

1 helpful discussion, one of the things we wanted to
2 focus on were the chronic effects of intravascular
3 radiation. I think we started there, and I'm not sure
4 if we ended there. So I just wanted a little
5 clarification about is your recommendation what I just
6 heard of 650 patients clinically, any angiograms that
7 might be gathered over the time, let's take a look at
8 the vessel area where we actually had the irradiation.

9 I also heard some mention about maybe some
10 function, too. So that maybe if there were some
11 functional sort of outcomes, that we would also take
12 a look at those, irrespective of what the method was.
13 But is that for the effects of intravascular radiation
14 exclusively or were some of those comments toward
15 taking a look more broadly at these patients also over
16 time in terms of a surveillance kind of approach?

17 That would be the only thing I might want
18 a little clarification on. Did that make any sense?
19 Doesn't look like it did.

20 CHAIRPERSON CURTIS: I'm not following it.

21 MR. DILLARD: ^{**} Well, the question was
22 focused on the long term effects of intravascular

1 radiation administration, and I think we started
2 focusing on it, but then I heard a lot of general
3 discussion about these patients also and about some
4 potentially useful endpoints that we might want to
5 look at.

6 Some of them didn't sound like they were
7 necessarily focused on the intravascular radiation
8 portion of this, and differentiating how important it
9 was for the radiation piece of it versus where we
10 might have stenting or another type of approach.

11 I just wanted some clarification about:
12 Was a lot that was talked about here in this
13 particular session -- was it focused on the
14 intravascular radiation portion or just follow-up in
15 general or general surveillance of these particular
16 kinds of patients?

17 CHAIRPERSON CURTIS: I think pretty much
18 the intravascular radiation, unless someone feels
19 otherwise, just because that's -- I mean, these
20 patients are going to have stents in other areas.
21 They are going to have angioplasties, atherectomies,
22 MIs, no MIs, heart failure, everything else.

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1 To really try to nit-pick their clinical
2 course based on what you did to one segment in one
3 artery, I think, is going to be pushing it. I don't
4 think there's that much you can learn.

5 I think the main thing you want to know --
6 If we know -- At least short term, there appears to be
7 efficacy. What we want to make sure is that something
8 bad doesn't happen way down the road.

9 Frankly, you know, one other comment I
10 could make is that if these patients do well over two,
11 three years of follow-up compared to what they would
12 have done otherwise, I'm not sure how much difference
13 it makes if something is stenosis ten years down the
14 road, or the patients themselves would probably be
15 thrilled with the fact that they got a good outcome
16 for a while anyway.

17 So I think I would say that we'd be
18 looking more at the chronic effects of the
19 intravascular radiation than anything else. Yes?

20 DR. MEHTA: I think we're all agreeing
21 that we do need to study the chronic effects of
22 intravascular radiation. How long chronic is can be

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1 debated, and exactly how we should can be debated.
2 But one opportunity that we have that we should not
3 pass up is the opportunity that we have 600 patients
4 on clinical trials with a randomized cohort that can
5 be compared with.

6 The history of radiotherapy is littered
7 with patients who we have said, well, we'll study them
8 as and when clinical events happen. What happens when
9 you do that is you bias all the results in one
10 direction, because you only pick up patients with one
11 or the other event, and you study only those patients.

12 You don't study the control group. Then
13 it becomes very, very difficult to interpret the data.
14 For example, will this type of radiotherapy four years
15 down the road or three years down the road lead to
16 aneurysmal development in some of these arteries?

17 Certainly, some other experiences and
18 other clinical scenarios would suggest that
19 theoretically that's a possibility. Now we might see
20 that on ten patients that are followed out of this
21 whole cohort, and that might be a paper down the road
22 that says nine of ten patients have aneurysms. Well,

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1 what does it mean, nine of ten patients?

2 We should have followed these 600. Now
3 we're not going to capture all 600, but if we have an
4 opportunity now to make a strong statement by
5 following this cohort and, even if we get 50 percent
6 capture rate, that's the only dataset we're ever going
7 to have in the future. It's our only chance to study
8 it.

9 CHAIRPERSON CURTIS: So what are you
10 proposing, routine angiograms?

11 DR. MEHTA: Well, at least maybe one
12 longer term routine angiogram. I don't know what that
13 longer term time point should be, maybe three or five
14 years perhaps.

15 CHAIRPERSON CURTIS: So if we've had
16 patients with repeated angiograms and we've seen
17 what's going on, I mean, we'll have the clinical
18 information. Are you suggesting that if a patient
19 doesn't otherwise have a need for an angiogram that
20 maybe getting one at five years would be appropriate
21 for the problem of potential aneurysm formation?

22 DR. MEHTA: Right.

1 CHAIRPERSON CURTIS: I think that sounds
2 reasonable to me.

3 DR. GRIEM: Currently, I think the
4 angiogram is the only answer. While I was on the
5 other study section here, devices, some resonant
6 fluorine ultrasound agent in bubbles has come out but
7 was not approved because of certain problems, but the
8 images I saw showed vessels -- and this stuff was
9 given intravenously.

10 Suppose that comes along and that's
11 approved finally. I think you're going to change to
12 this less invasive procedure to image this.

13 DR. TRACY: Are we following the non-
14 radiated patients also, because if we're not, there's
15 no point in doing angiograms. There's no point in
16 doing this.

17 DR. SIMMONS: There is if you're going to
18 find aneurysms.

19 DR. TRACY: I'm sorry?

20 DR. SIMMONS: There is, if you're going to
21 find aneurysms.

22 DR. TRACY: But if you're finding an

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1 aneurysm that's clinically irrelevant, what good does
2 it do you?

3 DR. SIMMONS: I don't know if there is.

4 DR. TRACY: I don't think it does you any
5 good. So either you do it or you don't do it. Either
6 you follow everybody, you do angiograms or you don't
7 do it. You follow them clinically, and you obtain the
8 angiograms if they're done. You return them to the
9 core lab and evaluate them for the para-radiated
10 portion of the vessel.

11 Unless we indicate that we want everybody
12 followed, then I don't think that we can indicate
13 special angiograms in the radiated patients. I
14 personally don't think that something that's
15 clinically irrelevant is relevant.

16 DR. SIMMONS: Isn't the problem going to
17 happen as the placebo patients are going to be
18 dropping out like flies? I mean, if they're really
19 talking about 50 percent of these people every year or
20 so are going to have restenosis, they're going to all
21 get ended up crossing over.

22 So you're not going to have five or ten

1 years from now a significant placebo group. But it's
2 still worthwhile information to know, I think, as far
3 as advising patients on what's going to happen to them
4 five years from now.

5 What if you found that ten percent of them
6 had sudden death or that they have aneurysms that are
7 rupturing, and you didn't follow them --

8 CHAIRPERSON CURTIS: That's the thing, is
9 that we don't know that. You know, if there were an
10 aneurysm, you don't know that it would be
11 inconsequential. Maybe it would rupture.

12 DR. TRACY: Then it becomes clinically
13 apparent.

14 DR. WILSON: I don't know if cardiac
15 patients are different than cancer patients, but
16 frequently we build into our clinical trials the need
17 for downstream tests, for example, biopsies or other
18 invasive measures. It's very difficult in the patient
19 who is not having any difficulties, symptoms or other
20 problems to persuade them to undergo an invasive
21 procedure just because of our curiosity.

22 I tend to agree with the comments on this

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1 side of the table that to proscribe this might create
2 a compliance problem, and I think the answer will be
3 revealed just if there is meticulous follow-up of the
4 patients that have already been treated as their
5 clinical course unfolds.

6 CHAIRPERSON CURTIS: Well, you know, I'd
7 say five years is a long time from now, and if in the
8 course of that time with patients who of necessity are
9 going to wind up getting other angiograms anyway, if
10 we start detecting things like aneurysms and problems
11 with them, then if you went back to a patient who is
12 doing well and said, gee, you know, we found this
13 problem, we need to know if you have it, they'll jump
14 on the table, I think, you know, to know if something
15 does get picked up like that.

16 So I think, one way or the other, the
17 information will become clear, as far as that goes.

18 The question about following the sham
19 radiated patients or the placebo patients -- I forgot
20 where the proposal for the post-market study was, but
21 was that to include the placebo patients or only the
22 radiated patients?

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1 DR. DONOHOE: We were following the
2 irradiated patients.

3 DR. TRACY: I think then we have to
4 concentrate then only on that stent section of the
5 vessel, because as we've already discussed, there are
6 so many other things that can affect myocardial
7 function in these patients, and will be affecting both
8 the placebo patients and the radiated patients.

9 We are then forced back to the question of
10 should we look at the in-stent effects of the
11 radiation around and at the stent placement, so
12 looking for things like aneurysms; because if you
13 start extending it beyond that to ventricular function
14 which might concern us, then we're going to be
15 hopelessly lost, I would think.

16 So I think we have to concentrate on
17 specific endpoints that we can look at around the
18 radiated section. But I --

19 CHAIRPERSON CURTIS: I don't know, too,
20 how you look at clinical events in an irradiated group
21 only, you know. Then if you get, you, a ten percent
22 MI rate -- compared to what?

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1 DR. TRACY: Compared to what. We're back
2 to that.

3 DR. HARTZ: Well, if we can believe this
4 protocol, and GAMMA I says there's this economic
5 substudy, Appendix D, which measures all events in all
6 patients -- Is this being done? I mean, I like it.

7 There's this one pot of dollars to treat
8 this disease, and so if it turns out that the
9 radiation patients are going to consume 80 percent of
10 the Medicare dollars, that would be bad. So I hope
11 that this economic substudy is underway, because it
12 pretty much covers a lot of the issues we've been
13 discussing about follow-up studies.

14 DR. DONOHOE: The plan as stated in the
15 protocol is to comply with that, following the
16 patients out to look for repeated events.

17 DR. HARTZ: So there is a group that's
18 specifically designed with this cost/quality adjusted
19 life expectancy?

20 DR. DONOHOE: Yes, there is.

21 CHAIRPERSON CURTIS: I think we're at a --
22 Before we get to the voting section, I'd like to ask

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1 the sponsor if any of you want to make any final
2 comments. Okay. If not, does the FDA want to make
3 any final comments?

4 MR. DILLARD: Not at this time. Thank
5 you.

6 MS. MOYNAHAN: I'd like to read the voting
7 options for the panel.

8 The Medical Device Amendments to the
9 Federal Food, Drug and Cosmetic Act, as amended by the
10 Safe Medical Devices Act of 1990, allows the Food and
11 Drug Administration to obtain a recommendation from an
12 expert advisory panel on designated medical device
13 premarket approval applications (PMAs) that are filed
14 with the Agency.

15 The PMA must stand on its own merits, and
16 your recommendation must be supported by safety and
17 effectiveness data in the application or by applicable
18 publicly available information. Safety is defined in
19 the Act as reasonable assurance, based on valid
20 scientific evidence that the probable benefits to
21 health (under conditions on intended use) outweigh any
22 probable risks.

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1 Effectiveness is defined as reasonable
2 assurance that, in a significant portion of the
3 population, the use of the device for its intended
4 uses and conditions of use (when labeled) will provide
5 clinically significant results.

6 Your recommendation options for the vote
7 are as follows:

8 1. APPROVAL - If there are no conditions
9 attached.

10 2. APPROVABLE with conditions - The panel
11 may recommend that the PMA be found approvable subject
12 to specified conditions, such as physician or patient
13 education, labeling changes, or a further analysis of
14 existing data. Prior to voting, all of the conditions
15 should be discussed by the Panel.

16 3. NOT APPROVABLE - The panel may
17 recommend that the PMA is not approvable if:

18 The data DO NOT provide a reasonable
19 assurance that the device is safe, OR

20 If a reasonable assurance HAS NOT been
21 given that the device is effective, under the
22 conditions of use prescribed, recommended, or

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1 suggested in the proposed labeling.

2 Following the voting, the Chair will ask
3 each panel member to present a brief statement
4 outlining the reasons for their vote.

5 CHAIRPERSON CURTIS: Unfortunately, we
6 lost Dr. Domanski who had another commitment, and he
7 was going to make the motion. So I'm going to have to
8 ask if one of the other panel members would like to
9 step up and make a motion about this PMA.

10 DR. HARTZ: A motion to vote or a motion
11 to approval or a motion to -- what?

12 CHAIRPERSON CURTIS: The motion would
13 either be to approve, to approve with conditions, or
14 that it's not approvable, one of those three options.

15 DR. HARTZ: I'll make a motion to approve
16 with conditions.

17 CHAIRPERSON CURTIS: Seconded. All right.
18 Now what we can do is have a discussion specifically
19 about the motion and about what conditions. If we
20 could -- If any of the panel members has a specific
21 condition they want to propose, please do so. We're
22 going to vote on each condition independently before

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1 we vote on the main motion. Dr. Crittenden?

2 DR. CRITTENDEN: I move that we amend the
3 labeling section as discussed previously. Do we need
4 to be more specific about the details?

5 CHAIRPERSON CURTIS: I guess the question
6 is if the FDA is clear about what we're amending, it
7 doesn't matter. Do you want us to clarify that?

8 MR. DILLARD: Jim Dillard. I don't think
9 --, Based on the labeling section, I think we took
10 good notes. So I don't think we need any
11 clarification there.

12 CHAIRPERSON CURTIS: All right. So we
13 have a motion and a second. Is there any other
14 discussion about the changes to the labeling?

15 If not, can we have a vote on that
16 condition. All in favor, all the voting members? All
17 opposed? All right, so that condition carries.

18 Any other conditions? Remember, this is
19 going to include post-market surveillance.

20 DR. MEHTA: The other condition I have --

21 CHAIRPERSON CURTIS: Use the microphone,
22 please.

1 DR. MEHTA: The other condition that I'd
2 like to propose is that this be carried out with a
3 multi-disciplinary team approach, which would address
4 the patient and physician education -- or at least the
5 physician education component.

6 CHAIRPERSON CURTIS: So then the motion
7 is?

8 DR. MEHTA: In the presence of an
9 interventional cardiologist, a radiation oncologist,
10 and a radiation physicist.

11 CHAIRPERSON CURTIS: Do we have a second
12 for that?

13 [Second.]

14 CHAIRPERSON CURTIS: Any discussion?

15 DR. NAJARIAN: Perhaps in addition, just
16 to involve those people is to have the sponsor provide
17 training in a regulated fashion. In other words, if
18 a team wants to do this procedure at their hospital,
19 then that team of physicians, cardiologists, medical
20 oncologists and physicists would be trained in a
21 training session, you know, to be determined, I
22 guess, not simply that they meet the criteria for

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1 handling the isotopes or that they meet the criteria
2 for delivery of the agent, but that they train
3 together as far as indications and contraindications
4 in a training course provided by the sponsor.

5 CHAIRPERSON CURTIS: So that an
6 interdisciplinary team of physicians and radiation
7 specialists, as outlined previously, be adequately
8 trained and mandated to be present for these
9 procedures.

10 DR. NAJARIAN: I think you phrased it
11 well.

12 CHAIRPERSON CURTIS: Thank you. Other
13 discussion? All right. Then all in favor of the
14 second condition? All opposed? All right, the motion
15 carries.

16 Other conditions? Yes?

17 DR. PARISI: The conditions we've already
18 voted on include reporting on further late thrombosis
19 and the efficacy of antiplatelet treatment on late
20 outcomes that may be adverse, you know, from long term
21 therapy -- is that included in this post-marketing
22 surveillance recommendation that we already made or do

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1 we have to make specific conditions?

2 CHAIRPERSON CURTIS: Well, I think we've
3 discussed post-market surveillance, but we have not
4 made any specific recommendations or had a vote or
5 created a condition about that. So if you would like
6 to propose a condition about post-market surveillance,
7 that would be great.

8 DR. PARISI: I would propose that we have
9 information about the late coronary occlusion rate and
10 late thrombosis rate relative to the proposed
11 antiplatelet regimens, that we have an ongoing
12 registry of that information divulged, and also that
13 we have some mechanism to follow long term the
14 original cohort of patients who receive the radiation
15 with a control group as to what long term adverse
16 effects might ensue from this treatment.

17 CHAIRPERSON CURTIS: So then your motion
18 is that a post-market study is mandatory, and that it
19 would consist of --

20 DR. PARISI: This original cohort of the
21 GAMMA I patients, since we^{**} have a control group who
22 could be followed clinically for long term adverse

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1 effects, and also from their ongoing trials, the
2 patients they have now, at least accumulate the data
3 to make recommendations about long term antiplatelet
4 therapy, how long.

5 CHAIRPERSON CURTIS: So what duration of
6 antiplatelet therapy is adequate?

7 DR. PARISI: Right, so that could be
8 clarified.

9 CHAIRPERSON CURTIS: And your long term
10 study would be at least out to five years?

11 DR. PARISI: Yes.

12 DR. HARTZ: What about the control
13 patients in subsequent trials where we would actually
14 be collecting prospective data, because of the length
15 of platelet therapy. It's been 12 months in the past.
16 I would -- I don't know if this is feasible
17 financially, but like to continue the control patient
18 surveillance in subsequent studies as well as in GAMMA
19 I.

20 CHAIRPERSON CURTIS: Well, first let me
21 see if we have a second for the motion?

22 [Seconded.]

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1 CHAIRPERSON CURTIS: Okay. Now discussing
2 it, you're saying that the control patients --

3 DR. HARTZ: Yes. Is it feasible to
4 continue to do the same post-market surveillance on
5 the control patients in the subsequent trials?

6 CHAIRPERSON CURTIS: I think one of the
7 concerns I have is that, if you have this product
8 released and you have patients who have had, as the
9 one patient example, multiple procedures and multiple
10 restenoses and stents, at what point do you stop being
11 able to keep the patient in the placebo group and not
12 be able to offer them the radiation treatment.

13 I don't think you could keep somebody --
14 You can't keep them in a control group for five more
15 years just to see what's happening. I just don't
16 think it's feasible. So what do we do with a control
17 group?

18 DR. PARISI: Well, some of them won't
19 cross over, and at least we'll know what happens to
20 them, because they will have other angiograms, because
21 they will have problems in other branch vessels.

22 DR. SIMMONS: But you're talking about old

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1 patients, not new patients.

2 DR. PARISI: I don't think it's relevant
3 at this point.

4 DR. SIMMONS: You can't enroll new
5 patients in a control group. You can have new
6 patients in a registry where you could follow patients
7 for at least one year and determine late restenosis
8 rates and see if antiplatelet therapy for one year
9 significantly reduced it compared to the studies that
10 are going to be the historical control, but you can't
11 randomize somebody to a placebo group on a released
12 therapy. You can't mandate that, I don't think.

13 DR. HARTZ: The specific issue I'm trying
14 to get at is if you put a stent inside of a stent and
15 don't radiate it, do the patients require the same
16 length of antiplatelet therapy as do those who do get
17 radiated with a new stent.

18 So that I would like to at least see a
19 subgroup of those control patients followed in the
20 same fashion with the same intensity as in-stent
21 restenosis with radiation get.

22 DR. PARISI: But we do that all the time

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1 now. That's just done. We put stents inside of
2 stents now. The problem is that some of those
3 patients get further restenosis, and some you get away
4 with. So -- But the recommendations for those are
5 pretty standardized. So the question is --

6 DR. HARTZ: How long is that antiplatelet
7 therapy? Two weeks?

8 DR. PARISI: It's usually a month.

9 DR. HARTZ: I just see a loss of
10 standardization here. I'm trying to figure out a
11 handle on how to make sure that the same things are
12 happening to all the patients.

13 DR. BAILEY: Wasn't the proposed condition
14 to follow both arms of all of the --

15 DR. HARTZ: That's how I understood it.

16 DR. BAILEY: -- trials?

17 DR. PARISI: Well, yes, at least the
18 existing --

19 DR. BAILEY: For clinical.

20 DR. PARISI: -- particularly, GAMMA I,
21 though. "

22 DR. BAILEY: For clinical outcomes long

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1 term.

2 DR. PARISI: I'm not proposing future
3 trials be -- this be done for the future. I think you
4 have enough of a database here to work with.

5 MR. DILLARD: Jim Dillard. I think the
6 suggestions that are being made right now in terms of
7 leaving it to the FDA to try to handle things like
8 standardization, try to standardize as best we can,
9 try to work with the data that we currently have and
10 try to make the best out of it in terms of the post-
11 market period, in answering two issues that I heard,
12 which is post-market on antiplatelet therapy and
13 trying to figure out what appropriate antiplatelet
14 therapy is, as well as post-approval on the premarket
15 cohort.

16 Both of those, it sounded like, were for
17 five years. I was not clear about how much further or
18 if there was a need for a registry, but I think, to
19 the extent that you want to make a recommendation to
20 us in this arena to say here are some things you ought
21 to consider when you are considering the post-market
22 phase, I think would be good by way of recommendation.

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1 I don't know that you need to come to a consensus on
2 each one of the issues.

3 CHAIRPERSON CURTIS: I think those are the
4 main issues, as you just stated them. Is there
5 anything that's been left out? Any further discussion
6 on the post-market studies?

7 DR. MEHTA: I just have a question. One
8 of the questions I have, and this perhaps might be an
9 FDA question to try and address -- Iridium-192 is
10 commercially available. What we talked about today is
11 a device that puts Iridium-192 in a location.

12 How will the FDA regulate other commercial
13 Iridium-192 sources not necessarily tied to this
14 device from being used?

15 MR. DILLARD: Jim Dillard. We, obviously,
16 regulate medical devices, and we don't regulate the
17 practice of medicine, and a number of things we've
18 talked about today like certification of specific
19 individuals is not something that we necessarily
20 tackle.

21 In a situation like this -- and I don't
22 know if you can envision an entity like this, but at

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1 least my thought process about what we're talking
2 about here is some sort of catheter system, some sort
3 of shielding source, some way to deliver the
4 particular active Iridium source for some certain
5 amount of time, then shielding it again, withdrawing
6 it from the source area, perhaps placing a stent
7 before or after that particular situation.

8 So what we're really talking about is an
9 overall system to perform this particular type of
10 therapy. So I think the way we're looking at this is
11 an overall system that's going to have indications for
12 use that cover all of that type of procedure that
13 we're talking about that was performed in the clinical
14 study.

15 Could we envision something that could be
16 a bare wire source that could somehow be placed down
17 through a catheter, not irradiate the whole way down,
18 irradiate for a certain amount of time, and withdraw
19 it and be its own sort of stand-alone delivery device?
20 I can't sit here and envision that.

21 So I don't know that today I'd be
22 concerned about that. I think we would handle a

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1 similar delivery system that included a catheter, a
2 source, very similarly to the way we are handling this
3 one, if that helps clarify.

4 DR. AYRES: I guess I could add something
5 to that, too. Whereas, the FDA doesn't regulate the
6 use, we do. Unless it was approved for that use, it
7 has to go through a separate approval process on our
8 part, which is called a shield, source and device
9 review, radiation safety review and registration.

10 Unless that's accomplished, which includes
11 appropriate use, we won't authorize it. In other
12 words, we won't license one of our licensees to use
13 this, and agreement states also follow this same
14 process on shield, source devices.

15 CHAIRPERSON CURTIS: Any other comments on
16 the post-market study? If not, then I think we could
17 vote on this condition. All in favor? All opposed?
18 The motion carries.

19 Any other conditions that anybody can
20 think of?

21 DR. WILSON: We dealt with the warning
22 adequately, the wording of that?

1 CHAIRPERSON CURTIS: I think we had a
2 motion about the labeling changes, and they said that
3 they took their notes on that.

4 If there are no other conditions, then I
5 think we could vote on the main motion. The motion on
6 the table is that the PMA is approvable with
7 conditions, and the conditions as we've already
8 outlined them.

9 MS. MOYNAHAN: I can restate the
10 conditions that you mentioned. The first was to
11 amend the labeling as was discussed; to require the
12 multi-disciplinary team approach, and that included
13 the training to address the team approach; and the
14 post-market study, which is on the original cohort,
15 for five years. There are some other details that
16 were discussed as well.

17 CHAIRPERSON CURTIS: Okay. If there are
18 no other questions, all in favor of the motion? Oh,
19 we have to do individually? All right. Well, we'll
20 go around the table. Dr. Bailey?

21 DR. BAILEY: I'll vote in favor of the
22 motion. I believe that efficacy as defined in the

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1 proposal is persuasive, and that this is an important
2 device at least for short term treatment of an
3 otherwise untreatable condition.

4 CHAIRPERSON CURTIS: Dr. Tracy?

5 DR. TRACY: I vote in favor of the motion
6 with the conditions as stated.

7 CHAIRPERSON CURTIS: Dr. Wilson?

8 DR. WILSON: I vote in favor of the
9 motion. I'm persuaded by the presentation made that
10 efficacy was demonstrated, and with the conditions
11 that we voted, I think safety is assured.

12 CHAIRPERSON CURTIS: Dr. Najarian.

13 DR. NAJARIAN: Yes. I vote in favor of
14 the motion. I think this is a subgroup of patients
15 who otherwise would not be offered adequate treatment.
16 This is a good device.

17 CHAIRPERSON CURTIS: Dr. Crittenden.

18 DR. CRITTENDEN: I vote in favor of the
19 device with conditions, and I would agree that there
20 is clinical benefit for patients in this regard, and
21 that the device is safe.

22 CHAIRPERSON CURTIS: Dr. Simmons.

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1 DR. SIMMONS: I'll vote in favor.

2 CHAIRPERSON CURTIS: Dr. Hartz?

3 DR. HARTZ: I vote in favor of the device,
4 and I'm convinced of the acute safety of the device.
5 I'm not convinced about efficacy, which is why I feel
6 strongly about post-market approval, and I would
7 certainly strongly recommend to the investigators that
8 they continue to look for an experimental model to
9 settle some of the radiologic issues.

10 CHAIRPERSON CURTIS: Dr. Parisi?

11 DR. PARISI: I vote in favor. I thought
12 there was good angiographic substantiation of efficacy
13 which translated into clinical effectiveness with less
14 revascularization procedures.

15 I still think the data is a little fuzzy
16 as to how patients should be handled long term, but I
17 think the conditions will allow that to be solved.

18 CHAIRPERSON CURTIS: Dr. Mehta?

19 DR. MEHTA: I vote in favor of the motion,
20 because I believe these patients have limited options.
21 Radiation is a local modality and, when we look at the
22 local endpoints, efficacy has been demonstrated.

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1 I do remain somewhat concerned about local
2 complications which need to be followed further.

3 CHAIRPERSON CURTIS: And Dr. Griem?

4 DR. GRIEM: I vote in favor of the motion.
5 I believe that it's well conceived. It has good
6 bases, and I think the essential thing is that the
7 dosimetry and the fine details which will be involved
8 in follow-up and the comparison are important in the
9 analysis.

10 CHAIRPERSON CURTIS: Okay. Well, the
11 motion carries.

12 MR. DILLARD: A couple of closing
13 comments. I'd just like to thank this multi-
14 disciplinary team here today for reviewing this PMA
15 and providing us with a recommendation.

16 I also would like to thank the sponsors as
17 well as the audience that was here today. Thank you
18 again for a successful panel meeting.

19 CHAIRPERSON CURTIS: We stand adjourned.
20 Thank you.

21 (Whereupon, the foregoing matter went off
22 the record at 5:05 p.m.)

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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: Circulatory System Devices Panel of the
 Medical Devices Advisory Committee

Before: DHHS/FDA

Date: June 19, 2000

Place: Gaithersburg, MD

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



A handwritten signature in black ink, appearing to be "K. M. [unclear]", is written over a horizontal line.