

1 DR. PAGE: Okay. So --

2 CHAIR YANCY: It's not on approvable  
3 with condition. It's just on this condition.

4 DR. PAGE: So we're voting on the  
5 condition being added to the eventual vote.

6 CHAIR YANCY: That's correct.

7 DR. PAGE: Not approvability with this  
8 condition.

9 CHAIR YANCY: Yes.

10 DR. BLACKSTONE: Clyde, according to  
11 the flow sheet, there is to be discussion of the  
12 new condition and --

13 MS. WOOD: Dr. Yancy, if I could --

14 CHAIR YANCY: Please.

15 MS. WOOD: -- address the panel?

16 CHAIR YANCY: Please.

17 MS. WOOD: I'm Geretta Wood. I'm  
18 Director of the Advisory Panel Program. The  
19 flowchart that you have in your folder should guide  
20 you through the voting procedure.

21 We are now looking -- the motion has  
22 been placed on the floor and seconded for

1           approvable with conditions. You cannot vote on  
2           that motion until you know what the conditions are.

3                        So, this is the first condition. If  
4           you disagree with that condition, your vote simply  
5           means you disagree with that condition, not that  
6           you are voting on the final motion.

7                        Once we have all the conditions on the  
8           floor, the vote will be taken on the main motion of  
9           approvable with conditions.

10                      So right now, we are looking at each  
11           individual condition that the panel feels needs to  
12           be placed on this device.

13                      Does that help?

14                      CHAIR YANCY: That does help. And Dr.  
15           Blackstone is correct. I really need to offer the  
16           opportunity for discussion on this motion, on this  
17           condition. But let's please be very very direct.

18                      Dr. Domanski.

19                      DR. DOMANSKI: Yes, the problem I have  
20           is the 24 months. That may not be the right time  
21           interval.

22                      CHAIR YANCY: Okay, so any other

1           comments?

2                         DR. BLACKSTONE:   The same.

3                         CHAIR YANCY:   Two comments in that  
4           regard. Three comments in that regard.

5                         DR. SOMBERG:   Can I say something?  I  
6           said I was willing to modify that.  I chose 24  
7           months because it was about six to twelve months  
8           initially.  So I just doubled that window, in case  
9           there was necessity.  If anyone has a more  
10          insightful way of reaching a time, you have to put  
11          a number on it.

12                        CHAIR YANCY:   So what we can do now,  
13          you can either elect to withdraw your motion or we  
14          have to go forward with the vote.  Are you  
15          withdrawing the condition?

16                        DR. SOMBERG:   I could change it if  
17          someone had another suggestion of you know, more  
18          than 24 or less than 24 months.  But I just picked  
19          a number that sounded reasonable.

20                        CHAIR YANCY:   So you're not withdrawing  
21          the condition?

22                        DR. SOMBERG:   No.

1 CHAIR YANCY: So if there is no further  
2 discussion, we will vote on the condition as is.

3 DR. HOPKINS: I agree with this time  
4 interval. That might not be the right interval.

5 Conceptually, I would have preferred to  
6 see the first motion be whether we're going to  
7 include pediatric or adult, because I think that  
8 would then drive this time interval. But if we're  
9 going to do this time interval, I would use data  
10 such as re-operative intervals that we see in  
11 homograph conduits, which it would be somewhere in  
12 the pediatric, if we're going to restrict the  
13 pediatric age group, somewhere around six years.  
14 So, I would rather see a longer interval.

15 So I would disagree with that interval,  
16 but I agree with the concept of an interval.

17 CHAIR YANCY: So the motion on the  
18 floor that has not been withdraw is the first  
19 condition. And the first condition is patients at  
20 high risk for re-operation within 24 months.

21 If there is no further discussion, we  
22 need to vote on this motion. So all in favor of

1           this motion, as stated, signify by raising your  
2           hand.

3                           (Show of hands.)

4                           CHAIR YANCY: Dr. Page, Dr. Somberg,  
5           Dr. Weinberger, Dr. Katz are in favor.

6                           Those opposed?

7                           (Show of hands.)

8                           CHAIR YANCY: Doctors Hopkins, Zahka,  
9           Jeevanandam, Neaton, Domanski, Hirshfeld.

10                          So that motion fails. So is there  
11           another condition that can be put forward? Does  
12           anyone have a motion for another condition?

13                          Dr. Blackstone.

14                          DR. BLACKSTONE: Yes. The exact same  
15           wording, but substitute the number six years.

16                          CHAIR YANCY: So a new motion is on the  
17           floor for the first condition that will read, in  
18           patients with a high likelihood of re-operation  
19           within six years. Discussion? Second -- I'm  
20           sorry. Second? Thank you, James. Is there a  
21           second?

22                          DR. HOPKINS: Second.

1 CHAIR YANCY: There's a second by Dr.  
2 Hopkins.

3 Discussion? Dr. Somberg.

4 DR. SOMBERG: I'm not familiar with how  
5 the usual time in pediatrics for homograph surgery.  
6 The trouble with six years, I submit to the  
7 committee is that it's getting closer to a  
8 chronicity we didn't study. And that's much longer  
9 than we did in the study. So we're getting out of  
10 the study realm, so we're basing on no data.

11 And I was hoping that we could get by  
12 by saying if it has to be a short chronicity  
13 between the first and second operations, we  
14 wouldn't have to say pediatric. And the advantage  
15 of not having to say pediatric for those who want  
16 to say it so strongly is that it would let the  
17 sponsor develop the data bases you want for longer  
18 intervals to putting all sorts of patients into a  
19 registry, etcetera, and to be able to do it on a  
20 large scale basis and we would get data.

21 Otherwise, you will get not data and  
22 you will see, unlike in so many other fields, a

1 large off-label experiential adventure.

2 CHAIR YANCY: I appreciate your  
3 comments. Dr. Domanski.

4 DR. DOMANSKI: Well actually, the  
5 sponsor can. They can get an IDE, which is easy  
6 enough to do. You don't need to have the product  
7 approved and do a post-approval study to study the  
8 question that you're talking about. They can just  
9 get an IDE like they did the first time.

10 CHAIR YANCY: Thank you for that input  
11 as well.

12 Dr. Page.

13 DR. PAGE: I agree with Dr. Domanski.  
14 And I am concerned about taking experience out  
15 about a year and making it six-fold, when we don't  
16 have data to support that. I think it's too long.

17 CHAIR YANCY: Further discussion? Dr.  
18 Neaton.

19 DR. NEATON: Yes, my concern is kind of  
20 more restrictive yet. I guess I buy the argument  
21 that adhesion is independent of age and it would  
22 reasonably -- if there is a correlate with clinical

1 outcomes, one might expect to see it. Again, we  
2 didn't see it in the pivotal study. But I'm not  
3 sure that I buy the argument that the safety  
4 concerns are independent of age.

5 And so, I guess I would like to see  
6 this done in a more restrictive population, a  
7 pediatric population, where kind of a re-operation  
8 is anticipated.

9 CHAIR YANCY: Further discussion on  
10 this motion?

11 (No response.)

12 CHAIR YANCY: Then we're ready to take  
13 a vote on this motion, which is in patients with  
14 high likelihood of re-operation within six years.

15 All those in favor, raise your hand  
16 please.

17 (Show of hands.)

18 CHAIR YANCY: Doctors, Hopkins, Katz,  
19 Zahka, Jeevanandam, Blackstone.

20 Those opposed?

21 (Show of hands.)

22 CHAIR YANCY: Doctors Hirshfeld,

1 Domanski, Weinberger, Somberg, Page, and Neaton.

2 That condition is voted down.

3 Is there a motion for a new first  
4 condition for approvable with condition? Dr.  
5 Domanski.

6 DR. DOMANSKI: Well I suppose what  
7 we've got to do is, I think what you said, Jack, is  
8 do what we planned to do in the first place and  
9 that is decide whether we want to limit this, as a  
10 panel, or recommend limiting it to a pediatric  
11 population.

12 And I will make a motion but I would  
13 like first hear to a discussion of what age group  
14 we're really talking about. Because pediatric in  
15 a regulatory sense means 18 and below. And clearly  
16 18 goes far beyond the data that have been brought  
17 forward. So what age group? If one were  
18 restricting it, what would be the appropriate  
19 restriction? I would like to have it, I'm just  
20 raising the question first. I'll make a motion  
21 later.

22 CHAIR YANCY: As a point of

1 clarification, we need to have a motion that will  
2 prompt the discussion. You need to have a motion  
3 and a second and then --

4 DR. DOMANSKI: How about if I move we  
5 discuss it?

6 (Laughter.)

7 CHAIR YANCY: Please don't second that.

8 DR. HOPKINS: No, no.

9 (Laughter.)

10 DR. HOPKINS: To move this along, I  
11 move that it be restricted to the pediatric age  
12 group, as defined by the FDA.

13 CHAIR YANCY: Is there a second?

14 DR. ZAHKA: Second.

15 CHAIR YANCY: Discussion? Dr. Page.

16 DR. PAGE: I was just going to move  
17 that we restrict the age significantly, perhaps to  
18 the age of two or under. So I could not favor a  
19 pediatric population up to the age of 18. I just  
20 don't think we have efficacy and safety data to  
21 support that.

22 CHAIR YANCY: So this is the discussion

1 Dr. Domanski wants us to have in the context of the  
2 motion that is on the floor, pediatric age range as  
3 defined by the FDA.

4 Any further comments about pediatric?

5 Dr. Somberg.

6 DR. SOMBERG: I don't think the issue  
7 is how old the patient is really that much. I  
8 think it's how long between the operations. And so  
9 therefore, I'm not sure it matters so very much.

10 CHAIR YANCY: So further discussion on  
11 this motion? I'm sorry, is your hand up, Dr.  
12 Weinberger? Okay.

13 We will take a vote -- I'm sorry. Dr.  
14 Jeevanandam.

15 DR. JEEVANANDAM: I can, in terms of  
16 restricting by age, I think 18 may be a little too  
17 much in terms of pediatric dates. I propose we do  
18 something like ten years. I mean, because if you  
19 may have your third re-op by the time you're two  
20 and a half or three.

21 DR. HOPKINS: Yes, that's my point.

22 DR. JEEVANANDAM: And you would be

1 beyond the two year age group.

2 DR. HOPKINS: Yes, that's my point.

3 DR. JEEVANANDAM: And that may be  
4 somebody who is going to need an operation down the  
5 line.

6 DR. HOPKINS: If this really --

7 DR. JEEVANANDAM: On the other hand --

8 DR. HOPKINS: -- works, it's the  
9 second, third, fourth pre-op that I'm the most  
10 interested in using it. So, I think conceptually  
11 I'm struggling in my mind between your approach,  
12 which is should it be limited by age at all. So  
13 I'm kind of a less limiter. It's either pediatric  
14 versus adult or it's everybody, or you could even  
15 say young adult, everybody under the age of, I  
16 mean, I'm going to get some people mad here, under  
17 the age 55 is a young adult.

18 But, it's really, I think, the big  
19 discussion or the big limiter is the interval in  
20 which you as a clinician expect to have to re-op.  
21 So the two things are linked, but the real limiting  
22 feature is going to be the re-op expectation. The

1 45-year-old getting a pig valve is not going to  
2 need a re-op in six years. They probably will in  
3 ten, but not in six.

4 CHAIR YANCY: So --

5 DR. HOPKINS: So that's why these two  
6 things are so intrinsically linked that I think we  
7 have to come to a decision as to which is going to  
8 be the most restrictive and then vote through it.

9 CHAIR YANCY: So the language of the  
10 motion on the floor that that has been moved and  
11 seconded is that this is applied to a pediatric  
12 population, as per the definition of the FDA. That  
13 is 18?

14 DR. HOPKINS: It's 18.

15 CHAIR YANCY: Dr. Zuckerman?

16 DR. ZUCKERMAN: It's 21 actually.

17 CHAIR YANCY: Twenty-one or less.

18 DR. ZUCKERMAN: Twenty-one.

19 CHAIR YANCY: All in favor of this  
20 motion -- I'm sorry. There's more discussion. Dr.  
21 Neaton.

22 DR. NEATON: I just was going to ask,

1 was the part of it about at high risk for a second  
2 procedure involved in that motion at all?

3 CHAIR YANCY: No, that's not in that  
4 motion.

5 CHAIR YANCY: This is only about the  
6 target patient population.

7 And so this is the first condition  
8 under approvable with condition in pediatric  
9 patients, as defined by the FDA. All in favor,  
10 raise your hand, please.

11 (Show of hands.)

12 CHAIR YANCY: Doctors Hopkins, Katz,  
13 Zahka, Jeevanandam, Blackstone, Somberg.

14 Those opposed?

15 (Show of hands.)

16 CHAIR YANCY: Doctors Hirshfeld,  
17 Domanski, Page, Weinberger, I'm sorry, I couldn't  
18 see, Neaton.

19 That motion passes. So, the first  
20 condition is approvable with conditions. Condition  
21 number one, in a pediatric population as defined by  
22 the FDA.

1                   We're now prepared to accept another  
2                   condition. Is there a motion for a new condition?  
3                   Dr. Somberg.

4                   DR. SOMBERG: The likelihood of re-  
5                   operation within six years.

6                   CHAIR YANCY: The motion is likelihood  
7                   of a re-operation within six years. Is there a  
8                   second?

9                   DR. BLACKSTONE: Second.

10                  CHAIR YANCY: That motion has been  
11                  seconded by Dr. Blackstone. Discussion.

12                  DR. DOMANSKI: Yes, I'd like to ask a  
13                  question. So, if we, if this is passed and it's 21  
14                  and less, but only if the re-operation is  
15                  anticipated within six years. I mean, is that the  
16                  point of it?

17                  CHAIR YANCY: Condition two that has  
18                  just been proposed establishes a requirement for  
19                  re-operation, likelihood of re-operation and a time  
20                  interval of within six years.

21                  DR. DOMANSKI: And the reason it's not  
22                  four or seven perhaps? I'm just not sure about the

1 number.

2 CHAIR YANCY: This is the purpose of  
3 the discussion.

4 DR. SOMBERG: The reason -- you're the  
5 one who is --

6 DR. HOPKINS: Just trying to pick a  
7 median number, in terms of the number of years in  
8 the pediatric age group in which you would need to  
9 do a re-operation for conduit repairs. And this  
10 would, of course, easily encompass the hypoplastic  
11 left hearts in all of the neonates.

12 CHAIR YANCY: Dr. Jeevanandam.

13 DR. JEEVANANDAM: How about, I guess  
14 I'm nobody's motions, I mean how about if we just  
15 say the high likelihood of re-operation and not put  
16 a time limit on it? Because we're already talking  
17 about a patient population of less than 21.

18 CHAIR YANCY: So that's appropriate as  
19 a part of the discussion and can be taken in the  
20 context as we cast a vote.

21 Dr. Blackstone? You're hand wasn't  
22 up? I'm sorry. Other discussion on this motion?

1 (No response.)

2 CHAIR YANCY: So we have completed the  
3 discussion on this motion. And to restate the  
4 motion, it has two facets. The first is at a high  
5 likelihood for re-operation and the second is  
6 within six years. You've heard the discussion and  
7 we are going to take a vote on this specific  
8 condition, which would be condition two under  
9 approvable with condition, which establishes a  
10 requirement for a high likelihood of re-operation  
11 within six years.

12 Those in favor, raise your hand.

13 (Show of hands.)

14 CHAIR YANCY: Dr. Neaton, Dr. Somberg.  
15 We have two in favor. That motion fails.

16 Is there a new motion to come forward  
17 as a second condition?

18 DR. JEEVANANDAM: Just a pediatric  
19 patient at high risk for re-operation.

20 CHAIR YANCY: Is there a second for Dr.  
21 Jeevanandam's motion?

22 DR. DOMANSKI: I'll second that.

1 CHAIR YANCY: That motion has been  
2 moved and now seconded by Dr. Domanski.

3 Discussion. Dr. Weinberger.

4 DR. WEINBERGER: I have a question for  
5 my surgical colleagues. Is this intention to re-  
6 operate or at risk to re-operate?

7 DR. HOPKINS: Well, if they are at  
8 risk, I'm intending to. But it would also include  
9 the patients where you have some probability that  
10 they will return relatively soon and that it's not  
11 a permanent repair, but one that you are predicting  
12 a re-operation in which there would be a benefit,  
13 if there is efficacy to reduce adhesions.

14 So I actually like the new version.

15 CHAIR YANCY: Further discussion on  
16 this motion? Dr. Hirshfeld.

17 DR. HIRSHFELD: I have yet to vote yes  
18 on any of these motions. And my concern is going  
19 back to the original premise of the request. And  
20 that is that I think if we look at all the data  
21 that we have seen today, we don't have concrete  
22 evidence that this device is not safe, but we have

1           some tentative signals that there may be a safety  
2           issue associated with it.

3                        As far as efficacy is concerned, I  
4           think we've seen concrete evidence that at the  
5           endpoint as defined in the protocol, was satisfied.  
6           But we have seen no evidence of clinical efficacy  
7           in terms of patient outcomes that goes along with  
8           that.

9                        So if we're recommending to the Agency  
10          that it approve this device as safe and effective,  
11          I don't think that we have really rigorous evidence  
12          to support either of those statements.

13                       CHAIR YANCY: So in the context of this  
14          discussion, we can incorporate Dr. Hirshfeld's  
15          perspective when we cast our vote. And that  
16          opinion can be reflected in the vote if that is the  
17          wish of the majority.

18                       Other discussions -- other discussion  
19          points?

20                       (No response.)

21                       CHAIR YANCY: Having heard that then,  
22          the second condition as moved by Dr. Jeevanandam

1 and seconded by Dr. Domanski in the context of all  
2 the discussion points, is that a high likelihood  
3 for re-operation, pediatric patient high likelihood  
4 for re-operation without a time limit.

5 All in favor raise your hand, please.

6 (Show of hands.)

7 CHAIR YANCY: Doctors Hopkins, Katz,  
8 Zahka, Jeevanandam, Blackstone, Neaton, Weinberger,  
9 and Domanski.

10 That motion passes. So, to date we  
11 have approval with conditions and the two  
12 conditions are in a pediatric population as defined  
13 by the FDA and at a high likelihood for re-  
14 operation. Is there another motion to be put forth  
15 for a condition to govern this PMA?

16 Dr. Jeevanandam.

17 DR. JEEVANANDAM: How about the  
18 contraindication for not usage in a VAD? Is that  
19 something that we need to vote on as well? Is that  
20 part of their PMA submission? So do we need to  
21 remove that -- if we want to remove that as a  
22 contraindication, do we need to vote on that as a

1 condition?

2 CHAIR YANCY: My understanding is that  
3 that is included. So we would have to vote, if we  
4 are uncomfortable with that. That's part of the  
5 PMA. It exists in writing. It's been submitted by  
6 the sponsor and if we vote favorably without  
7 addressing that, it would go forward as is.

8 DR. JEEVANANDAM: Okay. Can I proposed  
9 a motion to eliminate that statement that this is  
10 not a contraindication for LVAD use?

11 CHAIR YANCY: So the motion is on the  
12 floor to modify the label language to remove the  
13 contraindication statement as submitted by the  
14 sponsor. Is there a second to that motion?

15 DR. WEINBERGER: Second.

16 CHAIR YANCY: There is a second.

17 Discussion? Dr. Katz.

18 DR. KATZ: I would not be in favor of  
19 that motion, because I would like to see, since it  
20 was the sponsor's initiation of putting that  
21 contraindication in, I'd like to see a study done  
22 in VAD patients, with that. So therefore, I would

1 vote against that.

2 CHAIR YANCY: So Dr. Katz's comments  
3 can be taken under consideration when we vote.

4 Other discussion points? Dr.  
5 Jeevanandam.

6 DR. JEEVANANDAM: One of the reasons I  
7 made the point by removing them as a  
8 contraindication is the big use of this device  
9 might end up being in the pediatric patients and  
10 now they are available, very small pediatric LVADs.  
11 So, unlike the HeartMate that they had problems  
12 with, these are different devices, including  
13 potentially the Impella device which is, you know,  
14 put in through a very very small graft.

15 So there are newer devices for smaller  
16 patients that are available and I wouldn't want to  
17 prevent this from being used in those patient  
18 populations where it could potentially be useful.

19 CHAIR YANCY: So if it were removed, it  
20 would become be an on-label use and could be  
21 captured in the post-approval study. Is that your  
22 intent?

1 Dr. Weinberger, Dr. Domanski.

2 DR. WEINBERGER: I think that the  
3 intent of the sponsor, and maybe we should somehow  
4 encapsulate that intent, is to warn people not to  
5 use it with the HeartMate LVAD. And if there were  
6 a warning about that and be silent about other  
7 LVADs, that would accomplish what you are trying to  
8 do.

9 Forget about contraindication. Just  
10 leave a warning in for use with the HeartMate.

11 CHAIR YANCY: Again, a comment that can  
12 be considered. Dr. Domanski?

13 DR. DOMANSKI: Yes. You know, I'd like  
14 to underscore both of those things and say that the  
15 only way we can get to that, because the FDA can  
16 put in a warning, I think, Bram, you can correct  
17 me, but they can put in a warning without any  
18 motion by us. But to change the PMA to pull a  
19 contraindication probably needs a vote.

20 So they can write about the HeartMate  
21 and for exactly the reason you say. I mean, there  
22 are different VADs. It's not just the HeartMate.

1                   CHAIR YANCY: So the motion is to  
2                   remove the language that identifies an LVAD as a  
3                   contraindication and we've heard a reasonable  
4                   discussion. Those in favor of removing that  
5                   language from the label indicate by raising your  
6                   hand, so we can call your names.

7                   (Show of hands.)

8                   CHAIR YANCY: Doctors Hopkins, Zahka,  
9                   Jeevanandam, Neaton, Blackstone, Page, Weinberger,  
10                  Domanski, and Hirshfeld.

11                  That motion passes. That  
12                  contraindication statement is removed.

13                  Dr. Blackstone?

14                  DR. BLACKSTONE: I move that the words  
15                  "the incidence," leaving the word "severity," and  
16                  then removing "and extent" be removed from the  
17                  indication. So that the sentence would read  
18                  "Indicated for reducing severity of post-operative  
19                  adhesion formation."

20                  CHAIR YANCY: Is there a second? That  
21                  motion has been seconded twice. Discussion.

22                  DR. HOPKINS: I agree.

1 CHAIR YANCY: Seeing no discussion, I'm  
2 calling for a vote. Indicate by raising your hand,  
3 please.

4 (Show of hands.)

5 CHAIR YANCY: Doctors Hopkins, Katz,  
6 Zahka, Jeevanandam, Neaton, Blackstone, Page,  
7 Somberg, Weinberger, Domanski, and Hirshfeld. That  
8 motion passes.

9 At this point, then we are at  
10 approvable with conditions for this PMA in a  
11 pediatric population as defined by the FDA at a  
12 high likelihood for re-operation without respect to  
13 a time interval, with removal of LVAD as a  
14 contraindication statement, and with a more  
15 restricted indication statement, which only  
16 addresses reducing the severity of adhesions.

17 Are there any other conditions that we  
18 wish to add? Dr. Domanski.

19 DR. DOMANSKI: You know, I guess maybe  
20 I need a clarification here. But we've been  
21 talking about a post-marketing approval study as  
22 well.

1 CHAIR YANCY: So is your motion to  
2 proceed forward with --

3 DR. DOMANSKI: Yes, I guess the  
4 clarification I need though is, how specific do we  
5 need to be or do we need to say it at all, Bram?

6 DR. ZUCKERMAN: It is very helpful if  
7 you believe that a post-approval study should be  
8 done for one of the five reasons outlined that you  
9 put it in this motion. However, the degree of  
10 specificity post that statement is not absolutely  
11 necessary.

12 Again, when you are voting on  
13 conditions of approval, you're trying to get the  
14 broad brush strokes here. And then you can let FDA  
15 and the sponsor worry about the details.

16 CHAIR YANCY: So Dr. Domanski, would  
17 you like to make a motion?

18 DR. DOMANSKI: No, I'm not going to  
19 make a motion on that.

20 CHAIR YANCY: We are open for any  
21 additional conditions for this motion.

22 There is a motion from Dr. Somberg.

1 DR. SOMBERG: I move that there be a  
2 post-marketing study recommended and that that  
3 study try to capture real world experience, and  
4 adversity, and efficacy, and if possible, to have  
5 a concomitant control group.

6 CHAIR YANCY: So the motion is for a  
7 post-approval study that would encompass additional  
8 questions of safety and would include a control  
9 group. That is a bit problematic, but that's the  
10 motion as stated. Is there a second?

11 (No response.)

12 CHAIR YANCY: Without a second, the  
13 motion dies.

14 Is there a new motion to be put  
15 forward? Dr. Hopkins.

16 DR. HOPKINS: I propose we place a  
17 condition that a post-approval study be done.

18 CHAIR YANCY: The motion is simply that  
19 a post-approval study be done. Is there a second?  
20 Second by Dr. Katz. Discussion?

21 DR. SOMBERG: What type of post-  
22 approval study, just for the fun of it?

1 DR. HOPKINS: Again, I think that is  
2 one, there are so many issues here that for us to  
3 design that study today. But, I am satisfied that  
4 for the indications as presented to us, the safety  
5 and efficacy has been shown. So the post-approval  
6 study would be for other reasons, from my  
7 standpoint, to look at consequences of its use in  
8 the general population, etcetera.

9 So, I think a post-approval study can  
10 be designed that would be very very effective, but  
11 I'm not prepared to design that myself, right now  
12 as part of --

13 CHAIR YANCY: A couple points of  
14 clarification need to be made, again, on post-  
15 approval study. Remember, the reason for post-  
16 approval study really is not to address efficacy.  
17 We have to make a decision about efficacy based on  
18 the fund of knowledge, the data we have currently.

19 DR. HOPKINS: No, that's my point.  
20 It's extending this use from these 15 highly  
21 selected centers to the real world to the community  
22 of reconstructive cardiac surgery in children. So,

1 and that post-approval study, I think will be very  
2 very helpful.

3 CHAIR YANCY: That's sufficient. Dr.  
4 Zuckerman, did you have a comment?

5 DR. ZUCKERMAN: No. I just want to  
6 again express to the panel again Dr. Hopkins very  
7 wise comments that the key issue is whether or not  
8 you need a post-approval study and the main reason  
9 why, which he has given. It's very difficult to  
10 design a study on the fly, as he stated, regarding  
11 control, endpoints, etcetera.

12 Subsequently, the Agency and sponsor  
13 will try to use the good discussion that occurred  
14 today to develop that study. But if we had any  
15 further questions, we would get back to an expert  
16 like Dr. Hopkins, who I am sure will volunteer to  
17 finish up on any final touches.

18 CHAIR YANCY: So that's an excellent  
19 point of clarification.

20 The motion that is on the floor is to  
21 approve this with one additional condition, that  
22 being a post-approval study. Further discussion,

1 Dr. Zahka?

2 DR. ZAHKA: I think the main reason for  
3 a post-approval study is to address the rare  
4 adverse events. The fact of the matter is, there  
5 is a very small community that is going to be using  
6 this for these indications already, especially when  
7 it comes to hypoplastic left heart. But  
8 identifying the rare adverse events, I think is the  
9 key part of it.

10 CHAIR YANCY: Dr. Neaton.

11 DR. NEATON: I would like to second  
12 that point, just for the record. I support the  
13 motion that we can't design it here today, but the  
14 study, I believe, should be done to address the  
15 uncertainty we have about safety.

16 CHAIR YANCY: So in the context of the  
17 discussion we have just heard, I would like to call  
18 for a vote on a very simple motion that another  
19 condition for approvable with conditions is to  
20 require a post-approval study.

21 All in favor?

22 (Show of hands.)

1 CHAIR YANCY: Doctors Hirshfeld,  
2 Domanski, Weinberger, Page, Neaton, Blackstone,  
3 Jeevanandam, Zahka, Katz, and Hopkins. That motion  
4 passes.

5 So currently we have approvable with  
6 condition for this PMA in the pediatric patient,  
7 high likelihood for re-operation, with a label that  
8 has been modified to remove LVAD as a  
9 contraindication with more restrictive language  
10 that only implicates reducing the severity of  
11 adhesions and with the requirement to proceed  
12 forward with a post-approval study.

13 Are there any additional conditions  
14 that any panel member wants to put forward prior to  
15 taking a vote on the overall motion?

16 (No response.)

17 CHAIR YANCY: Seeing no additional  
18 conditions come forward, we are now ready for a  
19 main motion vote.

20 It has been moved and seconded that the  
21 SyntheMed Incorporated PMA application P07005 for  
22 the REPEL-CV bioresorbable adhesion barrier film be

1 approved with the conditions the panel has just  
2 voted on.

3 We will now vote on the main motion.  
4 With a show of hands, please indicate if you concur  
5 with the recommendation that the above named PMA be  
6 found approvable with conditions.

7 (Show of hands.)

8 CHAIR YANCY: Doctors Hopkins, Katz,  
9 Zahka, Jeevanandam, Blackstone, Neaton, Weinberger  
10 and Domanski vote in favor.

11 Those opposed?

12 (Show of hands.)

13 CHAIR YANCY: Doctors Page, Hirshfeld.

14 Those abstaining? Oh, and Somberg.  
15 I'm sorry. Anyone abstaining? That's it. That  
16 motion passes eight to three.

17 It is the recommendation then, of the  
18 panel to the FDA that the SyntheMed Incorporated  
19 PMA application P07005 for the REPEL-CV  
20 bioresorbable adhesion barrier film be approved  
21 with the previously voted upon conditions.

22 Those conditions were the following.

1 In a pediatric population, in a high likelihood for  
2 re-operation without a time limit, with removal of  
3 the contraindication of left ventricular assist  
4 device, with more restrictive indication language  
5 for a reduction in the severity of adhesions, and  
6 with the requirement for a post-approval study.

7 Prior to ending this meeting, we need  
8 each panel member to specifically comment on their  
9 vote and give us their final statement about the  
10 deliberations and the motion. Dr. Zuckerman?

11 DR. ZUCKERMAN: And can I ask panel  
12 members, if they are so interested, also to  
13 indicate what type of data they would require for  
14 an adult population indication.

15 CHAIR YANCY: So there are two things  
16 that you will need to address as we go around the  
17 table. Indicate the rationale for your vote, your  
18 final considerations of this motion, what persuaded  
19 you one way or the other and then what other data  
20 points which you need to go into an adult  
21 population.

22 We'll start with Ms. Mottle, if you're

1 ready.

2 MS. MOTTLE: No, I'd rather wait.

3 CHAIR YANCY: You'd rather wait? Thank  
4 you. We'll start with Dr. Yaross.

5 DR. YAROSS: I think my comments are  
6 probably more appropriate also at the end. In  
7 terms of the issue though for a, well I guess  
8 they're not.

9 CHAIR YANCY: Well we can come back to  
10 you, then.

11 DR. YAROSS: Okay.

12 CHAIR YANCY: So, Dr. Hirshfeld.

13 DR. HIRSHFELD: Well I think I stated  
14 my reasons before. I think that the data that we  
15 have available to us does not assure us that this  
16 device is safe and that the evidence that it  
17 actually confers a clinical benefit to patients in  
18 terms of their ultimate outcome is lacking.

19 CHAIR YANCY: Dr. Domanski.

20 DR. DOMANSKI: You know, I could  
21 express, to a degree, the same concern, but I think  
22 that a reasonable demonstration has been done that

1 the device is effective for the intended  
2 indication, which is reducing adhesions and  
3 persuaded that that is something that is important.  
4 I don't feel comfortable saying that they have  
5 shown safety and efficacy, though in an adult  
6 population when all they've operated on is a 140-  
7 odd hypoplastic hearts in neonates.

8 CHAIR YANCY: Dr. Weinberger.

9 DR. WEINBERGER: I think that the  
10 context of my vote was primarily the patient  
11 population defined, which was a very sick  
12 population. And I don't feel that going outside of  
13 that population is justified, based on the data  
14 that has been presented.

15 In terms of youths and adults, I think  
16 that given the magnitude of the benefit and given  
17 the relatively limited likelihood of re-operation,  
18 I need to have a much more efficacious device to  
19 even want to proceed to ask that question. Or at  
20 least define a group of patients who are at high  
21 risk for re-operation in a fairly short period of  
22 time.

1 CHAIR YANCY: Dr. Somberg.

2 DR. SOMBERG: I voted against the  
3 motion because I thought the recommendations were  
4 needed for a post-approval study and that without  
5 a concomitant control group, and without and  
6 adequate power to get an inclination of toxicities  
7 in this population, that we were not able to  
8 address under the smaller pivotal study we would  
9 have inadequate information and that's what we may  
10 be stuck with. I also feel that in terms of adult  
11 approval, you know, that would be based mostly on  
12 safety data and I think that that could have been  
13 easily obtained, if we were just going to have that  
14 more expanded. If you were going to try to do a  
15 safety, in a PMA, an IDE in a PMA, then you have to  
16 have a safety efficacy balance and considering  
17 people get re-operated in 20 to 30 years, plus  
18 minus getting the study done in under that, it's 40  
19 years. I hope to be back on that panel, but I  
20 think it's unlikely.

21 CHAIR YANCY: Dr. Page.

22 DR. PAGE: I couldn't support this

1 proposal as it was put forth, although I, based on  
2 the fact that I felt the efficacy was relatively  
3 soft without any clinically meaningful endpoint,  
4 the safety data were troubling in spots, but I  
5 could live with them. In the narrow population  
6 that was studied, the average age was 12 days old.  
7 Now we're going to be potentially exposing 20-year-  
8 olds to this device. And I just don't feel in my  
9 role that I could support approval for the  
10 indications that we've approved today.

11 CHAIR YANCY: We appreciate your  
12 comments. Dr. Neaton.

13 DR. NEATON: I think the study was done  
14 in kind of a population that was the only one  
15 really feasible to establish efficacy and I think  
16 the trial that was done was very well done. And  
17 while we looked at it a number of different ways,  
18 I felt the adhesion severity reductions is a real  
19 signal there.

20 I think it's a concern that it wasn't  
21 properly powered for some of the safety outcomes  
22 and also for clinical efficacy. And I hope that's

1 considered in the post-approval study that they do.

2 As far as the adult population, I  
3 accept the argument that it may be difficult,  
4 although I think maybe LVADs, as has been  
5 indicated, have changed a lot, so that may not be  
6 so difficult now, as opposed to five years ago.  
7 But still, one can do a safety study in adults and  
8 it would seem like that would be a reasonable thing  
9 to consider.

10 CHAIR YANCY: Thank you. Dr.  
11 Blackstone.

12 DR. BLACKSTONE: I would think that it  
13 is possible to, even for the idea of evaluating  
14 adhesions, to have a more quantitative look. Now,  
15 five or nine years ago, OR cameras weren't perhaps  
16 so popular. I think many people today take a  
17 picture of every single patient that they do. So  
18 I think the FDA idea of actually photographing  
19 these and trying to preliminary them might be  
20 important. And then having some real clinical  
21 efficacy or, yes, the clinical efficacy points  
22 would be extremely important, like how much

1           bleeding is there from these adhesions.

2                         And then my concern about foreign  
3           bodies in the mediastinum. I think mediastinitis  
4           represents a way out to one side of things. And  
5           that could be broadened. And then I think, and  
6           also I think one should look underneath this  
7           device. For example, the GORE-TEX devices may help  
8           between the sternum and that sheet, but then what  
9           about between that barrier and the heart, which  
10          could obscure things.

11                        And the final thing I would say is that  
12          both in the context of this and some other panels,  
13          we see studies powered for efficacy without being  
14          simultaneously powered for safety. And that puts  
15          all of us on the panel at jeopardy, so that in this  
16          case, it looked like there was a signal for  
17          efficacy, but there was no power to really talk  
18          about safety. And I think that's something that  
19          FDA needs to be thinking about.

20                        CHAIR YANCY: So that's a perfect role  
21          for this panel in an advisory capacity. So thank  
22          you for those comments.

1 Dr. Jeevanandam.

2 DR. JEEVANANDAM: I think getting any  
3 device approved for decreasing adhesions is a  
4 daunting task. And I think this was a difficult  
5 study and the patient population that was studied  
6 is probably the only one you could. But then, of  
7 course, extrapolating that to adults is  
8 problematic. So, I voted to approve it in that  
9 patient population, and then we just extended it to  
10 the pediatric population.

11 I think that a post-market  
12 surveillance, or the post-market study needs to be  
13 focused on safety. And I think that there enough  
14 VADs, especially the non-pulsatile VADs now that  
15 you can use this to test it on an adult patient  
16 population.

17 CHAIR YANCY: Dr. Zahka.

18 DR. ZAHKA: I struggled with all the  
19 information that we had in terms of safety and  
20 efficacy and felt unbalance in the population that  
21 was studied that the potential for benefit clearly  
22 outweighed the risks. And, with the conditions,

1 thought it would be an appropriate vote in the  
2 affirmative.

3 CHAIR YANCY: Dr. Katz.

4 DR. KATZ: I think that the problem  
5 with post-operative adhesions in cardiac surgical  
6 patients is very real, very dangerous and very hard  
7 to elucidate for people who don't do the surgeries.

8 I think that a device that can limit  
9 those adhesions or exclude, hopefully one day,  
10 those adhesions would be a great benefit to all of  
11 our patients. And that it is my hope that the  
12 approval for this, and I think it's going to be a  
13 relatively limited population, will help spur the  
14 company to do further studies, as stated both by  
15 Dr. Blackstone and Dr. Jeevanandam, to look  
16 specifically under the layer to look at the cardiac  
17 structures under it at the area around the  
18 pericardium and its utilization in adults  
19 specifically with ventricular assist devices.

20 CHAIR YANCY: Dr. Hopkins.

21 DR. HOPKINS: The extension of the data  
22 from the neonatal infant population to the older

1           pediatric population is warranted because of the  
2           much larger benefit to risk ratio for that subgroup  
3           in terms of the risk of multiple re-operative  
4           surgeries. I'm very much in agreement with the  
5           panel's decision not to extend this beyond that,  
6           you know, pending an additional IDE, because I  
7           don't think the data was there.

8                        I completely agree with a post-approval  
9           study. That's why I made the motion. But I would  
10          make a recommendation to the FDA that very careful  
11          attention be made to what constitutes the control  
12          group, that some element of quantification be  
13          approached with today's technology, and I can think  
14          of two or three things that could be done. I would  
15          suggest that some thought be given to systemic  
16          inflammatory markers and advanced imaging  
17          techniques that can now resolve epicardial motion  
18          from sternal motion and actually the two  
19          epicardiums from each other.

20                      That the post-approval study whatever  
21          it's form, and of course is always restricted by  
22          cost, but there is no point, and I agree, there is

1 no point in doing it unless it is powered both for  
2 safety and efficacy. Thank you.

3 CHAIR YANCY: Dr. Yaross, are you  
4 ready?

5 DR. YAROSS: Yes, thanks for coming  
6 back to me.

7 I think the burden for a first of a  
8 kind study is always very high and I think we saw  
9 an example of that today, particularly in a very  
10 challenging but important indication. So I want to  
11 commend the panel for finding a way to work with  
12 the data set and the sponsor. And commend FDA and  
13 the panel also for a very fair and careful process.  
14 And I commend the sponsor for the work that they've  
15 done.

16 CHAIR YANCY: Ms. Mottle.

17 MS. MOTTLE: Thank you. I concur with  
18 what you just said, Dr. Yaross, too. But I would  
19 also like to echo the fact that for an adult  
20 indication that a separate IDE be done, because I  
21 just don't think we can extrapolate that.

22 CHAIR YANCY: As the Chair, I would

1       like to add that I concur with the vote of the  
2       panel and would strongly emphasize the importance  
3       of an appropriately designed post-approval study  
4       for all the reasons that have been stated.

5               There are experiences that we need to  
6       realize as more patients on label receive this  
7       device. And I support the idea that to broaden  
8       this indication, it would require de novo  
9       investigations that admittedly would be  
10      challenging. But it's the only fair thing to do in  
11      this patient population.

12             As a general statement, both to the  
13      sponsor, your peers, and to the FDA, I fully  
14      support the comments made by Dr. Blackstone that we  
15      continue to compromise the process with  
16      underpowered studies that make it difficult to  
17      interpret signals. I recognize we're in a  
18      physiologic clinical state with severely ill  
19      patients and devices are not drugs, but we need to  
20      continue to work hard and diligently to improve the  
21      design of the studies.

22             I want to thank the sponsor for your

1 patients, for being so forthcoming with your  
2 information, and responses to our questions, and  
3 for handling everything professionally.

4 I'd like to thank the FDA for very  
5 clear presentations and for similarly laying things  
6 out so that we could add that to our deliberative  
7 process.

8 I'd especially like to thank the panel.  
9 This is my first time through. Phew.

10 (Laughter.)

11 CHAIR YANCY: So thank you for working  
12 with me. And I will give the final word to Dr.  
13 Zuckerman.

14 DR. ZUCKERMAN: Yes. Thank you, Dr.  
15 Yancy. You did an outstanding job today for your  
16 first panel and I was most impressed by the  
17 performance of this panel. The Agency and sponsor  
18 have received a lot of valuable input on a truly  
19 challenging area.

20 I would also like you to think about  
21 Dr. Blackstone's comments in preparation for  
22 tomorrow. Again, we're talking about first of a

1 kind technology. What he has noted seems to be a  
2 general problematic issue. There is a real  
3 opportunity to impact the development of an  
4 important technology tomorrow, so I hope you get  
5 lots of sleep tonight.

6 CHAIR YANCY: The meeting is adjourned.

7 (Whereupon, at 5:48 p.m., the meeting  
8 was adjourned.)

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