit to do so. That is their  
14 decision.

15 DR. WOODS: I don't understand the  
16 rationale of not allowing a post-pubescent, relatively  
17 mature, teenager to have this procedure as a  
18 humanitarian device. I think I need more explanation  
19 from Dr. Epstein as to why he feels that way.

20 DR. EPSTEIN: Karen, I think that is what  
21 we are saying, is to allow it as a humanitarian  
22 device.

1 DR. WOODS: Well, I don't understand why  
2 it should be humanitarian. Why can't we just approve  
3 it.

4 DR. EPSTEIN: No data.

5 DR. MCCLANE: Well, how about over 82?

6 DR. KOLTUN: Well, I have a question. If  
7 it is a humanitarian device, is it obligatory that  
8 they have to continue to try to recruit data in that  
9 regard?

10 In other words, if they implant it as a  
11 humanitarian objective with this device do they have  
12 to keep more accurate date in those individuals?

13 DR. TALAMINI: No, but they do have to  
14 have IRB approval.

15 DR. KOLTUN: So they have to have IRB  
16 approval.

17 DR. TALAMINI: Yes.

18 DR. KOLTUN: So if a 15 year old came and  
19 he was considered a candidate the physician would have  
20 to go through the IRB?

21 DR. TALAMINI: Correct.

22 DR. KOLTUN: That might not be

1 unreasonable.

2 DR. GELLENS: Right. That is not  
3 unreasonable when there is data.

4 CHAIRMAN KALLOO: Also, isn't it possible  
5 to approve it for under 18 with a condition that it be  
6 followed data as well? Is that possible or not?

7 DR. TALAMINI: That's not necessarily.

8 CHAIRMAN KALLOO: Okay. Then that is the  
9 answer.

10 DR. BROGDON: I think that would be  
11 difficult.

12 DR. MCCLANE: How long will this go on for  
13 humanitarian purposes, 1 or 2 years?

14 DR. EPSTEIN: Well, you don't --

15 DR. MCCLANE: Well, the expiration --

16 DR. BROGDON: Unless someone else gets  
17 approval for a similar device in that population.

18 CHAIRMAN KALLOO: Any other comments?

19 MS. NEWMAN: It just seems that if there  
20 is no data on that group, then I agree with you that  
21 we don't totally exclude it if there is an issue. But  
22 there is no data on it.

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1 CHAIRMAN KALLOO: Any other comments? If  
2 not, we will vote on condition of approval, the  
3 condition being that if the patient is over 18 or  
4 rather if the patient is under 18 that we would  
5 recommend that the device be placed only under  
6 humanitarian conditions. And if I can see a show of  
7 hands raised.

8 DR. MCCLANE: Is it for post-pubescent,  
9 under 18?

10 CHAIRMAN KALLOO: Post-pubescent, under  
11 18. Thank you for that clarification. If you could  
12 please raise your hands if you agree with this  
13 recommendation.

14 (A show of hands.)

15 CHAIRMAN KALLOO: Four. And those  
16 against, please raise your hands?

17 (A show of hands.)

18 CHAIRMAN KALLOO: Three. And could you  
19 please tell us the reason for your dissent.

20 DR. WOODS: I think that post-pubescent,  
21 under 18, should be included in the approval, and  
22 should not have special -- should not have to require

1 IRB approval for a humanitarian device.

2 I also think as the sponsor pointed out  
3 that one of the stumbling blocks to getting this  
4 device implanted is that insurance companies may not  
5 pay for it when it is considered investigational, and  
6 I have some concerns that some of those in most need  
7 might be denied the opportunity to have the device.

8 DR. EPSTEIN: And one thing is that we  
9 have obviously mandated that experimental therapy be  
10 covered by insurance. I think it is going to be less  
11 of an issue.

12 CHAIRMAN KALLOO: Who else? Please state  
13 your reasoning.

14 DR. GELLENS: Okay. I actually agree with  
15 this condition, but since I don't think the PMA should  
16 be approved, then I have to disagree overall.

17 CHAIRMAN KALLOO: Okay.

18 DR. MCCLANE: I think it should be  
19 approved for post-pubescent under 18 just because  
20 there may be many obstacles for those patients, and  
21 they may not get the device if they really need them.

22 DR. KOLTUN: Are there any other

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1 conditions of approval that any of the panel members  
2 would like to raise? I will therefore ask the panel  
3 members to vote in favor --

4 DR. KOLTUN: I would like to bring up  
5 another condition.

6 CHAIRMAN KALLOO: Yes, that's fine.

7 DR. KOLTUN: I don't like unduly  
8 restrictive qualifications on the packaging insert.  
9 Therefore, trying to list restrictions in regards to  
10 immunosuppressed patients, and patients who may  
11 represent --

12 CHAIRMAN KALLOO: I'm sorry, but your  
13 condition is?

14 DR. KOLTUN: What I am trying to say is  
15 there some way that we can explore the continuing  
16 accrual of data in regards to potentially high risk  
17 patients, and this is what I am unclear about.

18 CHAIRMAN KALLOO: So your question is  
19 about patient safety on patients who are at high risk?

20 DR. KOLTUN: The only alternatives that I  
21 have in my mind are labeling that says strongly not  
22 advised for patients on immunosuppressants that are

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1       undergoing transplantation, and patients who are  
2       otherwise at high risk because of co-morbid  
3       conditions.

4                   I feel that is somewhat against my  
5       principles in regards to how a physician manages their  
6       patient. It should be up to the physician and patient  
7       to make such decisions.

8                   But on the other hand, I think there is an  
9       opportunity here for us to clearly delineate who  
10      benefits from this. There is not enough data about  
11      risk, and what patients are at the greatest risk, and  
12      what are the factors in that regard.

13                   And how can we continue to accumulate data  
14      so that five years from now we know what patients  
15      don't benefit from this, and should not be considered.  
16      That's what I am saying.

17                   DR. TALAMINI: You can proffer a post-  
18      market study as a condition.

19                   MS. NEWMAN: That is what we have done.  
20      Since they don't have two years, then that will give  
21      us some of the information that you need. So what we  
22      have been asking for is to continue to see information

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1 at the FDA so that maybe some of these restrictive  
2 things don't go away because the data shows up.

3 CHAIRMAN KALLOO: So we are talking about  
4 one of the conditions of approval being a post-  
5 marketing study on patients who specifically are  
6 immunosuppressed; is that correct?

7 DR. KOLTUN: Well, all the individuals who  
8 have been doing the research and doing the work in  
9 this can probably judge that. That's why I asked Dr.  
10 Congilosi that. She has feelings of radiated  
11 parineums, for example.

12 I can see that I don't want to be in a  
13 fantasy world, but I can see physicians, for example,  
14 considering preoperative chemo radiation for low lying  
15 renal cancer, and resecting part of the sphincter in  
16 that context after it has been shrunk by radiation,  
17 while at the same sitting putting in an artificial  
18 sphincter to avoid APR.

19 I can consider in my own mind some very  
20 crazy things. If those things are going to start  
21 taking place or such circumstances are going to start  
22 happening, I would like to know the data.

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1 I don't want selective data. I don't want  
2 to see data that tells us our successes, but then does  
3 not delineate the exact failures. So what I am trying  
4 to ask is I would like to know about high risk  
5 patients with radiated perineums, and patients who are  
6 on immunosuppressants, steroids and other  
7 immunosuppressants like F.K. and cyclosporine.

8 Patients who the investigators have  
9 already deemed as being predisposed to failure. For  
10 example, the trauma patients that they have  
11 identified.

12 I mean, some categories here need to be  
13 further investigated to assess their appropriateness  
14 for being even considered for this therapy if they  
15 have an even higher failure rate than 50 percent.

16 CHAIRMAN KALLOO: Any other comments or  
17 suggestions?

18 DR. BROGDON: Well, it sounds like what  
19 you are discussing a newly designed post-approval  
20 study, is that correct, as opposed to continued  
21 follow-up of already enrolled subjects?

22 DR. KOLTUN: Yes, probably. But I may be

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1 confused about this approval issue. What I mean by  
2 that is that I think that the only way you are going  
3 to get the data is by getting more patients.

4 So the approval I would like to see put in  
5 place, but I want those patients undergoing  
6 implantation to be followed.

7 CHAIRMAN KALLOO: Is it possible to  
8 require the company to report on post-marketing on the  
9 data that he is trying to look for?

10 DR. BROGDON: I guess it is possible to  
11 require. I think you have to look at whether that is  
12 really feasible to expect the sponsor to collect data  
13 unless it is being gathered under a designed study.

14 DR. TALAMINI: Well, for instance, we  
15 could -- I think potentially we could proffer -- and  
16 continuing as I mentioned before, continuing to study  
17 the patients that we already have here out to two  
18 years.

19 DR. KOLTUN: But, you see, the problem  
20 with that is that they don't have these patients.  
21 They don't have a large group of diabetics, and they  
22 don't have a large group of radiated parineums, et

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1 cetera.

2 So that's why I am saying that the  
3 alternative to what I am saying, which is very  
4 difficult I acknowledge, is to say a strongly worded  
5 labeling that says not recommended for radiated  
6 perineums, and not recommended in diabetics, but then  
7 you don't really know. We don't really know whether  
8 to recommend it.

9 DR. TALAMINI: We don't have a condition  
10 on the table, but I think that would be very difficult  
11 to mandate as part of an approval, and I think really  
12 that is part of surgical and medical practice for that  
13 data to come out as devices operations are used and we  
14 learn more about them.

15 DR. KOLTUN: But that would be very  
16 difficult to put out as a condition of approval.

17 DR. TALAMINI: And I agree. I agree.

18 DR. KOLTUN: I don't see how we could do  
19 it. Dr. Smith, do you have a comment?

20 DR. SMITH: Yes, I agree with you that it  
21 would be pointless -- studies are done all the time  
22 about devices as they come out, and you have bigger

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1 and bigger series, and people public their results.

2 And that is where you accrue data, and  
3 then I think you should limit it and you should just  
4 wait and see what happens over the course of time.  
5 People will be publishing their data all the time.

6 DR. GELLENS: Can I make a comment?

7 CHAIRMAN KALLOO: Yes.

8 DR. GELLENS: My understanding though is  
9 that if we feel that the data that is currently being  
10 presented is not adequate to prove safety and/or  
11 efficacy, then it should not be approved. And if you  
12 want to gather more data, maybe it should be done  
13 before the device gets FDA approval.

14 CHAIRMAN KALLOO: Right. But the summary  
15 of the comments of the panel from when we discussed  
16 that issue was fairly clear when it was voted on, that  
17 it was felt that based on the data that we had that  
18 the device was indeed relatively safe.

19 But that is the consensus when we voted.  
20 So that is something that you can define in your vote  
21 when you actually vote if you still feel uncertain.  
22 Yes?

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1 DR. EPSTEIN: Can we take a vote on this?

2 CHAIRMAN KALLOO: Well, we need to be sure  
3 that there are no other conditions before we bring  
4 this to a vote.

5 MS. NEWMAN: But do we want to say that we  
6 would like additional -- maybe another year on this  
7 current data, or that won't solve some of these  
8 issues?

9 CHAIRMAN KALLOO: Yes, we can. We can ask  
10 for a post-marketing follow-up of one year as a  
11 requirement for this as a condition. Is that  
12 something that we should discuss?

13 DR. KOLTUN: From my standpoint, it  
14 doesn't answer my questions. But having said that,  
15 prostheses --

16 CHAIRMAN KALLOO: I don't think anything  
17 could answer your questions.

18 DR. KOLTUN: Right. Exactly. I know.  
19 That's why I said the alternative in my mind is very  
20 restrictive labeling, which I don't like either. But  
21 having said that, I think that might be a good point,  
22 simply because prostheses tend to erode over time, and

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1 we all know that.

2 CHAIRMAN KALLOO: All right. So let's  
3 just get some comments about a post-marketing for  
4 maybe another 12 months for the patients who are  
5 already enrolled in the study so we can get all the  
6 long term data. Dr. Talamini.

7 DR. TALAMINI: Well, actually, I will make  
8 it even a little bit more specific. I would say that  
9 we follow this data another year, and that that data  
10 be part of updated labeling as it becomes available.  
11 So I would put that on the table as a condition to  
12 discuss.

13 DR. SMITH: In that form, I would agree  
14 with that. I think that there is no reason that  
15 another year would be better than when you could say  
16 2 years or 3 years, or 5 years. So I think if it is  
17 approved, and you say you can change the labeling  
18 after one year, I think that is appropriate.

19 DR. WOODS: I will agree to that.

20 DR. STEINBACH: I think that study should  
21 -- and I would ask the sponsors to attempt to chase  
22 down the patients that were excluded from the second

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1 quality of life questionnaire.

2 CHAIRMAN KALLOO: I think what we are  
3 trying to do is to get your opinion on --

4 DR. STEINBACH: Well, as part of this  
5 second year, to include the patients that were missing  
6 from the first year data.

7 DR. KOLTUN: I would agree because that is  
8 the best option that we have for gathering additional  
9 data.

10 CHAIRMAN KALLOO: Ms. Newman.

11 MS. NEWMAN: I agree.

12 CHAIRMAN KALLOO: Dr. Epstein.

13 DR. EPSTEIN: I disagree.

14 CHAIRMAN KALLOO: Any further comments?

15 DR. MCCLANE: I agree, but I do think you  
16 really need to include those patients that have not  
17 been included in the one year follow-up and to try and  
18 track them down and to include that condition.

19 CHAIRMAN KALLOO: Okay. So we are going  
20 to vote on the condition that there is a post-  
21 marketing study of all the patients, to include the  
22 ones that were lost to follow-up, that the results of

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1 which would be included on a subsequent label change.  
2 All those in favor, please raise your hands?

3 (A raising of hands.)

4 CHAIRMAN KALLOO: Six. And against,  
5 please raise your hands?

6 (A raising of hands.)

7 CHAIRMAN KALLOO: Two. And could you give  
8 your reasons why, please?

9 DR. EPSTEIN: I just think that once the  
10 device is out in the market that we will learn much  
11 more about it, like we do with medications, and we  
12 will get information and follow-up, and people will  
13 figure out very quickly how to use this device and  
14 whom. And again I think the surgeons will exercise  
15 good judgment.

16 CHAIRMAN KALLOO: Dr. Gellens.

17 DR. GELLENS: Well, the same thing for me.  
18 I don't think it should be approved. I think we  
19 should get more data before it is approved. I think  
20 we should follow these patients for another year, and  
21 then look at the data after a year, and then decide  
22 whether or not to do it.

1 CHAIRMAN KALLOO: Any other conditions  
2 that any of the panel members would like to bring  
3 forth?

4 (No audible response.)

5 CHAIRMAN KALLOO: Okay. Will all those  
6 voting members in favor of approval with the  
7 conditions that we just listed and voted on raise  
8 their hands?

9 (A raising of hands.)

10 CHAIRMAN KALLOO: Seven. And all those  
11 against, please raise your hand?

12 (A raising of hands.)

13 CHAIRMAN KALLOO: One. Would you please  
14 give us your reason again.

15 DR. GELLENS: The reason that I think it  
16 should not be approved is that I think you need a  
17 longer observation period. This study is only for one  
18 year and I don't think that is adequate for that  
19 amount of time.

20 I think another year is a difficult thing  
21 to ask to follow these patients for another year. I  
22 think there needs to be closer attention to who gets

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1 it and who has complications from it. And that can  
2 give physicians subsequently a better idea of who to  
3 suggest putting this device in.

4 And I also think that changing the  
5 antibiotic regimen already showed significant  
6 improvement in the infection rate in only those 16  
7 patients.

8 I think that if you followed that for  
9 another year that then the company could make much  
10 better recommendations to physicians about antibiotic  
11 regimen. And I think if it is not approved already,  
12 we could mandate a training program, and it would not  
13 be something that may or may not happen after the  
14 device is approved now.

15 CHAIRMAN KALLOO: Thank you. Well, in  
16 conclusion, the panel has voted in favor of approval  
17 with a vote of 7 to 1, with the conditions that are on  
18 your slide with regard to the training program, and  
19 modified labeling for both physicians and patients,  
20 age greater than 18, and a post-market follow-up study  
21 for one year on current study subjects.

22 This concludes the report and

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1 recommendations of the panel on P01-0020, Acticon  
2 Neosphincter for people with incontinence.

3 (Brief pause.)

4 CHAIRMAN KALLOO: And I have now been made  
5 to understand that we each have to give a short  
6 summary of why we voted like this. So if you could  
7 quickly give your comments once more.

8 DR. BROGDON: Could I ask for a  
9 clarification first? Is the approval recommended 18  
10 and older, or is it greater than 18 as listed there?

11 CHAIRMAN KALLOO: Eighteen and older.

12 DR. BROGDON: Eighteen and older. All  
13 right. Thank you.

14 CHAIRMAN KALLOO: So, Dr. Smith, please  
15 give us your reasons for your final decision?

16 DR. SMITH: I approve of the device for  
17 all of the reasons that have been enumerated  
18 repeatedly at this meeting.

19 DR. WOODS: Ditto. I think it is an  
20 effective device when used as outlined in the  
21 protocol, and that it is an option that is absolutely  
22 necessary for patients who suffer from this

1 devastating problem. I think it is a nice option for  
2 them short of an ostomy.

3 DR. STEINBACH: I think it is safe and  
4 effective with our conditions of approval.

5 DR. KOLTUN: I think it is very safe and  
6 very effective, and it varies from patient to patient  
7 and the patient population needs to be very careful of  
8 stipulating who should get it.

9 CHAIRMAN KALLOO: Dr. Epstein.

10 DR. EPSTEIN: I think that the device will  
11 help a certain subpopulation with severe fecal  
12 incontinence who are otherwise devastated by the  
13 illness, and in conclusion there are not a lot of good  
14 alternatives as we have heard.

15 CHAIRMAN KALLOO: Dr. Gellens, once more,  
16 please.

17 DR. GELLENS: I just don't think there is  
18 enough data.

19 DR. MCCLANE: I think it is an effective  
20 device, and it is going to do a lot of good for a lot  
21 of patients.

22 DR. TALAMINI: I think it is effective and

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1 safe within the definitions that we have reviewed, and  
2 it will help a select set of patients with a desperate  
3 problem.

4 CHAIRMAN KALLOO: In conclusion, I would  
5 have to say that I have been on many panels, but I  
6 would have to say that this is one of the best panels  
7 I have been on. So I would like to personally thank  
8 each and every one of you, and to let you know that  
9 the meeting is now adjourned. Thank you.

10 (Whereupon, at 3:36 p.m., the meeting was  
11 concluded.)

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CERTIFICATE

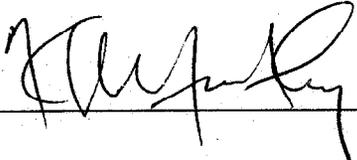
This is to certify that the foregoing transcript in the  
matter of:                   Gastroenterology and Urology Devices  
                                  Panel of the Medical Devices Advisory  
                                  Committee

Before:                       DHHS/FDA-CDRH

Date:                         August 17, 2001

Place:                        Rockville, MD

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

  
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