DR. KELLY WADE: No worries.

MS. MARIEANN BRILL: For the Flourish question number one --

DR. KELLY WADE: I don't seem to be able to hear you, Marieann. I'm not sure if that's a problem for others as well.

DR. SARAH HOEHN: Yeah. I cannot hear her either. It cut out.

DR. VASUM PEIRIS: Yeah. Kelly, I couldn't hear either.

DR. KELLY WADE: Okay. Marieann, can you go back and start again?

MS. MARIEANN BRILL: Sure. This is Marieann Brill. Can you hear me now?

DR. KELLY WADE: I can hear you now.

MS. MARIEANN BRILL: Okay. Wonderful. For the Flourish question number one, we have 13 yes and 1 abstain.

DR. KELLY WADE: Thank you. Now that the vote is complete, we will go down the meeting roster and have everyone who voted state their name, vote, and if you want to, you can state the reason why you voted as you did into the record. We will start with Angela Czaja.

DR. ANGELA CZAJA: Angela Czaja. I voted yes based on the last instructions by the FDA that, if yes, I agree that those should be included, warnings, and a no would indicate that I did not think the warnings should be included. I did want to add the caveat that I thought that those would be necessary but probably insufficient for addressing the concerns about the risk.

DR. KELLY WADE: Thank you. Dr. Dracker?

DR. ROBERT DRACKER: Bob Dracker. I voted yes in support.

DR. KELLY WADE: Dr. Fischer?

DR. GWENYTH FISCHER: Gwen Fischer. I voted yes in support for the same reasons that Dr. Czaja just mentioned.

DR. KELLY WADE: Thank you. Dr. Flick?

DR. RANDALL FLICK: Randall Flick. I voted yes.

DR. KELLY WADE: Dr. Havens?

DR. PETER HAVENS: Peter Havens. I voted yes and support the other comments that have been made.

DR. KELLY WADE: Dr. Hoehn?

DR. SARAH HOEHN: Sarah Hoehn. I voted yes. I agree with the other comments and I agree with Dr. Czaja that we need more warnings. I think we should incorporate what Dr. Flick has highlighted which is the need for qualified pediatric surgery involvement.

DR. KELLY WADE: Dr. Holubkov?

DR. RICHARD HOLUBKOV: Rich Holubkov. I voted yes. I fully support the other comments, the other statements just made. Thanks.

DR. KELLY WADE: Thank you. Dr. Jones?

DR. BRIDGETTE JONES: This is Bridgette Jones. I voted yes. I agree with the other comments and I'd also like to add that I would recommend changing the wording from "would mitigate" to "may" and also that there should be clarification as far as the warnings, specifically that the warnings will be included in the directions for use and also be incorporated in the physician training.

DR. KELLY WADE: Thank you. Dr. Lukish?

DR. JEFFREY LUKISH: I voted yes. I support and agree with all the comments that my colleagues have provided.

DR. KELLY WADE: Dr. McMillan?

DR. GIANNA MCMILLAN: Gianna McMillan. I voted yes and support the other comments.

DR. KELLY WADE: Thank you. Dr. Ortiz-Aguayo?

DR. ROBERTO ORTIZ-AGUAYO: Roberto Ortiz-Aguayo. I voted yes and also support the comments.

DR. KELLY WADE: Randi Oster?

MS. RANDI OSTER: I voted to abstain for the exact reason that everyone stated that they wanted in their yes vote these comments to be added, such as insufficient warnings. My concern was, if I had just voted yes, that it would be lost, and that if I had voted no, it was going to accomplish the opposite. The abstain vote is the one that I believe fully explains to the FDA our expectations to the PAC.

DR. KELLY WADE: Thank you. Jennifer Plumb?

DR. JENNIFER PLUMB: Hi, Dr. Jennifer Plumb. I'm unable to turn on my video. I don't know if you need to see a face for a vote.

DR. KELLY WADE: No. That's fine.

DR. JENNIFER PLUMB: Okay. I also voted yes. I think it'd be pretty hard to sum it up any better than my colleagues have. I think that anything we can do to heighten people's due diligence in thinking about and respectfully and safely using this device is a good one.

DR. KELLY WADE: Thank you. Wael Sayej?

DR. WAEL SAYEJ: Hi, this is Wael Sayej. I voted yes. I echo and agree with the comments mentioned by my colleagues. I have full faith and confidence in the FDA that they will ensure that appropriate warnings are added to the labeling, and I honestly have good faith in Cook, that they will aid the FDA in making sure those warnings are appropriate.

DR. KELLY WADE: Thank you to members of the PAC for that discussion. We can now move onto question two as seen on this voting slide number two. There are multiple clinical factors that can impact the effectiveness of the anastomosis. Does the committee agree that physicians should be given additional information regarding the clinical variables to better identify suitable candidates for the treatment with the Flourish device? The answers are the same: yes, no, and abstain. We will start by any specific questions to the wording of the question. Then we will move on from there.

Hands raised if it's specific comment or question about the wording. If there are no questions or comments concerning the wording of question number two, we will then proceed with the question and open the question for discussion. I would like to remind public observers that, while this meeting is open for public observation, public attendees may not participate except at the specific request of the panel. Simply raise your hand if you would like to comment or question the voting slide number two before us. Great. Dr. Havens, we'll start with you.

DR. PETER HAVENS: Thank you. Presumably, this would be, with inclusion of this material, in the product label, or did the FDA have something more extensive in mind?

MS. JIAN CONNELL: Thank you for your question. Currently, the additional clinical factors, other than the patient less than one year old and with an atretic gap of less than four centimeters and with those specific esophageal atresia types, other clinical factors are not included. Cook proposed the FDA with this additional clinical factors, as I mentioned earlier, patients anatomy or esophageal pouches and also the placement of a PEG tube where the stoma place is. FDA has a pending question to Cook asking exactly what type of information will be collected at Cook's post-approval study. FDA has not received that response yet. I can defer that question to Cook if you feel that would better clarify your question. Also, we want the panel member to maybe give us some advice on exactly what type of clinical factors you think would be helpful for the physician in selecting patient that would be best to maximize the benefit of the Flourish device.

DR. PETER HAVENS: Then, would this be included in the product label? Would it only occur as a part of the training that Cook currently supplies?

MS. JIAN CONNELL: If based on the collection from the post-approval study that there is enough information to make a recommendation, then yes, that would be included in the labeling.

DR. PETER HAVENS: Okay. You're not considering doing this right now? This would be after further information is collected in the post-approval study?

MS. JIAN CONNELL: Correct. Cook said based on currently limited information and the difficulty to recreate a benchtop model applying to this specific patient factors, it's very difficult to do it currently. They propose to do it when they complete the post-approval study. This is a term for the long run, regarding your

response to the first question, to better improve this device and make it most safe-used device. This is something FDA considering that might be helpful to the physicians. Yes.

DR. PETER HAVENS: Got it. Thank you very much.

MS. JIAN CONNELL: Sure.

DR. KELLY WADE: The next comment or question is from Dr. Flick.

DR. RANDALL FLICK: I think this goes without saying, that we should be supportive of this. Obviously, it depends on what the additional information, what the clinical variables are. I would say that this gets back to my earlier comment that, in the absence of an appropriate comparator, it's difficult to determine what are the clinical variables that will identify suitable candidates. I know that the sponsor's doing the best they can, and I applaud them for that. I think understanding how the device performs relative to similar patients will be very important in determining what variables are relevant. Thanks.

DR. KELLY WADE: Thank you. Dr. Jones?

DR. BRIDGETTE JONES: Bridgette Jones, PAC member. Again, I'm struggling with the language here and from what was earlier described as what this question actually means. It's not that we already know the potential clinical factors that impact but the next step would be for the sponsor to collect more data and then those clinical factors be identified for consideration to be provided to physicians as additional information. To me, this question sounds a little bit premature, a premature step, because it states that there are multiple clinical factors or that that's likely so, but we don't know. We also don't know, depending on what's identified, what should be

provided to physicians. The wording here sounds premature with the current information that we have, unless the sponsor or any of the other panelists can provide more information. Are there clinical factors that we do know about now that you would feel strongly that should be provided to physicians now that we know enough information about?

MS. JIAN CONNELL: From my understanding, no, not yet. Does any Cook representative that would respond to this question, if you have a more clear picture now regarding what kind of variables would impact?

DR. KELLY WADE: Yeah. I welcome clarifying comments from a Cook representative if you'd like to do so.

DR. JEFFREY LUKISH: Yeah. Hi, this is Dr. Lukish. Can you hear me or see me?

DR. KELLY WADE: Yes.

DR. JEFFREY LUKISH: Yeah. The number one clinical factor, if we look at all of the MDRs, is the difference between using the device in children with the type C atresia -- that is the atresia with the distal tracheoesophageal fistula -- and the type A atresia, which is the pure esophageal atresia. Those are the two critical clinical factors where the device will perform differently. It should be clearly described to the physicians that are entertaining using this device. By clarifying that to the physicians that are using this device, that will be articulated to the IRB during the approval phase of the HDE.

We've already outlined other clinical factors, gap width of the atresia. We know that atresias that are greater than four centimeters can't be brought together with

this, can't be utilized. Then we talked about also how we are determining that gap width. Those pieces need to be described in the labeling because they are predictive of the effectiveness of the device in creating an anastomosis. I hope that clarifies.

DR. TED HEISE: Dr. Wade, this is Ted Heise, the sponsor.

DR. KELLY WADE: Thank you. Yes, you're welcome to provide comment.

DR. TED HEISE: Yes. Thank you for the question. As we discussed previously with Dr. Lukish and as he just reiterated, there is I think a strong likelihood that prior surgeries associated with correction of type C atresia before use of the Flourish device is very likely to reduce likely chance of success. Understandably and appropriately, FDA typically expects data to support labeling changes. We don't have specific data to support such a change. We do hope to get it from the PAS data collection that's underway. Even with 20 cases, it's not clear that that data will be completely adequate to support such a labeling change. I think we'll just have to see what we get when we get it.

DR. KELLY WADE: Do you have a comment?

MS. JIAN CONNELL: Yes, Dr. Wade. I want to ask Ted if currently you have any specific factors in mind that you collect during your post-approval study.

DR. TED HEISE: Yes. This is Ted Heise with the sponsor. I do think prior surgery is a definite candidate, one we want to look at carefully. Other options could be the type of angulation that may be in place between the gastrostomy and the gastric pouch and whether that compromises the ability to achieve a suitable alignment. That'll be a much more challenging variable to assess. We'll have to rely on what we

can get out of imaging, which is somewhat challenging when you're dealing with maybe at most two views of plain radiographs.

MS. JIAN CONNELL: Thank you, Ted. I know there is a PAC member commenting. This might be pretty much your question, but FDA take this as an opportunity. Based on the small number of the patient who currently use the device and limited information collected, we may not be able to make a conclusion yet. I thought this is an opportunity for us to collect additional data in the post-approval study. Therefore, we already make up our minds that certain information is important and needed for the future patient's use of the device.

Then I would think, why not take this opportunity and collect all this information, and then we complete a study that won't be too late we said, "Oh, PAS already completed. We can't do additional thing." To avoid that, I would rather propose to do it now so when it's conclude, the study, we'll have better information about what's the best recommendation we should provide so the physician would have a more informed use of the device.

DR. KELLY WADE: Thank you. That was helpful. Dr. Dracker?

DR. ROBERT DRACKER: Actually, what Jian just mentioned was exactly what I was going to suggest. Given the small number of patients who have had the procedure and the fact that clinical variables are going to be increasing with time, it needs to be a concurrent and dynamic approach providing physicians with information as they change, supporting really what Bridgette had said as well, that it's really too early to tell or to give advice to clinicians. As long as the company's collecting data and providing the utmost and most concurrent information to the physicians involved with

utilizing the device, I think it makes no sense.

DR. KELLY WADE: Thank you, Bob. I agree as well. It's Kelly Wade. I would just add, too, that we really need to make all efforts of enrolling those patients that had these adverse events because, if we don't have them in our post-marketing study, then we won't have the critical information together to know really where the warnings need to lie. Really I think, again, multiple members of the committee have talked about the importance of enrolling as many patients as we can in the post-marketing study. If there are no further discussion on this question, then we will now begin the voting process.

You should've received an email from the pediatricadvisorycommittee_vote@fda.hhs.gov with voting instructions as you did with the prior question. Please Reply All to the message. When responding, only type your vote, yes, no, or abstain in the body of the message, nothing else. In case you enter technical difficulties, please email the ocoptpacteam@fda.hhs.gov. We will start voting on Flourish question number two. You have 60 seconds.

MS. MARIEANN BRILL: Kelly, this is Marieann Brill. The one minute is up.

DR. KELLY WADE: Thank you. This completes our voting. We will now take a 10-minute break while the FDA compiles the votes. The vote will then be displayed on the screen, and the designated federal officer will read the vote from the screen into the record. This will begin our 10-minute break.

[BREAK]

DR. KELLY WADE: Kelly Wade. Welcome back everyone. This

concludes our break. We will now show the results of vote number two. Marieann Brill, the designated federal officer, will summarize the results.

MS. MARIEANN BRILL: For the vote in question number 2 for the record, there are 14 yes, zero no, zero abstain. Again, 14 yes, zero no, zero abstain. Thank you.

DR. KELLY WADE: Thank you. Now that the vote is complete, we will go down the meeting roster and have everyone who voted state their name, their vote, and if you want to, you can state the reason why you voted as you did into the record. We will start with Angela Czaja.

DR. ANGELA CZAJA: Angela Czaja, member of the PAC. My vote was yes.

DR. KELLY WADE: Bob Dracker.

DR. ROBERT DRACKER: Bob Dracker. I agreed and voted yes with the caveat that data continues to be updated and provided to the clinicians.

DR. KELLY WADE: Dr. Fischer.

DR. GWENYTH FISCHER: Gwen Fischer. I voted yes.

DR. KELLY WADE: Dr. Flick.

DR. RANDALL FLICK: Randall Flick. I voted yes.

DR. KELLY WADE: Dr. Havens.

DR. PETER HAVENS: Peter Havens. I voted yes.

DR. KELLY WADE: Dr. Hoehn.

DR. SARAH HOEHN: Sarah Hoehn. I voted yes.

DR. KELLY WADE: Dr. Holubkov.

DR. RICHARD HOLUBKOV: Rich Holubkov I voted yes.

DR. KELLY WADE: Bridgette Jones.

DR. BRIDGETTE JONES: Bridgette Jones. I voted yes.

DR. KELLY WADE: Jeffrey Lukish.

DR. JEFFREY LUKISH: I voted yes. Can you hear me?

DR. KELLY WADE: Yes.

DR. JEFFREY LUKISH: Yeah. Perfect.

DR. KELLY WADE: Thank you. Gianna McMillan.

DR. GIANNA MCMILLAN: Gianna McMillan. I voted yes.

DR. KELLY WADE: Thank you. Roberto Ortiz-Aguayo.

DR. ROBERTO ORTIZ-AGUAYO: Roberto Ortiz-Aguayo. I voted yes.

DR. KELLY WADE: Thank you. Randi Oster.

MS. RANDI OSTER: Randi Oster and I voted yes.

DR. KELLY WADE: Jennifer Plumb.

DR. JENNIFER PLUMB: Jennifer Plumb and I voted yes.

DR. KELLY WADE: Thank you. Wael Sayej.

DR. WAEL SAYEJ: Wael Sayej and I voted yes.

DR. KELLY WADE: Thank you everyone. We will now move on to question number three. Question number three is on the slide now. It states, "The FDA will report on the following to the PAC in 2022: the annual distribution number, the PAS follow-up results, an MDR review, and a literature review." Does the committee agree with the FDA's plan for continued surveillance of the Flourish device? As usual, we will start with questions specifically addressing the wording of this question before

us. After that, we will move into further comment and question regarding the topic itself. Are there any clarifying questions about the wording of the question?

Okay. If there are no questions or comments concerning the wording of question number three, we will now proceed with the question and open the question for further discussion. I would like to remind public observers that, while this meeting is open for public observation, public attendees may not participate except at the specific request of the panel. The first raised hand I'll call on, Randi Oster.

MS. RANDI OSTER: Yes. Thank you. Randi Oster, consumer representative. I'm wondering if in the bullets we could add in some of the data that we've been talking about today, specifically the breakdown and the segregation of the patient population from the pure to the other kinds of issues that they have, the comorbidities, as well as requesting an understanding of the doctor's and the number of times they've done this to see if there's any correlation between repeat surgeries and learning and the reduction of the adverse events.

DR. LAUREN MIN: This is Lauren Min from FDA. I'll start by addressing your comment about the type of esophageal atresia. That information is being systematically collected from medical records in the post-approval study, which is why we've been saying throughout the day that it's of the utmost importance to get these patients, as many of them as possible, enrolled in the PAS. Outside of this mandated study, I believe that in the non-PAS patients that data will continue to be collected anecdotally as that information is relayed from the treating physicians and the healthcare providers to Cook. On your point about experience of the doctors, that's not something that's required reporting from the FDA's perspective. Perhaps Ted from Cook or another

company representative could address your second point.

DR. KELLY WADE: It's Kelly Wade. If a Cook representative would like to address that comment, you're welcome to speak into the record.

DR. TED HEISE: Thank you, Dr. Wade. Ted Heise for the sponsor. We do have a number of variables on the plan for the PAS data collection, including the type of unrepaired atresia, if the patient had a TEF verification of successful repair and time from repair, the procedures performed to reduce the gap prior to device placement, as well as information on prior thoracic surgical procedures, for example, that may HAVE involved the esophagus. We do not have any specific information regarding the specialty or training of the physicians carrying out the procedures. I expect we can probably get that information, though. Thank you.

DR. KELLY WADE: Thank you. Dr. Havens.

DR. PETER HAVENS: Thank you very much. The first question is will this be the last opportunity for the FDA to review the PAS results, and what if there's an inadequate number of patients included in the PAS?

DR. LAUREN MIN: This is Lauren Min from the FDA. The PAS study will close after the company has met its requirement of providing complete data in 20 patients. As we mentioned before and as Cook has mentioned, we expect that data collection to be completed by the end of next year, which means we hope to provide much of those results to share them with the PAC during fall of 2022. I don't believe it'll be a complete dataset at that point. I believe that in the following year we'll have a complete post-approval study, hopefully. PAS enrollment and data collection will continue until Cook has completed the requirements for that study, which again is 2

years of follow-up or follow-up until study exit in 20 patients. We're really counting on that data to learn more about the safety and effectiveness of the device, particularly concerned about some of the safety issues that we've been talking about today. We'll present more during the next PAC and hopefully a full PAS dataset in 2023.

DR. PETER HAVENS: Thank you. I would urge FDA to consider that its power under the HDE to include an IRB at each site and your ability to demand data collection be used to enhance reporting activity at the sites. This would not necessarily delay anybody's use of the product. In fact, when I want to use an experimental antimalarial that I have to get from the CDC, it is demanded that I get an IRB and it's demanded that I make a report. That could be a part of the use of these. There is no more willing partner than Cook at working with the FDA. They've shown that over and over. This would be a way for the FDA to use its power under the HDE to enhance reporting. This is a critical issue not just for this device but in many things used for rare pediatric diseases. Thank you.

DR. KELLY WADE: Thank you, Peter. Kelly Wade. I'm wondering if I can direct the same topic and a question back to Lauren at the FDA. I was wondering if it's possible to do a preliminary look at that retrospective PAS because they're about 50 percent enrolled right now. I want to make sure that we're able to capture infants that had some of these adverse events because, if we don't have enough of the adverse events in that dataset, it won't be able to inform us with the information that we're looking for. Even a quick preliminary look to see if there are significant adverse events in the dataset may be important now so that moving forward, if more efforts are needed to include certain outcomes, we can do that work now rather than at the end. Can you speak to

that, Lauren?

DR. LAUREN MIN: Sure. Currently, Cook is required to provide biannual reports. I believe their next PAS interim report is due next month, which is great. That will be our next chance to look at, as you said, close to half of the patients that are required for the post-approval study. We're looking forward to that data. The next look will be six months later. So that the committee is aware, we're not waiting full year to have eyes on these data, and we'll continue to communicate with Cook about concerns with MDRs or other issues that are reported as we see them come in.

DR. KELLY WADE: Thank you so much.

DR. LAUREN MIN: Sure.

DR. KELLY WADE: Are there any other clarifying comments or questions from members of the PAC? Okay then, if there is no further discussion on this question number three, we will now begin the voting process. You should've received an email from the Pediatric Advisory Committee Vote with voting instructions. Please Reply All to the message. When responding, only type your vote, yes, no, or abstain, in the body of the message, nothing else. In case you encounter technical difficulties, remember to email the ocoptpacteam@fda.hhs.gov. We will start the voting on the Flourish question number 3, and again you'll have 60 seconds to respond to the vote.

Thank you. This concludes the voting window. We will now take a 10-minute break while the FDA compiles the votes. The vote will then be displayed on the screen. The designated federal officer will read the vote from the screen into the record. This will begin our last 10-minute break.

[BREAK]

DR. KELLY WADE: This is Kelly Wade. The vote is complete and the results are read to display. Unless there are objections, I'm going to bring us back form break two minutes early so that we may also adjourn this meeting on time. Let's see the results. The results are shown on your screen, and Marieann will read them into the record.

MS. MARIEANN BRILL: Thank you. For the final question, question number 3, for the record there are 14 yes, zero no, zero abstain. Again, 14 yes, zero no, zero abstain. Thank you.

DR. KELLY WADE: Thank you. Now that the vote is complete, we will go down the meeting roster and have everyone who voted state their name, vote, and if you want to, you can state the reason why you voted as you did into the record. Angela Czaja.

DR. ANGELA CZAJA: Angela Czaja. My vote was yes.

DR. KELLY WADE: Bob Dracker.

DR. ROBERT DRACKER: Bob Dracker. My vote is yes.

DR. KELLY WADE: Gwen Fischer.

DR. GWENYTH FISCHER: Gwen Fischer. My vote was yes.

DR. KELLY WADE: Thank you. Randall Flick.

DR. RANDALL FLICK: Randall Flick. My vote was yes.

DR. KELLY WADE: Peter Havens.

DR. PETER HAVENS: Peter Havens. I voted yes.

DR. KELLY WADE: Sarah Hoehn.

DR. SARAH HOEHN: Sarah Hoehn. I voted yes.

DR. KELLY WADE: Richard Holubkov.

DR. RICHARD HOLUBKOV: Rich Holubkov. I voted yes.

DR. KELLY WADE: Bridgette Jones.

DR. BRIDGETTE JONES: Bridgette Jones. I voted yes.

DR. KELLY WADE: Thank you. Jeffrey Lukish.

DR. JEFFREY LUKISH: Jeffrey Lukish. I voted yes.

DR. KELLY WADE: Gianna McMillan.

DR. GIANNA MCMILLAN: Gianna McMillan. I voted yes.

DR. KELLY WADE: Roberto Ortiz-Aguayo.

DR. ROBERTO ORTIZ-AGUAYO: Roberto Ortiz-Aguayo. I voted yes.

DR. KELLY WADE: Randi Oster.

MS. RANDI OSTER: This is Randi Oster. I voted yes but I want to go on record that I appreciated the sponsor's willingness to look at the doctors' experience. We discussed today training is an important component of reducing adverse events. I would like that training or the doctor experience to be considered as one of the bullet points in addition to the ones that are there.

DR. KELLY WADE: Thank you. Jennifer Plumb.

DR. JENNIFER PLUMB: Jennifer Plumb. I voted yes.

DR. KELLY WADE: Thank you. Wael Sayej.

DR. WAEL SAYEJ: Wael Sayej. I voted yes and I completely agree with Randi's comments. I am happy with the sponsor's participation so far. Thank you.

ADJOURNMENT

DR. KELLY WADE: Well, thank you everyone. Before we conclude this meeting, this is Kelly Wade and I would like to thank the members of the PAC for their engaging discussion today and participation. I would also like to thank the members of the FDA and the sponsor for the excellent background materials that were provided to us today and the excellent presentations provided as well. I think this has been an important day for us to come together to review the update regarding the Flourish device and to think about outcomes as they regard to successful anastomosis but also safety concerns of adverse events, including those in the MDR.

As you've heard from our discussion today, the committee supports the inclusion of additional warnings in device label, instruction for use, and physician training. Additional warning is an important first step in the ongoing work to optimize patient selection and minimize improper device use and manipulation. I applaud your efforts that are ongoing to gather the necessary data to inform optimal use and patient selection and limit the adverse events in this critical population. We are keenly interested in the clinical variables and site expertise factors associated with successful anastomosis and the safety of device use, including the minimization of adverse events including perforation and the minimization of strictures. I will bring this meeting to a conclusion with that and thank everyone for their participation today.

MS. JIAN CONNELL: I also want to thank the chairperson, Dr. Wade, and all the PAC members on behalf of our FDA team. We appreciate your time and expertise and we value your opinions. We take it seriously. We also thank Cook for the

cooperation with FDA. FDA will continue work with Cook to best improve this device for safe use and optimize use for other uses. Thank you.

DR. KELLY WADE: Thank you very much.

[WHEREUPON THE MEETING WAS ADJOURNED]