

1 and/or anatomy, and that kind--I think that's what you're
2 trying to say. Just by saying vessels or lesion, I mean,
3 it's kind of vague.

4 ACTING CHAIRPERSON TRACY: Okay. So we'll ask
5 that they add morphology or anatomy in there.

6 DR. NAJARIAN: How's that?

7 ACTING CHAIRPERSON TRACY: Sounds good.

8 I think we've already talked about 4C, which was:
9 Please comment on the warning and precautions section as to
10 whether it identifies all potential hazards regarding device
11 use. Any additional comments regarding that?

12 My only comment, just from the standpoint of
13 finding them, it's just a little bit difficult. It might be
14 nice if they--it's fine that they're interspersed throughout
15 the text, but it might be nice to have it put together in
16 one particular--one concise table so that it would be easy
17 to look at it rather than having to kind of go through the
18 whole section.

19 DR. KRUCOFF: Mitch Krucoff. I don't know if this
20 really belongs in the warning section, but to me one of the
21 biggest print items I'd like to see in this package is a
22 message to the users on the importance of your whole team
23 and having the team together and sustaining that team. And
24 we'll come back to this, I think, when we talk about
25 training. But one of my biggest concerns is that as this

1 device becomes more routine in a cath lab, the tendency for
2 us to move cases along and to orchestrate the team work that
3 really is implied in the safe and effective use of this is
4 going to be lost to the larger agenda of moving faster and
5 in general use.

6 So I don't know if warnings and precautions is the
7 place exactly to say it, but to me a warning and precaution
8 that you really need every key member of the team to safely
9 and effectively apply this device in patients is implied in
10 the data and the experience to date.

11 ACTING CHAIRPERSON TRACY: Any other comments?

12 [No response.]

13 ACTING CHAIRPERSON TRACY: Okay. Question 4D:
14 Please discuss whether any improvements could be made to the
15 labeling to help minimize the occurrence of device failures
16 and malfunctions as discussed under Question 2. Maybe
17 that's where some statement being made about the importance
18 of maintaining a team approach to this could be made.

19 DR. AYERS: And this is probably the place to talk
20 about that sheath introducer, too.

21 ACTING CHAIRPERSON TRACY: Okay. Any additional
22 comments on 4D?

23 [No response.]

24 ACTING CHAIRPERSON TRACY: If not, 4E: Please
25 comment on the remainder of the device labeling as to

1 whether it adequately describes how the device should be
2 used to maximize benefits and minimize adverse events.

3 DR. KRUCOFF: Mitch Krucoff. I guess my one
4 concern here is still whether the emergency bail-out
5 procedure is optimally done pulling the guide wire or
6 whether the actual time and exposure involved to--even if
7 you're not sure where the source train is within the system,
8 to backing the system out over the wire, which is something
9 that would take less than a second to do versus something
10 that would probably in skilled hands take maybe 10 seconds
11 to do, but in less than a second you lose the lumen of the
12 vessel by pulling out the guide wire, where in 5 to 10
13 seconds you take the train out and put it in the box but
14 leave the guide wire.

15 I'd like to hear from--actually, if it's
16 appropriate, from some of the people who have used this what
17 they really think. Is the optimal bail-out procedure so
18 urgent that it's worth pulling the wire?

19 DR. : Again, I'm Mohawn (?) from
20 University of Maryland. It's been our experience--again, I
21 think if you look in the data, I think there were six
22 circumstances that the manual removal procedure was
23 initiated. In our clinical experience at the university, I
24 would agree with you that time difference in skilled hands
25 is really not significant, and I think leaving the wire down

1 clinically, at least in our cardiologists' hands, that's
2 much more important of an issue than the actual 10 seconds
3 that it might take to keep it down. So we keep the wire
4 down, but, again, I think that has to be a clinical
5 determination. I don't think that the dosing is so
6 significant, that difference, that we need to make a
7 recommendation that it always has to be pulled.

8 ACTING CHAIRPERSON TRACY: Dr. Popma?

9 DR. POPMA: Jeff Popma. Just in the lab, these
10 are in-stent restenosis lesions that you're dilating, and
11 recrossing the lesion is not usually a big deal. And I
12 think as we're talking about the importance of getting this
13 out and getting it in a contained space as quickly as
14 possible, the fact that there may be some delay in doing an
15 over-the-wire exchange technique and at least given the
16 perception that all this period of time we have no idea
17 where the seeds are is the reason that we said to go ahead
18 and pull everything out.

19 Basically, this is an in-stent restenosis trial,
20 and the patient's had a successful treatment, and to rewire
21 the lesion isn't that big a deal. But I understand if any
22 individual operator has really had difficulty wiring the
23 lesion and it's been very difficult to do, that's a clinical
24 decision they're going to have to make because they may
25 spend another 30 minutes getting it back across the lesion.

1 But the majority of cases, it's more important, I
2 think, to get the device into a box than it is to worry
3 about recrossing the lesion.

4 ACTING CHAIRPERSON TRACY: Maybe I could just
5 summarize to say that there seems to be a divergence of
6 opinion whether it's better to leave the wire or pull the
7 wire, but that that, as an electrophysiologist's point of
8 view, would be an individual experienced operator's choice
9 probably should not be mandated in the labeling for bail-
10 out. I wouldn't think that that would be something you
11 would want to mandate.

12 DR. KRUCOFF: Well, it's already pretty explicitly
13 mandated in what's here.

14 ACTING CHAIRPERSON TRACY: Can you point--I'm
15 having a hard time finding what you're looking at.

16 [Pause.]

17 DR. KRUCOFF: Page 42 of the IFU. It's basically
18 lines 12 through about, whatever, 24.

19 ACTING CHAIRPERSON TRACY: If the source does not
20 return to the active transfer device, is that where--

21 DR. KRUCOFF: Correct. Loosen the hemostatic use
22 for more saline, remove the Beta-cath and guide wire from
23 the patient.

24 ACTING CHAIRPERSON TRACY: All right. Is that--
25 this looks like what they're discussing here, the active

1 source is considered to be lodged in the delivery catheter.

2 DR. KRUCOFF: That's what bail-out's basically
3 for.

4 DR. KRUCOFF: I can take Dr. Popma's point,
5 though. I think that, again, in this--as a well-defined
6 patient population who have in-stent restenosis that's been
7 dilated with a good result before you engage in a radiation
8 direction, that the recrossing with a wire is probably less
9 of an issue than an whole general population, while the
10 indeterminate positioning of the source train--maybe that is
11 the better priority.

12 DR. NAJARIAN: Ken Najarian. No one would argue
13 that you have to remove the catheter system. The question
14 is whether the guide wire comes with it or not. That should
15 be up to the individual doing the case. So why don't we
16 just take out that part that says "and the guide wire from
17 the patient" and just say "remove Beta-cath delivery
18 system," and it's up to the operator whether to--how that
19 person does it. That would make everybody happy.

20 DR. AYERS: Or you could add a note to that. You
21 know, based on clinical--

22 ACTING CHAIRPERSON TRACY: All right, it--

23 DR. AYERS: The clinician's decision, medical
24 decision.

25 ACTING CHAIRPERSON TRACY: That may be fair

1 because it sounds like there was not necessarily the same
2 protocol followed even in all of the centers, so that's
3 probably reasonable. Okay.

4 Then I think we're moving on to--

5 DR. BAILEY: Excuse me. Bailey. If we're still
6 on 4E, I guess if there is a place where one would want to
7 include that information that the sponsor so nicely
8 presented on the interaction between lesion length and
9 efficacy, it seems like this would be the place to include
10 it, with a summary. And even though it's--you know, if you
11 look at enough variables, you can always--you know, if you
12 have basically an 0-5 level treatment effect, you're bound
13 to find some subsets where it's great and other subsets
14 where it's not. But I think this is a logical variable as
15 well, the lesion length and--or any variable that
16 predisposes--that changes the likelihood of restenosis to
17 begin with, you're bound to see most of the treatment effect
18 in patients where there's a highly likelihood of restenosis,
19 whether that's the post-procedure residual stenosis or the
20 lesion length. But, you know, just the fact that you're not
21 likely to see much benefit from this procedure if the lesion
22 length is small, like I don't know what the exact number is,
23 but let's say under 8 millimeters.

24 ACTING CHAIRPERSON TRACY: The only consideration
25 I would have with that is that the data were not broken down

1 or presented in such a detailed fashion as has been
2 previously reported in terms of lesion characteristics and
3 restenosis rates. I'm not sure that we're really given
4 specific enough information to make a determination that
5 that should be stated. I don't know, maybe Mitch or
6 somebody else--does Dr. Najarian or somebody else have a
7 comment on that?

8 I didn't feel comfortable that that was enough
9 information to include here as an additional sort of
10 surrogate indication or surrogate contraindication.

11 DR. BAILEY: Right, and it's not related to level
12 of a contraindication. I think it's more guidance as to
13 which patients are most likely to benefit. And I don't know
14 if that belongs in here or not, but certainly from the
15 public's point of view, it's in their interest to have that,
16 if it's available.

17 DR. KRUCOFF: Mitch Krucoff. My feeling would be
18 that the basic inclusion and exclusion criteria, including
19 the lesion length, range treated with the 20-millimeter
20 balloon and vessel diameter are the heart and soul of the
21 data source. And while we can--we may talk, I guess, at
22 some point later today about what else we would like to
23 know. But I think from a labeling point of view,
24 identifying where safety and efficacy has been demonstrated
25 would be accomplished by addressing the lesion lengths and

1 sizes specified by the inclusion criteria of the protocol.

2 ACTING CHAIRPERSON TRACY: I think that's probably
3 a good point. We can discuss a little bit later what we can
4 do to get at a better idea of what particular patients might
5 be benefiting from this.

6 DR. AYERS: Just a comment while we're talking
7 about pulling the wire and it was mentioned--it was in page
8 412. It's also in the training--

9 ACTING CHAIRPERSON TRACY: Okay. Another--

10 DR. AYERS: It appears several places, an
11 administrative comment.

12 ACTING CHAIRPERSON TRACY: Okay. All right, 4F.
13 Does the panel have any other recommendations regarding the
14 labeling of the device?

15 DR. FREISCHLAG: I would comment that I think
16 perhaps--this is Julie Freischlag--that this should be
17 stated that it should not be used for primary treatment of
18 lesions, mainly for those same knuckle people you talked
19 about, that perhaps they--people would overlook the fact
20 that it's not a restenosis in a stent and it's not for
21 primary treatment and put it in big, bold letters.

22 DR. IBBOTT: Geoff Ibbott. It's already been
23 mentioned that there should be emphasis on the need for the
24 multi-specialty team, and I think it would be appropriate to
25 put a recommendation that there be a multi-specialty team--a

1 cardiologist, a radiation oncologist, and a medical
2 physicist--for the procedures, and as was suggested earlier,
3 that that team be maintained and so they get experience
4 together.

5 I think there should be more dosimetric
6 information made available in the instructions for use, at
7 least what we refer to as radial dose function, the dose as
8 a function of radial distance away from the center of the
9 source, probably out to 10 millimeters, and what we refer to
10 as anisotropy (?) function, the dose around the long axis
11 of the source train, to give the staff the information they
12 need to determine the dose at other points other than that
13 2-millimeter calibration point.

14 DR. AYERS: Geoff, I might mention, there's really
15 two anisotropy functions there, too. If the train becomes
16 separated and you've got the end without the gold marker,
17 and if it's in the normal position you get an end with the
18 gold marker.

19 DR. IBBOTT: That's right, yes. And, in fact, I
20 suppose if the train becomes separated in the middle, then
21 you've got a shorter train, and it would have a different
22 distribution.

23 DR. AYERS: Yes. Dosimetry information is more
24 important in the accident scenario than it is in the normal
25 treatment, to some degree.

1 DR. IBBOTT: That's right. And the final thing I
2 would like to see added is recommendations or recommended
3 procedure for the facility staff to verify the calibration,
4 the source strength by transferring a calibration factor
5 from an ADCL calibrated chamber, as was mentioned earlier.
6 That would be an excellent procedure.

7 Thank you.

8 ACTING CHAIRPERSON TRACY: Okay.

9 DR. KRUCOFF: Cindy, Mitch Krucoff. Can I ask a
10 question either of the experts on the panel or in the
11 audience? What can definitively be said about either too
12 much, a little, and then I guess too little radiation would
13 be like it doesn't exist. But I think we have--and
14 certainly in the panel pack, there are some ideas tossed
15 around that I found very hard to grasp, and I wonder whether
16 it wouldn't be worth including it in the labeling. Do we
17 really know that too much beta radiation destroys cell
18 integrity? Or what happens either in an animal model if you
19 overdose a segment? And then we have also talked about
20 whether a little bit dose is capable of stimulating cell
21 growth? Do we know these things? Are these speculation?
22 Have they been demonstrated in models to the point that it
23 would be worth mentioning in a package labeling that too
24 much beta radiation is likely to promote thrombosis or
25 tissue degeneration, or underdosing relative to prescribed

1 dosimetry levels would be likely to enhance restenosis? Do
2 we know any of this?

3 ACTING CHAIRPERSON TRACY: The only comment I
4 would make regarding a question like that is that we don't
5 have the data here in front of us in this information that
6 we are being asked to discuss the safety and effectiveness.
7 I think that's questions--these are all questions that we
8 need to have as a clinician scientist but not necessarily
9 appropriate for the labeling, I wouldn't think.

10 DR. AYERS: And I think most of the adverse
11 overdose radiation effects are listed under adverse events
12 here in the document, such as arterial damage and that sort
13 of thing, or many of them.

14 DR. KRUCOFF: I guess what I'm just thinking about
15 is, again, rather than have an interventional community kind
16 of casually look at the recommendations and treat this
17 device casually, how important is it to emphasize that
18 positioning, dwell time, and exit time are really important?

19 ACTING CHAIRPERSON TRACY: I think those are fair
20 comments, but I think that maybe just making those
21 statements in there would be appropriate, but I wouldn't
22 speculate beyond that or extrapolate to data outside of what
23 we really have information to support.

24 Okay, if we could move on to issues pertaining to
25 the training program, Question 5. A summary of the

1 physician training program has been provided in the section
2 E and in the addendum to the START clinical report's pages
3 18 through 25. Question 5A: Please discuss any
4 improvements that could be made to the training program to
5 help minimize the occurrence of device failures and
6 malfunctions as discussed under Question 2. Comments?

7 DR. AYERS: Bob Ayers. One thing I noticed from
8 reviewing the training, they have a very limited amount of
9 practice, one or two actual practices with the system,
10 before going to, I guess you'd call it proctored treatment.
11 And I know during--or it's my understanding during the
12 clinical trials that the sponsor limited the ability of
13 their medical institutions to actually, you know, practice
14 with the device on their own. And I think the point was
15 made during the discussions that with experience in using
16 the device and learning how much--you know, it's a lot of
17 finger kind of--is it the right torque? Is it the right
18 pressure, with some indicators such as the leads, that with
19 experience they get better and the error rate goes down.
20 And I just wonder if--I don't think there should be any
21 restrictions, and perhaps there should be more practice runs
22 as part of the training in actually getting the sources out
23 and retrieving them and hold them in place than there is
24 indicated in the present training. It seems to me that's
25 the best method of improving success rate.

1 ACTING CHAIRPERSON TRACY: Would that be sort of
2 expanding on the mock procedure with the entire team until
3 you get it right?

4 DR. AYERS: Yeah, that, and if the medical
5 institution that's doing these procedures felt that
6 additional practice from time to time was appropriate, there
7 shouldn't be any limitation on--whether it is or is not at
8 the present, I don't know, but there certainly shouldn't be
9 any bar to them performing or doing this practice, which I
10 think is a safety improvement item.

11 ACTING CHAIRPERSON TRACY: Okay, so something to
12 the effect that mock procedure with entire team until
13 proficiency of entire team is ensured and follow-up
14 procedures, mock procedures as indicated by team members.

15 DR. AYERS: Yeah. And, in fact, we normally
16 mandate recurrent training at least annually, particularly
17 on emergency procedures, as a normal kind of thing.

18 ACTING CHAIRPERSON TRACY: I think that's--

19 DR. SIMMONS: Or when a new team member is added.

20 DR. AYERS: I'm sorry?

21 DR. SIMMONS: Or when a new team member is added.

22 DR. AYERS: Oh, certainly. Yeah, one of the
23 things that I don't think should happen would be--in some of
24 the more specialized things is what we call pyramid
25 training, where Novoste would train the interventional

1 cardiologist, who would in turn train additional
2 interventional cardiologists. You lose continuity if you
3 dilute the training. You know, the vendor trains the first
4 position who trains the second, who in turn trains the
5 third. That kind of leads to problems. We always like
6 firsthand training.

7 DR. SIMMONS: What about the proctored--I'm not
8 sure that 3 to 5 is something that I'm really that
9 comfortable with either. I mean, if we're going to put
10 something in here, maybe it ought to be more like 10, a
11 minimum of 10.

12 ACTING CHAIRPERSON TRACY: Would it be perhaps
13 fair to say something--a minimum of 3 to 5, but until
14 proficiency is established--if somebody has experience with
15 other systems that are very similar in the future, they may
16 not need 10 proctored studies. So I think it would be time-
17 dependent also.

18 DR. AYERS: Yeah. It isn't so much the count as
19 achieving the objective, what you're saying, until
20 proficiency is established.

21 DR. KRUCOFF: Mitch Krucoff. I would really agree
22 with that. I think if we could identify what the objective
23 is, then rather than creating an impossible sort of training
24 scenario, we could refine a better training scenario. I
25 think as I look at this, one key word that needs to appear

1 is that this is not training that's recommended; this is
2 training that's required, and that it's required with the
3 demonstration of proficiency by certain measures that
4 ultimately would allow the distribution and sale of the
5 device to the cath lab or something along that line, that
6 it's not transferable. You know, if I go to a course, I
7 can't take it back and train Rick or someone else in my
8 stead, that this is primary training. And I guess
9 potentially for all levels of the team, that we're not
10 talking about a pyramid type of training experience.

11 I do think that there should be a means of
12 monitoring then the success of the training, and I think the
13 MDMs are one obvious way of recording procedure to procedure
14 whether a lab team has assembled and whether they have used
15 the device in a reasonable way.

16 I actually think the 3 to 5 proctored cases is
17 probably plenty, that if you have a team that has gone
18 through a training experience and a mock procedure who don't
19 get it by 3 to 5 actual human cases, there's a deeper rooted
20 problem, and it's probably got more to do with the team than
21 the training. I think everybody can recognize that it's not
22 fun as an interventionalist to put something in a human's
23 coronary artery and then be fumbling around and feel very
24 uncomfortable. There's an incentive from the operator's
25 side to get it and to understand how it works and to perform

1 it fairly sleekly.

2 The other thing that, for my two cents, I would
3 not burden either the cath labs or the practice with is
4 retraining. Once you've trained, if you are using the
5 device and the device is not failing, unless it truly
6 becomes a new device, the likelihood that you would unlearn
7 it I think is fairly small.

8 DR. AYERS: I think the retraining is--the way we
9 view it only generally appropriate on emergency procedures
10 which, fortuitously, seldom occur. So that training is lost
11 due to inactive or no use.

12 DR. KRUCOFF: And this is unequivocally planned as
13 an elective procedure, I think, and, in fact, to assemble
14 the team requires sufficient planning right there that you
15 can say this is not going to be an emergency type event.

16 ACTING CHAIRPERSON TRACY: Okay. So the keys seem
17 to be it's mandatory you have to demonstrate proficiency; if
18 the team changes, you have to retrain the new members, and
19 there has to be some surveillance that you're actually doing
20 it right.

21 5B--

22 DR. FREISCHLAG: I have one more comment, which is
23 not going to be popular, but when we've done new devices,
24 the commitment of the company has really impressed me of
25 some companies where, even though we're into the 132nd

1 device placement, there's always someone there from the
2 company. This device has an extra added risk not only of
3 the catheter and screen, but the radiation piece that I
4 guess I wonder about the commitment of the company always to
5 have someone there with the device. After 3 to 5, do you
6 let 70 sites all across the country just put them in and
7 then you find out there was a problem 100 procedures later?
8 Does your rep come in with the device? Because I know with
9 some of the devices we're using, they always come in. They
10 stay. They tell us about what went bad at another site. If
11 there is an emergency, they've done more than you have.
12 Hopefully you've done none. And, therefore, they're very
13 helpful. And I don't know how you put that in there, but
14 the commitment of the company to be always there with you,
15 especially with the first few hundred, I just can't imagine
16 they wouldn't want to be there. The other companies that
17 we've dealt with, they're there, and I think that would make
18 me feel better that the MDMs and everything else that's
19 going to happen, there's somebody very experienced in the
20 room from the company.

21 DR. SIMMONS: Well, I agree. I'm surprised that
22 you're 3 to 5. It makes you uncomfortable. I mean, just
23 something as simple as a pacemaker, you have to beat the
24 reps out the door if you don't want them there. And so to
25 ask them to be there for 10 cases when you've got a 20-

1 percent failure rate or possible malfunction rate on a
2 device, that doesn't seem to be unreasonable to me to have
3 them there for at least 10. And then to have yearly
4 retraining on the emergency protocols, you know, may never
5 happen, but certainly if you're going to have them, you want
6 them to go exactly right. It doesn't seem to be
7 unreasonable to me either. And to make it mandatory, if,
8 you know, a new team member is added also doesn't seem to be
9 unreasonable. That's my opinion.

10 MR. DILLARD: Jim Dillard. Just I'll make a
11 couple comments. The limit to our regulatory authority
12 certainly over the labeling is coming dangerously close here
13 to being well outside the bounds, at least of what our
14 ability is to require some of these. I can just give you a
15 general sense about where a lot of this labeling--and I
16 think you've already given us quite a few great ideas, but
17 the idea of proficiency in areas, trying to come up with
18 some sort of criteria that really demonstrates somebody can
19 actually manipulate and physically use the product to a
20 reasonable degree, as well as some sort of company backing
21 and oversight to help reach that proficiency, I think is one
22 of those things that is very individualized for clinicians
23 and many times is very individualized for a particular team.
24 And that tends to be the approach we take as opposed to
25 mandating some certain number that's a cookbook that we

1 think will determine what proficiency is.

2 So I would think that at least to the extent that
3 you've given us some very useful information, I don't know
4 that you need to continue. I think what you've given us is
5 quite helpful at this point. And I don't know, the company
6 may have a comment about what their commitment is to a
7 training program, and that may be worthwhile hearing. But I
8 thought I'd at least offer that.

9 ACTING CHAIRPERSON TRACY: Yes, let me summarize
10 for the company. We intend to be with you as you need us.

11 [Laughter.]

12 ACTING CHAIRPERSON TRACY: Is that fair enough?
13 All right. 5B, Please identify any other important elements
14 that should be contained in a physician's training program
15 for this device. Anything that we possibly didn't cover?

16 DR. AYERS: I guess the only thing that would be
17 an administrative item, if you're going to require training,
18 you should require that there be at least some sort of
19 certification they received the training.

20 ACTING CHAIRPERSON TRACY: Okay.

21 DR. AYERS: It may be useful for continuing--CEUs,
22 or something else, too, but mainly if you want the training,
23 you should at least have a sheet of paper saying you've
24 successfully completed it.

25 ACTING CHAIRPERSON TRACY: All right. So

1 documentation that training has actually taken place.

2 DR. AYERS: Yes.

3 ACTING CHAIRPERSON TRACY: All right. We'll move
4 on to post-market evaluation, Question 6. The panel pack
5 includes the available one-year data from the START trial--
6 and that's in the addendum to the START clinical report,
7 page 2--the available one- to four-year data from the BERT
8 feasibility trial in the BERT section, and the available
9 data from the BRE European trial.

10 Based on the clinical data provided in the panel
11 pack, do you believe that additional clinical follow-up data
12 or post-market studies are necessary to evaluate the chronic
13 effects of intravascular radiation and administration? If
14 so, how long should patients be followed, and what endpoints
15 and adverse events should be measured?

16 DR. FREISCHLAG: Julie Freischlag. I'll start
17 this one off because I asked all those questions if we know
18 what happens to an artery with the beta energy in it for
19 more than 6 months, and I think the answer was no, we don't
20 know it in a pig or anything else or a human, and I'm very
21 concerned about that. I think that we don't even know what
22 it does to a normal vessel greater than 6 months; therefore,
23 the window of at least 24 months to see what happens, and
24 then heaven only knows longer than that. But as far as the
25 vessel goes, I think 24 months at a minimum to see whether--

1 the worst could come at 12 months. The worst could come at
2 18 months. We don't know because we've only followed 8
3 months. All of these could thrombose, hypothetically, at 12
4 months and then we would determine this was no good.

5 So I think 24 months is minimal comparing it, and
6 also I'm very concerned about the question that Mitch asked.
7 Once treated and then needed to go on to have other
8 treatments or CABG, how do those patients do? Are those
9 vessels now not treatable? Do they have a worse outcome
10 with standard treatments? And we don't know that. So I
11 think we need to watch at least 24 months.

12 DR. AYERS: Previously, and I think it
13 appropriate, would be clinical follow-up about 5 years.
14 With radiation, adverse effects tend to be long term.

15 DR. SIMMONS: So you're suggesting we follow maybe
16 the START patient population that's already been identified
17 out for 5 years?

18 DR. AYERS: Mm-hmm.

19 DR. SIMMONS: And they could then follow up all
20 the patients who then--it's going to be difficult for them
21 to identify the ones that already had interventions for
22 their re-restenosis.

23 DR. AYERS: Yeah, they're no longer blinded at
24 this point.

25 DR. SIMMONS: So they can follow the patients

1 who've gotten radiation therapy who will end up with
2 restenosis or re-restenosis, how they end up doing. So you
3 could just follow that same cohort of patients of 470 for 5
4 years.

5 DR. AYERS: That was a recommendation of the
6 previous one.

7 ACTING CHAIRPERSON TRACY: I think that's--we all
8 would be interested in that. The only caveat I have is, of
9 course, you're dealing with a patient population who has
10 coronary disease, which is not a static population. So that
11 as time goes by and other lesions develop, it becomes
12 difficult to determine the effects of the initial
13 intervention versus disease progression.

14 DR. GRIEM: Griem, University of Chicago. There
15 is some data on intraoperative radiotherapy by Cansella (ph)
16 on patients done at the NCI and late effects above 18 Gray
17 from the single treatment. There's also some data from
18 Gillette, again--and this is on dogs--at about 18 Gray. So
19 I think we're sitting right on the edge of a single dose--
20 and these are photons, not electrons. And there is some
21 data on mycosis fungoides at about 15 Gray single shot on
22 the skin and in the dermis with some quite late effect
23 changes.

24 So I would think that 2 years is minimum and
25 probably 4 years would be a better recommendation for

1 follow-up.

2 DR. KRUCOFF: Mitch Krucoff. Let me at least
3 suggest a context since, again, this is all starting in
4 patients who already have a problem. And as I, when a
5 medical student, learned from Bill Roberts to think about
6 valve replacement as substituting one disease for another, I
7 think that this is a very--these are already patients who
8 are sick, and we have seen pretty unequivocal data that the
9 safety and efficacy of this intervention in the population
10 as defined in the START trial is an actuarial curve that
11 actually starts with the acute procedures inseparably and
12 then widens over time. And while I am certainly on board
13 with all the sentiments and as I've voiced, too, I think we
14 need to continue to follow this.

15 It would seem to me that it would still be
16 appropriate to let the device come forward, even while
17 recognizing that we need to know more about its longer-term
18 behavior and some subsets that longer-term behavior might
19 identify patients who need re-reintervention, et cetera,
20 that this is still a device that's capable of impacting on
21 people who are already sick, and better than the other tools
22 that we would routinely use.

23 So I would hope that while we do pay attention and
24 ask Novoste, you know, for their contribution and looking at
25 all of the unknowns about the long term, that we don't lose

1 track of the fact that these are people who are also sick in
2 the short term, and that the data and the safety and
3 efficacy that we've been shown are really the context that
4 we should be discussing this in.

5 DR. AYERS: Yeah, my comment about longer follow-
6 up was in terms of post-market evaluation, no way indicating
7 that it should stand in the way of present approval. It
8 would just be post-approval continued follow-up.

9 ACTING CHAIRPERSON TRACY: Okay. I think that was
10 the question the FDA was addressing: If this produce is
11 approved, what would be the post-market surveillance? And I
12 think we've covered most of the issues unless Dr. Bailey
13 wanted to specify follow-up on--it might be interesting to
14 follow up specific lesion types over time.

15 DR. BAILEY: Well, I think that would be in the
16 database, you know, if they continue to follow this START
17 cohort for five years, that should be--and as you say, other
18 aspects of coronary disease come into play, but I think that
19 still provides a useful context for what happened--you know,
20 even though this may provide relief in the first 6 months to
21 a year, you know, what is it looking like at 3 years, which
22 doesn't mean that you shouldn't do it, but just it's a
23 context.

24 ACTING CHAIRPERSON TRACY: Okay.

25 DR. SIMMONS: What about this? We had also

1 mentioned before being concerned about the device
2 malfunctions, both major and minor device malfunctions,
3 decreasing with adequate training and the different
4 improvements in the device. I mean, they're not going to be
5 able to address that with the START group of patients, and
6 the only way to do this in a post-marketing is they need to
7 follow 20 sites and 10 patients, or something. We need to
8 come up with a number if we're going to suggest something to
9 show that adequate training and, you know, the device
10 modifications are actually going to decrease this 18- to 20-
11 percent rate of minor device malfunctions.

12 DR. BAILEY: Well, we know that the rate will go
13 down from 15 percent just by redefinition of what's a long
14 time to withdraw the device.

15 DR. SIMMONS: That's true. That's true. Change
16 the rules.

17 ACTING CHAIRPERSON TRACY: Mr. Dillard?

18 MR. DILLARD: Jim Dillard. What might even be
19 more helpful than trying to specify number of patients,
20 which I think that's something that probably, at least in my
21 mind, if you could help us define what sort of endpoints,
22 you know, both safety and effectiveness we would need to
23 gather, perhaps both in--I think what you're suggesting or
24 what I'm hearing you suggest is perhaps potentially a new
25 cohort to look at device malfunctions; whereas, we could

1 follow the old cohort or--not the old, but the cohort from
2 the START trial in terms of looking for those sort of long-
3 term clinical events, it would be helpful perhaps to specify
4 those clinical endpoints and those adverse events.

5 I think if we had those, we could then work the
6 sponsor about the types of analyses that we would need and
7 the numbers that I think would go along with trying to help
8 clarify that.

9 ACTING CHAIRPERSON TRACY: I think we were being a
10 little tongue-in-cheek saying that just redefining what a
11 long time has reduced the number of device malfunctions.
12 But I think that choosing 5 seconds was probably a little
13 bit overly optimistic based on bench testing. But I would
14 think that there would be certain things that have come
15 forth, such as the actual delivery system, following for
16 problems with delivery or withdrawal of the device, any
17 problems that have not yet been seen, such as losing the
18 device somewhere in the vasculature.

19 DR. AYERS: Any bail-outs.

20 ACTING CHAIRPERSON TRACY: Any bail-outs.

21 DR. AYERS: Significant source drifts.

22 DR. KRUCOFF: It would seem to me that if, as a
23 part of the training program, a sort of a reasonable profile
24 of benchmarks of competence were dovetailed into this notion
25 of just following device failure, failure to deliver in the

1 bigger ways, that we might--a strategic might be evolved
2 that could accomplish both at once.

3 DR. AYERS: Most everything we're interested in
4 here falls well below FDA's normal device event reporting
5 criteria. I guess what we're suggesting is they establish a
6 lower threshold of interest for these devices.

7 ACTING CHAIRPERSON TRACY: Okay. I think that
8 answers the questions the FDA posed to us, so at this point
9 we have an open public hearing, and if there are any members
10 of the public that have any comments they would like to
11 make, if they would approach the microphone. Going once?

12 [No response.]

13 ACTING CHAIRPERSON TRACY: Anybody from the FDA at
14 this point who has any additional comments or questions they
15 would like to pose?

16 [No response.]

17 ACTING CHAIRPERSON TRACY: Then finally, if the
18 sponsor has any additional issues?

19 [No response.]

20 ACTING CHAIRPERSON TRACY: Okay.

21 MS. MOYNAHAN: I'd like to read the voting options
22 for today. The Medical Device Amendments to the Federal
23 Food, Drug, and Cosmetic Act, as amended by the Safe Medical
24 Devices Act of 1990, allows the Food and Drug Administration
25 to obtain a recommendation from an expert advisory panel on

1 designated medical device pre-market approval applications
2 that are filed with the agency. The PMA must stand on its
3 own merits, and your recommendation must be supported by
4 safety and effectiveness data in the application or by
5 applicable publicly available information.

6 Safety is defined in the act as reasonable
7 assurance based on valid scientific evidence that the
8 probable benefits to health under conditions on intended use
9 outweigh any probable risks. Effectiveness is defined as
10 reasonable assurance that in a significant portion of the
11 population the use of the device for its intended uses and
12 conditions of use when labeled will provide clinically
13 significant results.

14 Your recommendation options for the vote are as
15 follows:

16 One, approval, if there are no conditions
17 attached;

18 Two, approvable with conditions. The panel may
19 recommend that the PMA be found approvable subject to
20 specified conditions such as physician or patient education,
21 labeling changes, or further analysis of existing data.

22 Prior to voting, all of the conditions should be discussed
23 by the panel;

24 Three, not approvable. The panel may recommend
25 that the PMA is not approvable if the data do not provide a

1 reasonable assurance that the device is safe or if a
2 reasonable assurance has not been given that the device is
3 effective under the conditions of use prescribed,
4 recommended, or suggested in the proposed labeling.

5 Following the voting, the Chair will ask each
6 panel member to present a brief statement outlining the
7 reasons for their vote.

8 ACTING CHAIRPERSON TRACY: Dr. Simmons, do you
9 have a motion to make?

10 DR. SIMMONS: Yes. I'd like to make a motion that
11 we approve the device with conditions.

12 ACTING CHAIRPERSON TRACY: Do I have--

13 DR. FREISCHLAG: Second.

14 ACTING CHAIRPERSON TRACY: Okay. At this point we
15 should discuss what the conditions are that we are asking
16 the sponsor to meet, and then we will vote on each condition
17 separately before we vote on the entire motion.

18 DR. SIMMONS: I guess the first condition that
19 there be a post-market surveillance of 5 years of follow-up
20 or the current START patient population, the follow-up of
21 especially patients that treated for re-restenosis, follow-
22 up of--let's see, was there something else? Oh, and to
23 reanalyze the data on the current START patient population
24 for the 30-millimeter only to establish that there is
25 continued safety and efficacy without that 30-millimeter

1 group enclosed; that there be mandatory education, including
2 recurrent mock training for emergency bail-out or yearly
3 mock training procedures or when a new member is added to
4 the team; that a certification be provided--do we need to go
5 through all of this?

6 ACTING CHAIRPERSON TRACY: How about if we go
7 through one at a time?

8 DR. SIMMONS: Just one at a time.

9 ACTING CHAIRPERSON TRACY: Yes.

10 DR. SIMMONS: Okay. I propose that there be post-
11 market surveillance of 5 years for the START patients and
12 the follow-up especially for those treated for re-restenosis
13 after the radiation therapy.

14 ACTING CHAIRPERSON TRACY: Do we want to include
15 in that condition follow-up on new cohort for device
16 malfunctions, either previously seen or unanticipated? Is
17 that part of the same--

18 DR. SIMMONS: It's part of the post-market
19 surveillance, yes.

20 ACTING CHAIRPERSON TRACY: Okay. All right. So
21 the conditions of post-market surveillance then, follow-up
22 on the initial cohort and observations and data collection
23 on the new patient population for previously seen or
24 unanticipated problems.

25 DR. WILSON: Second the motion.

1 ACTING CHAIRPERSON TRACY: All in favor?

2 [A show of hands.]

3 DR. KRUCOFF: Can we discuss it?

4 ACTING CHAIRPERSON TRACY: Yes, do you have--

5 DR. KRUCOFF: Yes. I would lean toward separating
6 the device malfunction follow-up actually as a part of the
7 training, post-training follow-up. That will give us sort
8 of both at the same time. I'm not sure how we would really--
9 -I'm not sure how I would visualize a device malfunction
10 follow-up that would be systematic for all sites using the
11 device, which is sort of implied, or for just the START
12 sites.

13 DR. SIMMONS: Well, I--I don't know. Mr. Dillard
14 maybe can correct me, but I think that if we mandate a post-
15 market surveillance, whatever they decide with the company,
16 that they have some power to enforce that. If you say I
17 want education, and as part of education maybe you can go
18 ahead and collect this data for me, there would be no power
19 to enforce that type of a suggestion, if you would.

20 MR. DILLARD: Jim Dillard. This is my favorite
21 question. I get it every panel meeting.

22 In terms of your recommendation for post-market
23 surveillance, I think it does carry a little bit more weight
24 if actually what you want to see is some ongoing data
25 collection in a surveillance kind of mode as opposed to a

1 post-approval study where we're really targeting something.
2 Here I think your recommendation, it sounds like to me, is
3 to surveil things like device malfunctions, surveil longer-
4 term START cohort, so that we get a sense of how the
5 patients are progressing over a 5-year period of time, that
6 that does carry more weight than, say, something beyond
7 that, which might be just go out and improve the training
8 program or beef up the educational kind of program.

9 What I think you're recommending, it sounds like,
10 is to actually have some surveillance in the data-gathering
11 mode of some of these either targeted issues that came up
12 during the START trial or some of the device malfunctions
13 that you're talking about. But what I don't hear you
14 recommending, so this is why I'm clarifying it a little bit,
15 is that it be necessarily a post-approval study where we
16 have got targeted kinds of endpoints. It's more of a
17 surveillance-gathering mode so that what we get is a real-
18 live situation of the product and how it's being used.

19 That's what at least I'm hearing your
20 recommendation, and that's how I would interpret it.

21 ACTING CHAIRPERSON TRACY: I think that was the
22 intent of the panel. So then at this point we have the
23 condition. We have a second on that, and the condition then
24 is that there will be post-market surveillance of the
25 initial cohort as well as surveillance of--ongoing

1 surveillance on anticipated problems or problems that had
2 previously been identified with the device. All in favor?

3 [A show of hands.]

4 ACTING CHAIRPERSON TRACY: Opposed?

5 [No response.]

6 ACTING CHAIRPERSON TRACY: Abstain?

7 [No response.]

8 ACTING CHAIRPERSON TRACY: Okay. Your second
9 condition then?

10 DR. SIMMONS: That we reanalyze the data excluding
11 the 30-millimeter group to ensure that the safety and
12 efficacy data doesn't substantially change.

13 ACTING CHAIRPERSON TRACY: Exclusive--

14 DR. SIMMONS: Forty--the 40-millimeter. I'm
15 sorry.

16 ACTING CHAIRPERSON TRACY: Yes, okay.

17 DR. WILSON: Second the motion.

18 ACTING CHAIRPERSON TRACY: Okay. So the motion is
19 to analyze the data of only the 30-millimeter group
20 separately. All in favor?

21 [A show of hands.]

22 DR. BAILEY: Could I ask, what is the outcome of
23 this supposed to be? I mean, just to report back to the
24 committee or to include this in the information that's in
25 the summary?

1 DR. SIMMONS: I had meant it just to look and see
2 that it didn't substantially change the data, not--

3 DR. BAILEY: They won't be significant without the
4 40-millimeter data. I mean, if they were, that would have
5 been included in the packet. So it will be a trend, but, I
6 mean, what's--I'm willing to assume that the 40-millimeter
7 data are supportive, and I guess the question is: What are
8 we going to do with that information?

9 DR. SIMMONS: No, no. I thought we were--I
10 thought the suggestion was that the data that's in the panel
11 pack included both the 30- and the 40-millimeter data as far
12 as determining safety and efficacy, and that it was your
13 suggestion that we eliminate the 40-millimeter data and see
14 that it didn't substantially change the data as far as
15 safety and efficacy.

16 DR. BAILEY: Yeah.

17 DR. SIMMONS: Not that we're going to include the
18 40-millimeter data anywhere.

19 DR. BAILEY: Well, I suspect that the trends will
20 be there. It probably will not be significant at the 0-5
21 level, is my guess, for the clinical endpoints.

22 DR. SIMMONS: It won't be that big a deal for them
23 to go back and pull that data out just to make sure.

24 DR. CRITTENDEN: Even if they do, what difference
25 is it going to make--

1 DR. SIMMONS: Well, if it makes--

2 DR. CRITTENDEN: --withdraw our approval?

3 ACTING CHAIRPERSON TRACY: I mean, it doesn't seem
4 like an onerous thing to ask the company to do. It is what
5 they are asking approval for, so I think if we could just
6 agree to ask--on this condition, we can retake the vote
7 since we didn't have our discussion beforehand, but the
8 condition is reanalysis of the data excluding the 40-
9 millimeter device.

10 All in favor?

11 [A show of hands.]

12 ACTING CHAIRPERSON TRACY: Opposed?

13 [No response.]

14 ACTING CHAIRPERSON TRACY: Okay. Next?

15 DR. SIMMONS: Okay. The next condition is to make
16 education mandatory, that there be a certification letter,
17 at least, that there be mock procedures, that we--let me
18 see.

19 MR. DILLARD: Dr. Tracy, while Dr. Simmons is
20 thinking there for a minute, could I just get you to also
21 think about when you get to the point where--I wouldn't be
22 surprised if Dr. Simmons has a few labeling recommendations.
23 It sounds like there were some in the discussion. Could you
24 also factor in that last condition about the reanalysis and
25 in terms of where we might put that into the labeling?

1 ACTING CHAIRPERSON TRACY: Okay.

2 MR. DILLARD: Thank you.

3 DR. SIMMONS: Okay. That we change the clinical
4 training to establish that the mock procedures are done in
5 such a way to establish competency and that each time a new
6 member is added to the team, that mock procedures be
7 reinstated.

8 ACTING CHAIRPERSON TRACY: Okay. So demonstration
9 of proficiency both with mock and with actual procedures,
10 some certification of proficiency, and new training for new
11 team members.

12 DR. WILSON: I think the word "certification"
13 carries certain connotation that are inappropriate to have
14 inserted here. I think "documentation of" is what we're
15 looking for.

16 ACTING CHAIRPERSON TRACY: Okay. Fair enough.

17 DR. WILSON: Perhaps "competency" is another word
18 that has another set of connotations, like "continuing
19 competency." I don't--

20 DR. SIMMONS: Or documentation of completion of
21 training.

22 DR. WILSON: Right. I think that's--

23 ACTING CHAIRPERSON TRACY: Okay. Any other
24 discussion on this particular condition?

25 [No response.]

1 ACTING CHAIRPERSON TRACY: Do we have a second on
2 the condition?

3 DR. CRITTENDEN: Second.

4 ACTING CHAIRPERSON TRACY: All in favor?

5 [A show of hands.]

6 ACTING CHAIRPERSON TRACY: Opposed?

7 [No response.]

8 ACTING CHAIRPERSON TRACY: Okay.

9 DR. SIMMONS: Okay. Now, I'm not sure what we're
10 going to do for the labeling. I'm not sure--we kind of left
11 that kind of vague as far as what's going to be a
12 precaution, what's going to be a warning, what's going to be
13 a special consideration. I'm not sure I can put that into
14 words.

15 MR. DILLARD: Jim Dillard. Maybe I could help you
16 out a little bit here.

17 DR. SIMMONS: Good.

18 MR. DILLARD: If you could perhaps go through and
19 maybe reiterate some of the highlights about the sections,
20 Dr. Simmons, that you went through which were good
21 recommendations, and I think also what you could do is put
22 into your motion that we look back into the general
23 discussion about the labeling and that we consider the
24 individual panel recommendations at the time as we went
25 through and we had those discussions, and that can be part

1 of your recommendation in terms of what that issue is. And
2 I think that we can go from there.

3 DR. SIMMONS: So rather than just enumerate each
4 one, just say that discussion was made on the changes in the
5 wording of the indications, warnings, precautions, and
6 special considerations that should be made.

7 ACTING CHAIRPERSON TRACY: And if the data is
8 reanalyzed excluding the 40-millimeter, that seems that
9 should be included as a table somewhere analogous to the
10 Table 1, probably, that's in the labeling.

11 Any additional discussion on this point?

12 [No response.]

13 ACTING CHAIRPERSON TRACY: Okay. A second on that
14 condition?

15 DR. KRUCOFF: Second.

16 ACTING CHAIRPERSON TRACY: All in favor?

17 [A show of hands.]

18 ACTING CHAIRPERSON TRACY: Opposed?

19 [No response.]

20 ACTING CHAIRPERSON TRACY: Okay. Were there any
21 other conditions there, Dr. Simmons?

22 DR. SIMMONS: How about the--do we want to
23 specifically mention the bail-out and the guide wire issues?
24 Or do we just want to leave that as part of the labeling
25 issues?

1 DR. KRUCOFF: It's in the context of our
2 discussion, which is what that motion was.

3 DR. SIMMONS: Okay. That's it.

4 ACTING CHAIRPERSON TRACY: Okay. So at this
5 point, I think we have to vote on the entire motion, which
6 is approval for--

7 MR. DILLARD: Jim Dillard. You might just check
8 to see if anybody else has any other potential conditions.

9 ACTING CHAIRPERSON TRACY: I'm sorry. Anybody
10 else with conditions?

11 [No response.]

12 ACTING CHAIRPERSON TRACY: No? Okay. Then--

13 DR. GRIEM: Have we considered Question 6 in the
14 last--the one about the late effects?

15 ACTING CHAIRPERSON TRACY: I'm sorry?

16 DR. GRIEM: In other words, the chronic effects of
17 intravascular radiation administration was included in one
18 of our first proposals.

19 ACTING CHAIRPERSON TRACY: In the post-market
20 surveillance condition. I don't think that we--I think that
21 was not specifically stated, the effects of the radiation,
22 but that would be information that would come from following
23 the initial cohort of START patients.

24 Dr. Wilson?

25 DR. WILSON: Frank Wilson. I was wondering,

1 perhaps it's irrelevant, maybe it's automatic, but do we
2 need to say anything about encouraging the company's full
3 cooperation with FDA, and I suppose NRC and--

4 [Laughter.]

5 DR. WILSON: In the bench testing of engineering
6 modifications that are made. Is that necessary to say?

7 MR. DILLARD: Jim Dillard. I think you just did.
8 Thanks.

9 [Laughter.]

10 ACTING CHAIRPERSON TRACY: Okay. All right.
11 Well, then, we will vote at this point for the
12 recommendation, which was approval with conditions. All in
13 favor?

14 [A show of hands.]

15 ACTING CHAIRPERSON TRACY: Opposed?

16 [No response.]

17 ACTING CHAIRPERSON TRACY: Okay. And if I could
18 ask very brief comments from the individual panel members,
19 any comments they might make as to why they voted as they
20 did on the main motion? Any new comments you'd care to
21 raise?

22 DR. SIMMONS: Me.

23 ACTING CHAIRPERSON TRACY: Anybody. Dr. Ayers?
24 Let's go around the table.

25 DR. AYERS: I'm not voting.

1 ACTING CHAIRPERSON TRACY: I'm sorry. Voting
2 members only, then.

3 DR. BAILEY: I believe the data are supportive of
4 the motion and the conditions are reasonable.

5 ACTING CHAIRPERSON TRACY: Okay. Dr. Crittenden?

6 DR. CRITTENDEN: I voted in the affirmative
7 because the safety and efficacy of this device was supported
8 by the data.

9 ACTING CHAIRPERSON TRACY: Dr. Simmons?

10 DR. SIMMONS: I think this device is safe and
11 effective. I guess I am concerned about the minor
12 development malfunctions, and hope that the company does
13 work hard to try and find out why there are so many minor
14 device malfunctions.

15 I guess I'm also concerned that the dose response
16 curves as far as maximum and minimum effective radiation
17 were really never described. But overall I think this
18 device has shown to be clinically effective and overall
19 safe.

20 ACTING CHAIRPERSON TRACY: Dr. Ibbott?

21 DR. IBBOTT: Well, I would echo Dr. Simmons'
22 comments. I voted in favor because I believe the data
23 support the effectiveness issue. I had some concerns also
24 about the safety, but those have been addressed by the
25 sponsor.

1 ACTING CHAIRPERSON TRACY: Dr. Freischlag?

2 DR. FREISCHLAG: I agree with everything that was
3 said before. I do worry, and will for the next 5 years,
4 about the arteries. There's going to be--this is such an
5 opportunity to show this may work, because I don't work on
6 the heart, as you know, and this type of technology could be
7 applied to other arteries in the body, and we have an
8 opportunity now to follow some arteries and see what happens
9 to them. And if we don't do that, then the application to
10 other sites may be lost.

11 So I'm going to worry but look forward to the 5-
12 year data so we could perhaps apply the technology
13 elsewhere, and this is a great opportunity.

14 ACTING CHAIRPERSON TRACY: Dr. Krucoff?

15 DR. KRUCOFF: I voted in favor because I think in
16 the context of the disease and the study design to address
17 it that the data clearly show this is a safe and effective
18 device for application.

19 I also support the conditions because there are
20 clearly a number of technical unknowns and/or features
21 including design in evolution, and I think that a
22 responsible approach to that is to continue per the
23 conditions some data collection.

24 ACTING CHAIRPERSON TRACY: Dr. Wilson?

25 DR. WILSON: Under the conditions of use that were

1 employed in the START trial, I think that the data confirms
2 that the device is both efficacious and safe. Any concerns
3 I had about the latter in particular, knowing that there is
4 both a human factor and there is a device factor, were taken
5 care of by the responses that I heard, and I think that the
6 conditions that were applied by the panel will assure that
7 that safety is maintained.

8 ACTING CHAIRPERSON TRACY: Dr. Najarian?

9 DR. NAJARIAN: I believe the sponsor was able to
10 prove that the device is safe and effective in a small group
11 of unfortunate patients with coronary artery disease.

12 ACTING CHAIRPERSON TRACY: Dr. Griem?

13 DR. GRIEM: I'm impressed with the device and its
14 design. I'm impressed with the data collected. I agree
15 with Dr. Freischlag. We need to do a little more follow-up
16 and assure us that what we see as a very good report is
17 continued and that we have identified all of the problems.

18 ACTING CHAIRPERSON TRACY: Are there any final
19 comments from the sponsor that they would like to make at
20 this time?

21 MR. GREEN: I think we'd just like to say that we
22 appreciate your time and your review, and we thank you for
23 your recommendations.

24 ACTING CHAIRPERSON TRACY: The meeting is
25 adjourned.

1 MR. DILLARD: And likewise from the FDA, too.

2 Thank you all.

3 [Whereupon, at 5:15 p.m., the meeting was

4 adjourned.]