

1 DR. DUFFELL: A comment on the word
2 significant. I mean, I think, you know, we in the
3 clinical research area certainly interpret it
4 sometimes statistically, but I think we need also to
5 remember, most people who read this stuff are not
6 likely, I don't think, to interpret significantly in
7 that way. Certainly, patients would not, I don't
8 believe. Not many of them think of .05 and what that
9 means.

10 So maybe it could be clinically
11 significant or something like that, to define what the
12 term means. But I just think sometimes in these
13 discussions we get carried away with how we view
14 things in our own world, and it's not necessarily the
15 way the real world looks at them.

16 CHAIRMAN PATOW: Good point. Well, given
17 that, what I'm hearing is that there is some
18 discomfort over positioning this second sentence,
19 speech perception test results, etcetera, with the
20 first sentence, in that one seems to support a
21 scientific validity for the other.

22 I'm now less certain about this issue of

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1 significant, although without a validated test, one
2 wonders what significant means. Dr. Francis, help me
3 out.

4 DR. FRANCIS: Well, I'm still
5 uncomfortable with the term significant. I think that
6 in many ways in our minds significance, statistical
7 significance, doesn't necessarily imply a strong
8 effect. In parlance, we very often use significant to
9 mean something very significant, something very
10 strong. I really don't think we can support either at
11 this point.

12 CHAIRMAN PATOW: You wouldn't support the
13 claim at all?

14 DR. FRANCIS: Not significant.

15 CHAIRMAN PATOW: Not significantly. Let
16 me just -- For a different approach, is there -- would
17 the panel consider just the claim to be "when
18 listening to speech, the Vibrant Soundbridge was
19 preferred over presurgery hearing aid in various
20 listening situations." Dr. Kileny.

21 DR. KILENY: I think this would be -- This
22 would work, but if you want to keep the second

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1 sentence, then reverse the order, beginning with
2 "Speech perception test results in a controlled
3 soundfield environment did not demonstrate," etcetera.
4 Then the next sentence would be, "However" -- you can
5 add that -- "when listening to speech, the Vibrant
6 Soundbridge was preferred over the presurgery hearing
7 aid in various listening conditions."

8 That really does reflect exactly the
9 findings of the study.

10 CHAIRMAN PATOW: Comments by the panel?

11 DR. DUFFELL: I agree.

12 CHAIRMAN PATOW: Dr. Duffell agrees. I
13 think there appears to be a consensus on that
14 approach. Thank you, Dr. Kileny.

15 There was a proposal to combine claim 6
16 and 7 earlier. Were you able to write that down? The
17 proposed wording now would be: "The Vibrant
18 Soundbridge significantly improves the patient's
19 perceived benefit in many listening situations, such
20 as familiar talkers, ease of communication,
21 reverberation, reduced cues, background noise,
22 aversiveness of sounds, and distortion of sound."

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1 Let me read that again. This would become
2 claim 6. I guess we would do some renumbering here.

3 "The Vibrant Soundbridge significantly
4 improves a patient's perceived benefit in many
5 listening situations," and then a list of those
6 situations. Dr. Roeser?

7 DR. ROESER: I have a question about --
8 Would it be possible to use any or all of those words
9 in a marketing attempt? That's a question for the
10 FDA. So could I take one of those words and
11 capitalize on it?

12 CHAIRMAN PATOW: Meaning could the claim
13 be broken up into multiple small claims? Is that --
14 so that only one of those would be taken out of
15 context? Why is that important? I think the intent
16 here is that we would have a claim that would have
17 these, and it would be viewed as a total entity, but
18 I invite comment by the FDA.

19 MS. BROGDON: I don't know the answer to
20 that. There's another office that actually controls
21 advertising and promotion, but if you have strong
22 views on that, for instance, that one should not be

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1 separated from the other examples, then you ought to
2 say that.

3 CHAIRMAN PATOW: Thank you.

4 DR. ROESER Well, I think the point that
5 we discussed earlier and it was brought up to us is
6 the fact that this could be -- This is a marketing as
7 well as a performance issue in that, if we are going
8 to include those, then my feeling would be that they
9 should be included as a whole and not separated out as
10 individual conditions.

11 CHAIRMAN PATOW: Other comments by the
12 committee on the combined claim? Is there a consensus
13 that this is an appropriate wording of the two claims
14 put together? So the plan then would be to combine
15 claims in 6 and 7 into this new claim. I appreciate
16 the efforts of the sponsor in producing this for us.
17 That's very helpful.

18 Any other discussion then on question 6
19 before we move on to question 7?

20 Question 7 states: "In the clinical trial
21 patients with bilateral hearing loss were monaurally
22 implanted.

1 "(a) Should the intended use statement
2 explicitly state that the device is intended only for
3 monaural implantation in patients with bilateral
4 hearing loss?"

5 Comments by the panel? Dr. Roeser.

6 DR. ROESER I would agree with that, and
7 I would also like to point out the fact that, when we
8 are looking at these claims -- and this was brought up
9 today; it wasn't part of the information that was part
10 of my packet -- that the patients in the study were
11 wearing acoustic hearing aids on their non-implanted
12 ear.

13 So I think, as we review the claims, we
14 need to remember that, because the data are collected
15 from patients who were wearing the middle ear implant
16 on one ear and an acoustic hearing aid on their non-
17 implanted ear. So we're really not comparing the
18 middle ear implant to a hearing aid. We're comparing
19 middle ear implant condition with the use of a
20 simultaneous acoustic hearing aid on the non-implanted
21 ear to the hearing aid condition.

22 So it's just an overall issue that I think

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1 we need to keep in mind.

2 CHAIRMAN PATOW: Is there a particular
3 reason that you would oppose having a binaural
4 implant? I'm just -- or anyone else on the committee.

5 DR. WOODSON: Well, you can look at the
6 analogy for stapedectomy. I guess initially people
7 were afraid to do both sides, because they were afraid
8 of long term sequela, and now pretty much people do
9 one side and, if that works, then they do the other
10 side.

11 I guess you just -- The only reservation
12 would be what if we put this in, and then ten years
13 from now something awful happens? We don't have any
14 basis for expecting that's going to happen, but that
15 would probably be the only reason not to do it on both
16 sides other than the cost factor.

17 CHAIRMAN PATOW: Dr. Gulya.

18 DR. GULYA: I just don't see any data on
19 the effectiveness of bilateral implantation. I think
20 that's a whole different study. My take on this
21 question was what do we advise the patient who is
22 electing implantation on one side, what should they do

1 about the next?

2 It seems like what is implicit and perhaps
3 should be made explicit is that they are recommended
4 to either -- well, to have their hearing aided on the
5 opposite side. It would seem to make eminent sense to
6 have a general discussion of the benefits of binaural
7 hearing as part of the patient counseling, and
8 introduce them to the fact that they would more than
9 likely, as we saw with Dr. Fabry's data, 80 percent of
10 them are wearing their hearing aid in the other ear.

11 I would feel pretty comfortable with that,
12 but we don't have any data regarding bilateral
13 implantation, and that's a totally different study.

14 CHAIRMAN PATOW: Would you see that study
15 as being another post-market study that might be
16 considered?

17 DR. GULYA: Well, bureaucratically, I
18 don't know. I'm not clear if that is the way the FDA
19 would proceed. I mean, the marketing intended use for
20 this appears to be implicitly the unilateral
21 implantation. If they were to go looking for data to
22 support bilateral implantation, I would expect that

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1 they would need to develop additional studies to do so
2 rather than willy nilly -- and indeed we do stapes
3 bilaterally, but we also have the impression that
4 patients aren't quite as thrilled, although they get
5 the hearing benefit. They're not thrilled that the
6 second one as they are with the first.

7 So there may be a diminishing return with
8 the implantation.

9 CHAIRMAN PATOW: Dr. Duffell.

10 DR. DUFFELL: This kind of a question is
11 something that's relatively generic to industry, and
12 it has a big impact on us. So that's why I want to
13 make this comment.

14 I think it's really important that the
15 panel recognize that, unless the company is planning
16 on marketing this thing for bilateral, that if you put
17 such a statement in the labeling, you've done a couple
18 of things.

19 Number one, in the cases of reimbursement,
20 should that be an issue with these products, you may
21 have just tied your hands and your patient's hands
22 unnecessarily on getting reimbursement for it.

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1 Number two is liability. Should you elect
2 to do it as a physician and have done it in contra to
3 the labeling, you've opened yourself up for liability
4 and, needless to say, the company gets involved in it
5 as well.

6 You know, I think what I've seen done in
7 some other medical devices is -- and, in fact, in my
8 own device, for example, we have a statement in our
9 labeling under the area of precautions that just
10 simply says just what you just said. That is, we
11 don't have any data.

12 I think the statement in ours is -- and
13 I'm not suggesting this is what it would be, because
14 that's for them to work out. We don't need to do
15 Symphonix's work -- that the safety and effectiveness
16 of bilateral implants is yet to be established.

17 If the company wants to do that under
18 post-market surveillance, then they can open up an
19 application with FDA and pursue that as a labeling
20 claim. I think what is important, you know, from a
21 consumer standpoint -- we don't have that person here
22 today, but -- is that we just make sure that the

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1 company is not put in a position to market it for that
2 as a bilateral implant.

3 I think, by having put the presence of
4 such a precaution in the labeling, it doesn't condemn
5 it. It doesn't tie your hands liability or insurance-
6 wise or reimbursement-wise, or prevent it, but merely
7 again provides what I call full disclosure: I don't
8 know. So in the absence of that, you proceed at your
9 own risk.

10 If it becomes an issue from a post-market
11 standpoint where the agency recognizes widespread use,
12 it's always within their prerogative to require that
13 the manufacturer seek appropriate labeling, which may
14 in this case require the clinical studies or -- We
15 don't like hearing it, but -- warn against it.

16 Then in that case now, we've done what we
17 were kind of talking about right now, which I would
18 suggest the panel strongly not do at this stage of the
19 game, because there's no evidence to point that it
20 would be hazardous or a safety issue.

21 CHAIRMAN PATOW: ^{**} Other comments? Is the
22 panel comfortable with the suggestion that we

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1 recommend there be a statement that the safety and the
2 efficacy of bilateral implants has not been
3 established? There is a consensus for that.

4 7(b), the question is: What advice should
5 be given to the patient regarding the use of
6 amplification in the contralateral ear?

7 I think we've actually understood now that
8 most of the patients actually do use amplification in
9 the contralateral ear. Any other comments of the
10 panel? Dr. Roeser.

11 DR. ROESER: Since all of the subjects in
12 the study wore a hearing aid on their non --

13 CHAIRMAN PATOW: I think it was 70
14 percent.

15 DR. ROESER: Seventy, was it?

16 MS. ARTHUR: Excuse me. Preoperatively,
17 96 percent of those were binaural amplification.
18 Post-operatively is actually 77 percent, not 70
19 percent.

20 DR. ROESER: Most of them. What would be
21 -- Could I ask the manufacturers to respond. Since
22 that was a preferred mode, is that something that the

1 manufacturer intends to recommend?

2 MS. ARTHUR: As we stated earlier this
3 morning, Symphonix supports binaural amplification.

4 CHAIRMAN PATOW: Thank you. Any other
5 comments then by the panel on the questions for panel
6 discussion? We've gone through them individually.
7 Anything come to mind that we want to go back to
8 before we move on?

9 What I'd like to do now is actually to go
10 back through the claims in order. I think on many of
11 these we've made some suggestions, and I just want to
12 be sure that we have captured those suggestions
13 accurately.

14 Claim number 1 states: "The Vibrant
15 Soundbridge does not adversely affect residual
16 hearing." There was a suggestion that that be
17 modified "For most subjects, the Vibrant Soundbridge
18 does not significantly affect residual hearing."

19 Comments from the panel? Yes, Dr. Kileny?

20 DR. KILENY: Well, I would just like to
21 bring up this suggestion again. I made a slight
22 change. So if I may, I would like to read it again,

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1 and see where this would go.

2 CHAIRMAN PATOW: Please.

3 DR. KILENY: "The Vibrant Soundbridge may
4 adversely affect residual unaided hearing. The range
5 of threshold shift in the study population was 3 to 18
6 dB with a majority experiencing less than 5 dB
7 threshold shift."

8 CHAIRMAN PATOW: Comments of the panel?
9 Dr. Francis?

10 DR. FRANCIS: A lot more accurate, but I
11 guess it -- I wonder if there is another way we can
12 state it so that the lay public may be able to draw
13 something out of it. I'm just trying to think also of
14 the practicality of the statement for the consumer,
15 sort of.

16 CHAIRMAN PATOW: I think one of the issues
17 that was voiced before was we have a small population
18 of patients here and, if we specify up to 18 decibels,
19 that that, in fact, may not be the case after another
20 100 patients are done. It may be a better experience
21 or it may not be as good an experience.

22 Is there a way perhaps to relook at that

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1 phrase so that it is perhaps more general as opposed
2 to being as specific?

3 DR. ROESER: Could we say "may adversely
4 affect residual hearing for a few patients" or "in
5 some patients"? That gets away from the numbers and
6 the issue that was raised about 18 dB and what if a
7 patient has 30 dB.

8 CHAIRMAN PATOW: Is the panel comfortable
9 that that accurately reflects the available data?

10 DR. WOODSON: Of course, that's more of a
11 warning than a claim. I mean, a claim is supposed to
12 be something good. So I mean, you can claim that very
13 few patients have any hearing loss or something like
14 that, but I mean, we better make sure it's on the
15 right section in the labeling.

16 CHAIRMAN PATOW: Dr. Gulya?

17 DR. GULYA: I have an alternative
18 proposal. See how you like this. "The Vibrant
19 Soundbridge does not affect residual hearing for most
20 subjects; however, small numbers of subjects" -- and
21 this may be prone to FDA-specific language for
22 different percentages -- "but a small percent of

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1 patients" or "some patients may experience hearing
2 loss."

3 So that tells you that most of the people
4 didn't, but some do, and it leaves open what the
5 degree of hearing loss is, and that is something that
6 the individual practitioner can discuss with the
7 patient. So it gives a claim, gives a warning, and
8 opens the door for further discussion. I would think
9 that would be protecting a consumer so that they know
10 that there is something there to check into, but it's
11 not a -- perhaps not a horrible ogre.

12 CHAIRMAN PATOW: So it would -- "The
13 Vibrant Soundbridge does not significantly affect
14 residual hearing --"

15 DR. WOODSON: In most patients.

16 CHAIRMAN PATOW: -- "in most patients;
17 however, a small percent experience residual hearing
18 loss."

19 DR. GULYA: Yes. Something to that
20 effect, yes.

21 CHAIRMAN PATOW: Comments? Dr. Kileny,
22 does that represent what your thoughts were?

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1 DR. KILENY: Yes, pretty much.

2 CHAIRMAN PATOW: Okay. Is there a
3 consensus then in the committee that that accurately
4 reflects the available data?

5 Claim 2: "The Vibrant Soundbridge
6 significantly improves sound clarity and overall sound
7 quality." Then a suggestion was made to modify it,
8 "based on subjective responses." I think there was
9 general agreement on that before.

10 Claim 3: "The Vibrant Soundbridge
11 provides significant improvement in overall fit and
12 comfort," and there was a proposal to modify it,
13 "compared to conventional hearing aids."

14 I think we had, in fact, put the statement
15 ahead of that, "Patients report that the Vibrant
16 Soundbridge provides significant improvement in
17 overall fit and comfort compared to conventional
18 hearing aids." I see nodding heads, yes.

19 Claim 4: "The Vibrant Soundbridge
20 significantly reduces acoustic feedback." I don't
21 believe that there's really been a discussion about
22 that claim. Any comments?

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1 DR. ROESER: Data clearly show that.

2 CHAIRMAN PATOW: Thank you. Claim 5: The
3 Vibrant Soundbridge provides equal or increased
4 functional gain compared to a hearing aid." Comments?
5 That was generally accepted also.

6 Then claims 6 and 7 have now been
7 combined. "The Vibrant Soundbridge significantly
8 improves a patient's perceived benefit in many
9 listening situations, such as familiar talkers, ease
10 of communication, reverberation, reduced cues,
11 background noise, aversiveness of sounds, and
12 distortion of sound." Any additional comments? Okay.

13 Claim 8: "The Vibrant Soundbridge reduces
14 maintenance issues due to cerumen and moisture
15 accumulation." Comments? Generally accepted.

16 Claim 9: We reordered this so that it
17 would read: "Speech perception test results in
18 controlled soundfield environment (for example, NU-6
19 word scores, SPIN - low predictability word scores)
20 did not demonstrate a significant mean change in
21 scores between the Vibrant Soundbridge and the hearing
22 aid. However, when listening to speech, the Vibrant

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1 Soundbridge was preferred over the presurgery hearing
2 aid in various listening situations." Comments?

3 DR. ROESER: I think again we're mixing
4 performance, because the first statement is a speech
5 perception statement. The second statement is, we are
6 being told, not meant to be linked to speech
7 perception; and when we put them in the same context,
8 even though we have -- Well, when we put them in the
9 same context, the implication is that we're involving
10 speech perception. I think it's confusing.

11 DR. GULYA: Well, I can see that point.
12 However, the intent behind that, as I see that, is
13 that, look, we did these objective tests of
14 performance. We couldn't measure any difference
15 between the conventional hearing aid and the Vibrant
16 Soundbridge. Nonetheless, despite this failure to
17 show any objective difference in performance, people
18 liked the Vibrant Soundbridge better.

19 It's kind of putting a little bit of a
20 black mark in front of the claim, which is almost --
21 Again, it's almost like a non-claim, what you're
22 talking about, but it certainly does clarify exactly

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1 what the data said. They couldn't find any way to
2 explain -- or anything that showed any difference
3 between the conventional hearing aid and the Vibrant
4 Soundbridge, but doggone it, people liked the Vibrant
5 Soundbridge better. That was the only thing they
6 could show.

7 DR. WOODSON: Like in a Coke-Pepsi taste
8 test, they don't measure the pH. They just say which
9 do you like.

10 DR. GULYA: They don't measure the
11 caffeine content or the sugar content. No, they just
12 say who likes which better.

13 DR. ROESER: Why don't we reword the claim
14 to say that, that we couldn't show a difference, but
15 they sure liked it.

16 CHAIRMAN PATOW: I think that is the
17 intent. Is the committee comfortable enough with this
18 compromise that we can leave this as modified? I'm
19 getting consensus. Yes.

20 Then claim 10: "The Vibrant Soundbridge
21 provides significant improvement in word recognition
22 in the presence of background noise compared to

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1 unaided condition."

2 I don't think we have actually talked
3 about this claim. Comments?

4 DR. ROESER: When we started out this
5 morning, we heard from a number of people saying that
6 we should be comparing this new device to available
7 technology, and this claim in no way does that. It's
8 comparing the current device to no device, and I think
9 that it's -- Even though it states it, it can be
10 misperceived as being better than current technology.

11 So I would have difficulty accepting this
12 claim.

13 CHAIRMAN PATOW: Dr. Gulya? Yes?

14 DR. GULYA: I tend to agree with that. I
15 guess there are a couple of ways to handle it. I
16 mean, this is not really one of your more spectacular
17 claims, and we were basically saying we're better than
18 nothing.

19 One thing that may be a caveat would be to
20 say, well, you know, we did better in the presence of
21 background noise compared to the unaided condition,
22 but not when compared to the aided condition. That

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1 would certainly straighten -- That would certainly
2 eliminate any ambiguity.

3 I don't know if the manufacturer would be
4 real wild about adding that.

5 CHAIRMAN PATOW: Would the sponsor care to
6 comment?

7 MS. ARTHUR: Deborah Arthur. Yes, the
8 sponsor would be willing to accept "in the unaided
9 condition," you know, and also put the statement in
10 about the performance in the aided condition.

11 The other thing, once again, there are two
12 reasons that this claim was in there. Number one, as
13 I mentioned this morning, because there are those
14 individuals who have limited or are precluded from use
15 of a hearing aid in some situations.

16 The other one is that in the hearing aid
17 industry frequently what you see in terms of the
18 claims and in the clinical studies that are done with
19 those devices is that they make the comparisons to the
20 unaided condition. Hence, the reason for its
21 presence.

22 CHAIRMAN PATOW: Thank you. Let me -- Did

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1 you have a comment, Dr. Duffell? No? Let me see if
2 I've captured this correctly then.

3 "The Vibrant Soundbridge provides
4 significant in word recognition in the presence of
5 background noise compared to the unaided condition,
6 although not when compared to the aided condition."

7 Other comments by the panel? Okay.
8 Are there any other issues that the committee would
9 like to bring forth at this time regarding any aspects
10 of the proposal or its labeling, anything that came up
11 this morning in the presentations that we would just
12 like to follow up on?

13 I'd like to remind the panel that in
14 making a motion, we have three different
15 possibilities. One would be a motion to approve. One
16 would be to make a motion to approve with conditions,
17 and one to make a motion not to approve.

18 MS. THORNTON: Excuse me, Dr. Patow.
19 First, I think we need to go into the 30 minutes.
20 Then I will read the voting options, because they are
21 specifically structured for the meeting.

22 CHAIRMAN PATOW: I'm ahead of myself here.

1 We do then have a thirty-minute open public hearing
2 session. Are there any individuals who would like to
3 come forth and present any information to the panel?
4 Sir? If you would identify yourself and your
5 affiliation.

6 DR. ILECKI: Good afternoon. My name is
7 Henry Ilecki. I am the Director of Audiology
8 Practices in Audiology and Private Practice at the
9 American Speech-Language Hearing Association.

10 It has been gratifying to hear and see all
11 the work which has transpired since this panel met
12 just over a year ago in June. If I may, I would like
13 to echo the concerns expressed this morning by Lee
14 Richardson when he talked about the need for risk-
15 benefit analyses.

16 Doctors Balkany and Jaffee shed great
17 light on this topic, for which I think we are
18 grateful. But I would like to suggest that Mr.
19 Richardson's concerns be broadened to include the need
20 for cost-benefit analyses as well.

21 It was also reported earlier this morning,
22 I believe by Dr. Fabry, that digital and digital

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1 programmables have a higher return rate than analog
2 instruments. I think that a person might reasonably
3 infer that, at least in part, the higher return rate
4 is related to the purchase price of digital
5 amplification.

6 Higher purchase price equals higher
7 consumer expectation. I, for one, would be curious to
8 know something about consumer satisfaction when or if
9 the procedure were paid for by the consumer, just as
10 he or she had paid for his or her own hearing aid.

11 My other issue, if you will, concerns the
12 matter of assistive listening devices or ALDs. I have
13 not heard this issue discussed either today or last
14 year. Does the technology that we are talking about
15 today obviate the need for assistive listening
16 devices? If not, can that technology be designed to
17 interface with the wide variety of ALD products
18 currently available on the market?

19 Thank you. Appreciate your time.

20 CHAIRMAN PATOW: Thank you for your
21 comments. Are there any other individuals who would
22 like to come forward?

1 At this time then, I'd like the FDA to
2 present their closing comments.

3 MS. BROGDON: I just have one question
4 that was brought to my attention that I would like to
5 ask the panel to address.

6 Do you have any concerns about whether
7 explantation of the device might be needed if a
8 patient were to require an MRI? Do you see that this
9 needs to be addressed in any way, and specifically, do
10 you believe that any post-market surveillance is
11 needed for this issue?

12 CHAIRMAN PATOW: Comments of the panel?

13 DR. GULYA: Boy, it's hard to tell the
14 future. Well, certainly, with an analogous situation,
15 the stapes prosthesis, there have been throughout my
16 practice years instances where individuals have wanted
17 to undergo an MRI, and there's always a question of
18 compatibility of the particular stapes prosthesis used
19 with the MRI.

20 So it does boil down to an issue of MRI
21 versus removal of the prosthesis. With a stapedectomy
22 prosthesis it's way less feasible because of its

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1 interface with the inner ear.

2 I suppose it wouldn't be unreasonable to
3 gather that data. I'm not so sure what we would
4 change with that. It may just be a fact of life that
5 one may either need to elect undergoing an alternative
6 imaging study or one may undergo explantation. It's
7 very hard to answer that question.

8 It wouldn't be unreasonable to follow it,
9 but I'm not sure what we would do with that data, if
10 we had it.

11 CHAIRMAN PATOW: Maybe I could ask the
12 panel members who routinely do this kind of surgery or
13 have experience with it. Would there need to be any
14 information in the surgeon's information packet on how
15 to remove this device or is that something a surgeon
16 would be expected to know?

17 DR. GULYA: My anticipation is that would
18 be pretty straightforward. I mean, it's a malleable -
19 - Like Dr. Balkany pointed out, that's a malleable
20 titanium clip, and if you're an otologist -- Everybody
21 hates to admit this, but there are often stapes
22 protheses that you put on that aren't crimped just

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1 right. So you have to take them off, and you know
2 what? You learn how to put them on. You learn how to
3 take them off until you get them on right.

4 So I don't think that's going to be a huge
5 issue.

6 CHAIRMAN PATOW: Dr. Kileny.

7 DR. KILENY: Well, I think the issue here
8 is not the clip or the floating mass transducer, but
9 the implanted magnet, which poses the contraindication
10 for MRI, just like it poses in cochlear implants. So
11 I don't see what -- I mean, it's basically
12 contraindicated, and those patients who have an
13 implanted magnet in their skull cannot have an MRI.

14 CHAIRMAN PATOW: Dr. Woodson?

15 DR. WOODSON: I guess the real question is
16 how many situations are there where you absolutely
17 have to have an MRI? There's always times when you
18 think, well, it would be better than CT with contrast
19 or this or that, but we've more frequently run into
20 patients who are claustrophobic and don't want to get
21 into the machine, and we find out a way to get the
22 information, usually.

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1 So I guess the real question is how many
2 situations are there where you absolutely have to have
3 an MRI?

4 MS. BROGDON: Thank you.

5 CHAIRMAN PATOW: You're welcome. We have
6 now five minutes for the sponsor's closing comments.

7 MR. CROMPTON: This is Mike Crompton. I
8 just want to thank the panel for its careful
9 deliberations today. Very helpful on the formatting
10 the labeling claims so they accurately reflect patient
11 expectations for this new technology.

12 Again, our thanks to the agency. Karen
13 Baker put up a list of players there. They are
14 intimately involved in this project since 1994. So
15 six years of work have gone into bringing this new
16 technology, and it may be available to patients in the
17 very near term. So thank you again very much.

18 MS. THORNTON: Thank you. I will now read
19 the panel recommendation options for PMAs.

20 The Medical Device Amendments to the
21 Federal Food, Drug and Cosmetics Act, as amended by
22 the Safe Medical Devices Act of 1990, allows the Food

1 and Drug Administration to obtain a recommendation
2 from an expert advisory panel on designated medical
3 device premarket approval applications or PMAs that
4 are filed with the agency.

5 The PMA must stand on its own merits, and
6 your recommendation must be supported by safety and
7 effectiveness data in the application or by applicable
8 publicly available information.

9 Safety is defined in the Act as reasonable
10 assurance based on valid scientific evidence that the
11 probable benefits to health under conditions on
12 intended use outweigh any probable risks.

13 Effectiveness is defined as reasonable
14 assurance that, in a significant portion of the
15 population, the use of the device for its intended
16 uses and conditions of use when labeled will provide
17 clinically significant results.

18 Your recommendation options for the vote
19 are as follows:

20 Approval, if there are no conditions
21 attached.

22 Approvable with conditions: The panel may

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1 recommend that the PMA be found approval subject to
2 specified conditions such as physician or patient
3 education, labeling changes or a further analysis of
4 existing date. Prior to voting, all of the conditions
5 should be discussed by the panel.

6 Not approvable: The panel may recommend
7 that the PMA is not approvable if the data do not
8 provide a reasonable assurance that the device is safe
9 or if a reasonable assurance has not been given that
10 the device is effective under the conditions of use
11 prescribed, recommended or suggested in the proposed
12 labeling.

13 Following the voting, the Chair will ask
14 each panel member to present a brief statement
15 outlining the reasons for their vote.

16 Thank you, Dr. Patow.

17 CHAIRMAN PATOW: Is there then a motion
18 for the panel to recommend that the Vibrant
19 Soundbridge middle ear implantable hearing device, PMA
20 P990052, be approved, approved with conditions, or not
21 approvable?

22 DR. FRANCIS: Approve with conditions.

1 CHAIRMAN PATOW: We have a motion then for
2 the PMA to be approved with conditions. Is there a
3 second?

4 DR. KHAN: I second it.

5 CHAIRMAN PATOW: Discussion then? We're
6 working through a new voting methodology. So bear
7 with us a little bit. We have to exactly figure out
8 how this new methodology works.

9 So according to our new voting
10 methodology, each of the conditions then is introduced
11 separately, and then seconded, discussed and voted on.
12 Then after we've established all the conditions, then
13 we would go back and vote on it as an entire motion.

14 So at this time, is there any discussion
15 on the fact that we have a motion to approve with
16 conditions? Then do I have a motion for what the
17 first condition would be?

18 DR. GULYA: I guess I have a question
19 before I propose a motion. One of the stipulations we
20 are requiring are these changes in the claims. Now do
21 we need to take each one of those claims individually
22 or can we say that we would have this as a

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1 stipulation, that the claims be altered as we
2 recommended?

3 CHAIRMAN PATOW: It is suggested that we
4 would need to look at these individually.

5 DR. GULYA: Individually, okay.

6 CHAIRMAN PATOW: Do we have a comment from
7 the FDA?

8 MS. BROGDON: Yes. I think they would
9 need to be looked at individually. In addition, we
10 need to transcribe those words. That's what Dr.
11 Waxler is getting a laptop set up for.

12 CHAIRMAN PATOW: Dr. Roeser?

13 DR. ROESER: While we are waiting for the
14 claims to come up, can we talk about the intended use
15 statement?

16 CHAIRMAN PATOW: Yes, if you would like to
17 make a motion.

18 DR. ROESER: I would like to make a motion
19 that the revised intended use statement be modified to
20 include those who have a requirement -- that prior to
21 being considered for this device, conventional hearing
22 aids be worn for an adequate period of time.

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1 CHAIRMAN PATOW: Do I have a second?

2 MS. THORNTON: Morris? He's working on a
3 condition right now.

4 DR. DUFFELL: Sally, I don't mean to
5 disrupt the process, but since this is being recorded
6 and transcribed, is it really necessary to wait to do
7 all of this? It is? Okay.

8 MS. THORNTON: It is.

9 CHAIRMAN PATOW: Teri, then are you ready
10 to put this down? Dr. Roeser, if I could ask you to
11 repeat then the proposed intended use statement.

12 DR. ROESER: I think I might be able to
13 reconstruct it in some form.

14 Based on our discussion on intended use,
15 I would like to make a motion that the intended use --
16 the modified intended use statement that was presented
17 today be changed to have a -- to reflect a requirement
18 that, prior to being -- to receiving this device, that
19 patients wear conventional hearing aids for an
20 adequate period of time.

21 CHAIRMAN PATOW: Is there a second to that
22 motion?

1 MS. THORNTON: The motion as stated is:
2 Prior to receiving the device -- That's the beginning?
3 Prior to receiving the device, just for clarification.

4 DR. ROESER: That's right.

5 CHAIRMAN PATOW: Not hearing a second, is
6 there another motion for a condition? Dr. Kileny.

7 DR. KILENY: What is an adequate period of
8 time?

9 CHAIRMAN PATOW: In order to discuss it,
10 I think we would need a second.

11 DR. KILENY; Okay, I'll second the motion.

12 CHAIRMAN PATOW: Okay, we have a second.
13 Now is there discussion?

14 DR. KILENY: Can you define adequate
15 period of time?

16 DR. ROESER: Well, the revised indication
17 for use is that patients have moderate to severe
18 sensorineural hearing loss and desire an alternative
19 to an acoustic hearing aid. So the implication here
20 is that patients, before they experience
21 amplification, the current technology, would be able
22 to receive this device.

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1 The point, I think, that I'm trying to
2 make through this motion is that the data that we've
3 looked at have not -- based on the subjective reports
4 of the patients as well as some acoustic data, haven't
5 demonstrated that this device is equivalent to a
6 hearing aid, especially with respect to -- in view of
7 the fact that the patients were wearing the hearing
8 aid on their non-implanted ear.

9 So what we're being asked to do is to make
10 a decision that this device is equivalent to a hearing
11 aid, and I'm uncomfortable, based on the data, that
12 we've had that -- that's been shown.

13 CHAIRMAN PATOW: We had previously talked
14 about some language that was slightly different.
15 Maybe I could bring that up again. We had said that
16 these would be patients who have had experience with
17 a professionally fitted and adjusted hearing aid,
18 leaving out the word appropriate, which I think may be
19 where Dr. Kileny is concerned of what does appropriate
20 mean.

21 DR. ROESER: That is the spirit of what
22 I'm saying, and I don't want to -- I don't think we're

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1 wordsmithing at this point. I want to introduce a
2 motion that would indicate that amplification would be
3 experienced prior to being considered for this device.
4 That's the spirit of my motion.

5 CHAIRMAN PATOW: Dr. Woodson.

6 DR. WOODSON: Yes. I don't know how the
7 manufacturers would think about this, but if a patient
8 doesn't want to wear a hearing aid, he knows he
9 doesn't want to wear a hearing aid, and he wants to
10 buy it, is he going to be prohibited from that? Is
11 somebody going to force him to wear a hearing aid for
12 months before he gets an implantable hearing aid? If
13 somebody wants one, does that mean that he can't get
14 one or does that mean that that's what we recommend?

15 I can see for the purpose of doing a
16 trial, if you want to compare it to hearing aids, that
17 they've got to have the hearing aid first so you have
18 something as a basis of comparison, but why can't
19 somebody -- If somebody has got otosclerosis, do they
20 have to wear a hearing aid for three months before
21 they go to stapedectomy? **

22 DR. DUFFELL: I think the key is what you

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1 said, recommend. I think to force someone to do it is
2 -- Again, it brings in the issue of reimbursement
3 potentially and liability. What if you don't and you
4 did not certify that in your clinic notes before
5 implanting. Now are you in a libelous situation? I
6 don't know. You know better than I. But I think
7 recommend is a much better course myself, but I don't
8 get to vote on this one.

9 DR. GULYA: Well, you know, I will point
10 out that in the package insert, page 2, for the Audio
11 Processor Model 304 the manufacturer does have
12 individualization of treatment, and one of their
13 bullets is experience with an appropriately fit
14 acoustic hearing aid.

15 I really like the word either suggest or
16 recommend, that somehow this device is intended for
17 use for individuals who desire an alternative to an
18 acoustic hearing aid. It is recommended that they
19 have an experience with an appropriately fit hearing
20 aid or with a conventional acoustic hearing aid or
21 however you want to have that language.

22 Would that cover your concerns?

1 DR. DUFFELL: Yes.

2 DR. ROESER: And maybe I stated my motion
3 too strongly. So I would reword my motion so that it
4 would highly encourage patients to attempt standard
5 traditional hearing aids prior to receiving this
6 device.

7 CHAIRMAN PATOW: Can you say that slowly
8 so that Teri can transcribe it?

9 DR. ROESER: I think Dr. Gulya just said
10 it.

11 CHAIRMAN PATOW: Dr. Gulya? It is
12 recommended that --

13 DR. GULYA: I think we started off with
14 the intended use device statement as it is, and then
15 a period. Then you add: It is either suggested or it
16 is recommended that an individual have experience with
17 conventional hearing aids prior to implantation. We
18 can see what that looks like, and then wordsmith it.
19 I'm not sure that I was very articulate with that.

20 CHAIRMAN PATOW: Might I suggest
21 "professionally fitted and adjusted" as opposed to
22 conventional, because the term conventional may change

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1 over time. What's conventional now may be -

2 DR. GULYA: "Appropriately fit" is the
3 language that the manufacturer has in here. Maybe
4 that would be the best thing, experience with an
5 appropriately fit acoustic hearing aid.

6 CHAIRMAN PATOW: That sounds good.

7 DR. ROESER: I would say appropriately fit
8 hearing aids, because we're talking about binaural,
9 sensorineural hearing loss.

10 CHAIRMAN PATOW: "Appropriately fit" --
11 Here we go. Discussion by the panel? Then all in
12 favor of this condition -- Can we do this on -- Point
13 of order. Can we do this on voice vote or do they
14 have to be individually recognized? Show of hands?
15 Okay.

16 All in favor then of this condition as
17 amended, say Aye. None opposed. The motion then
18 carries to add this condition.

19 Do we have a second condition?

20 MS. BROGDON: Dr. Patow, point of
21 clarification. We saw two different wordings for the
22 indication, and I'm unclear which is the current one

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1 you're in favor of. Would it be the words "desire an
2 alternative to an acoustic hearing aid" or is it" who
3 do not perceive a benefit from acoustic hearing aids"?
4 Which is correct?

5 CHAIRMAN PATOW: A desire, and then an
6 alternative to an acoustic hearing aid is, I believe,
7 the correct version that was considered by the panel.

8 MS. BROGDON: Thank you.

9 CHAIRMAN PATOW: Is there now any
10 additional conditions that the panel would like to
11 have a motion to consider?

12 DR. GULYA: Well, I would propose we add
13 as a condition that the first criteria that we amended
14 be changed to the way we amended it, and you have it
15 written down that way. So why don't you read that?
16 Could you read that for me, please, sir?

17 CHAIRMAN PATOW: Claim Number 1 then would
18 read: "For most subjects, the Vibrant Soundbridge
19 does not significantly affect residual hearing;
20 however, a small percent experienced residual hearing
21 loss." **

22 Do I have a second?

1 DR. FRANCIS: Second.

2 CHAIRMAN PATOW: Discussion?

3 DR. GULYA: Move to call the question.

4 CHAIRMAN PATOW: I want to see that it
5 gets put correctly on the overhead before we continue.

6 It's been suggested that we could go ahead
7 and continue with the voting process. Then I would
8 like to call the question. All in favor of this claim
9 as amended, say Aye. That's unanimous.

10 Any additional conditions now? Do we have
11 a motion for an additional condition?

12 DR. GULYA: I move that we stipulate claim
13 Number 2 be altered to read in the fashion that you
14 have it written down on your piece of paper that we
15 discussed. That was basically looking at the
16 subjective nature of the data.

17 CHAIRMAN PATOW: Claim Number 2 or 3? I'm
18 sorry.

19 DR. GULYA: Claim Number 2.

20 CHAIRMAN PATOW: Claim Number 2, we just,
21 I think, voted on. **

22 DR. GULYA: I thought that was Claim

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1 Number 1. We had the intended use and the claim
2 Number 1. Then we can move on to Claim Number 2.

3 CHAIRMAN PATOW: Okay, I'm sorry. Claim
4 Number 2. I'm one ahead. Claim Number 2 -- Do we
5 have a second?

6 DR. FRANCIS: Second.

7 CHAIRMAN PATOW: And that would be then:
8 "The Vibrant Soundbridge significantly improves sound
9 clarity and overall sound quality based on subjective
10 responses." Discussion?

11 DR. ROESER: In your wording, you didn't
12 include "to hearing aids." So I would go back to what
13 we discussed and say "Based on subjective reports, the
14 Vibrant Soundbridge improves sound clarity and overall
15 sound quality compared to hearing aids." Just put in
16 "based on subjective reports."

17 CHAIRMAN PATOW: Comments? So it would
18 now read: "Based on subjective responses, the Vibrant
19 Soundbridge significantly improves sound clarity and
20 overall sound quality compared to hearing aids."

21 I'd like to call the question then. All
22 in favor? None opposed? That passes.

1 Are there additional then new conditions?

2 DR. ROESER: I make a motion that we
3 modify claim 3, and my suggestion is that we modify it
4 to "Compared to conventional hearing aids, patients
5 report that the Vibrant Soundbridge provides
6 significant improvement in overall fit and comfort."

7 CHAIRMAN PATOW: Is there a second?

8 DR. GULYA: Second.

9 CHAIRMAN PATOW: Discussion?

10 DR. WOODSON: Can I make one point? The
11 claims as they originally had them all started out
12 "The Vibrant Soundbridge." We're putting something in
13 front of every one of those. I mean, I don't know
14 what difference. Can we put "The Vibrant Soundbridge
15 provides significant improvement in overall fitness
16 and comfort compared to hearing aids," and put that at
17 the end instead of at the beginning?

18 CHAIRMAN PATOW: It's the phrase "patients
19 report that" -- I'm not sure how that you could work
20 that in without it being at the beginning, but I'm
21 open to suggestions.

22 DR. WOODSON: Okay. "Patients report that

1 the Vibrant Soundbridge provides better fit and
2 comfort than hearing aids." That's short.

3 CHAIRMAN PATOW: Okay, any other
4 discussion? Dr. Woodson, would you mind saying that
5 one more time?

6 DR. WOODSON: "Patients report that the
7 Vibrant Soundbridge provides better overall fit and
8 comfort than hearing aids."

9 CHAIRMAN PATOW: Any other discussion?

10 DR. ROESER: I would just modify it,
11 saying "compared to conventional hearing aids." It's
12 a minor wording change.

13 CHAIRMAN PATOW: Comments?

14 DR. WOODSON: "Better than conventional
15 hearing aids."

16 DR. ROESER: "Compared to," not "better
17 than."

18 CHAIRMAN PATOW: So we have now, "Patients
19 report that the Vibrant Soundbridge provides
20 significant improvement in overall fit and comfort
21 compared to conventional hearing aids."

22 Can we call the question then. All in

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1 favor? Again unanimous.

2 Are there other new conditions?

3 DR. ROESER: I would make a motion that
4 claim number 7 be removed.

5 CHAIRMAN PATOW: Do I have a second?

6 (Seconded.)

7 CHAIRMAN PATOW: Discussion? Call that
8 question then. All in favor? Opposed? Are there any
9 opposed then? Again a unanimous vote.

10 Any additional conditions then? Dr.
11 Gulya?

12 DR. GULYA: I move that claim Number 6 be
13 modified to read as we were provided the altered form.
14 Could you please read that, Carl?

15 (Seconded.)

16 CHAIRMAN PATOW: Claim Number 6 then would
17 be: "The Vibrant Soundbridge significantly improves
18 a patient's perceived benefit in many listening
19 situations, such as familiar talkers, ease of
20 communication, reverberation, reduced cues, background
21 noise, aversiveness of ^{**}sounds and distortion of
22 sound."

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1 We have a second. Discussion? All right,
2 we'll call that question. All in favor then? And
3 again a unanimous vote.

4 Any additional conditions?

5 DR. DUFFELL: I think your
6 transcriptionist -- she didn't keep up. She needs a
7 copy.

8 CHAIRMAN PATOW: We are going to pass her
9 the wording for that. Do we have a motion?

10 DR. FRANCIS: A motion that we modify
11 claim number 9 as previously discussed.

12 CHAIRMAN PATOW: And could you read that
13 language in for the record, please?

14 DR. FRANCIS: Okay. So I don't have it
15 here word for word. I think you have it.

16 CHAIRMAN PATOW: I'm not sure I have it
17 either.

18 DR. FRANCIS: But I believe we started out
19 with: "Speech perception test results in a controlled
20 soundfield environment, example NU-6 word scores, SPIN
21 - low predictability word scores, did not demonstrate
22 a significant mean change in scores between the

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1 Vibrant Soundbridge and the hearing aid. However,
2 when listening to speech, the Vibrant Soundbridge was
3 preferred over the presurgery hearing aid in various
4 listening situations."

5 CHAIRMAN PATOW: Thank you. Do we have a
6 second?

7 (Seconded.)

8 CHAIRMAN PATOW: Discussion? Hearing
9 none, we will proceed to a vote then. All in favor?
10 Opposed? The motion passes.

11 Any additional conditions?

12 DR. GULYA: I move that we recommend Claim
13 10 be altered, and that was: "The Vibrant Soundbridge
14 provides significant improvement in word recognition
15 in the presence of background noise compared to the
16 unaided condition, but not when compared to the aided
17 condition."

18 CHAIRMAN PATOW: Do I have a second?

19 DR. KHAN: Second.

20 CHAIRMAN PATOW: Discussion? Dr. Roeser?

21 DR. ROESER: " I would say the aided
22 condition refers to the hearing aid condition. Is

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1 that right? So when you say aided and unaided, it's
2 unclear. Let me think about it. Compared to an
3 unaided condition but not when compared to
4 conventional hearing aids, the use of -- but not
5 compared to conventional hearing aids. That's the
6 wording you want to put in.

7 DR. GULYA: I can have my motion amended
8 as recommended.

9 DR. WOODSON: Carl?

10 CHAIRMAN PATOW: Yes.

11 DR. WOODSON: The way we're wording it, it
12 almost, if you just kind of look at it, it almost
13 sounds like it's not as good as hearing aids. That's
14 not -- I mean, we should say something to the effect
15 that it provides equivalent noise reduction than
16 hearing aids. Right? I mean, the way it sounds, I
17 mean if you just look at it casually, it sounds like
18 you're saying it's not as good as a hearing aid.

19 CHAIRMAN PATOW: Dr. Gulya?

20 DR. GULYA: Well, the initial phrase says
21 it provides a significant improvement in word
22 recognition, and then when you compared it to the

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1 unaided condition, it does indeed provide a
2 significant improvement; however, when you compare it
3 to the aided condition (conventional acoustic aids),
4 it does not provide a significant benefit.

5 So as long as we have that phrase in front
6 there, I think you know -- I think we're not
7 misleading anybody what they're talking about. I
8 don't think we're downplaying what the device is
9 doing, because it says a significant benefit right off
10 the front. Then it tells the conditions where it did
11 do that and where it didn't do it, although I'm
12 perfectly happy to listen to alternatives.

13 DR. ROESER: And it reflects the data,
14 because the data -- I assume the data were collected
15 when the patient was wearing an acoustic hearing aid
16 in addition to the MEI. It was not? Okay, that's a
17 point of clarification. So direct comparison -- So
18 "compared to conventional hearing aids" is currently
19 the motion?

20 DR. GULYA: Yes.

21 DR. ROESER: Adding that to the end.

22 DR. GULYA: Right. That sounds fine.

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1 Let's see what that looks like.

2 DR. ROESER: I got to see it.

3 CHAIRMAN PATOW: Would you restate 10 then
4 for Teri so she can put it up? Dr. Roeser, can you
5 restate number 9?

6 DR. ROESER: Well, we're on 10. Well, it
7 would be: "The Vibrant Soundbridge provides
8 significant improvement in word recognition in the
9 presence of background noise compared to the unaided
10 condition, but not compared to the hearing aid
11 condition" -- or "not compared to the use of
12 conventional hearing aids."

13 DR. WOODSON: You can just say the effect
14 is not superior, because they didn't really directly--

15 CHAIRMAN PATOW: We need a specific
16 wording. So "when not compared to" --

17 DR. GULYA: I thought you had something
18 written down on your sheet from our previous
19 discussion.

20 CHAIRMAN PATOW: I had "when not compared
21 to the aided condition" -- "but not when compared to
22 the aided condition" is what we had originally started

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1 with. Is that --

2 DR. GULYA: Yes. That's where it started,
3 and maybe parenthetically behind "aided" you could say
4 "conventional acoustic aids." That would cover Dr.
5 Roeser's concern about that being misleading.

6 DR. ROESER: Clarifying which aid you're
7 talking about.

8 MS. ARTHUR: Do you want to have another
9 suggestion thrown in?

10 CHAIRMAN PATOW: Please.

11 DR. ROESER: Someone needs to break this
12 loose.

13 MS. ARTHUR: "The Vibrant Soundbridge was"
14 -- if I could see the original wording right there in
15 front of me -- "shows significant improvement over the
16 unaided condition and was equivalent to the
17 conventional hearing aid condition."

18 CHAIRMAN PATOW: I think that would
19 express your concerns, Dr. Woodson. Can that be
20 restated for Teri then?

21 MS. ARTHUR: "The Vibrant Soundbridge was
22 significantly" -- and I would have to see the claim.

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1 CHAIRMAN PATOW: "provides significant
2 improvement in word recognition in the presence of
3 background noise."

4 MS. ARTHUR: All right. "The Vibrant
5 Soundbridge provides significant improvement in word
6 recognition in the presence of background noise
7 compared to the unaided condition and is equivalent to
8 the conventional hearing aid condition."

9 CHAIRMAN PATOW: "and is equivalent to the
10 conventional aided condition." Okay. So the phrase
11 that's now on the screen that is claim number 10 would
12 be added to the original claim's wording, "but was
13 equivalent to the conventional aided condition" --
14 "and was equivalent to the conventional aided
15 condition." "Hearing aided condition"? "Hearing aid
16 condition."

17 Any other discussion then on this motion?
18 This is claim Number 10. All right, hearing none,
19 then all in favor? It's unanimous.

20 Are there any other motions for
21 conditions?

22 DR. KHAN: An additional one is: "Safety

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1 and effectiveness of bilateral implants has not been
2 established."

3 CHAIRMAN PATOW: There's a motion that
4 wording be included then, I presume, in the -- It's
5 not a claim. It would just be a part of the
6 information packet that safety and effectiveness of
7 bilateral implants has not been established. Do I
8 have a second?

9 DR. FRANCIS: Second.

10 CHAIRMAN PATOW: Discussion? The motion
11 is that the phrase "Safety and effectiveness of
12 bilateral implants has not been established," and that
13 that be added to the product labeling. Any discussion
14 from the panel? No?

15 Then let's take a vote. All in favor?
16 Again unanimous.

17 Are there any other conditions then that
18 would like to be raised as motions? Dr. Gulya?

19 DR. GULYA: I'd like to propose that the
20 manufacturer be required to follow the patients in
21 their post-marketing surveillance for device
22 extrusion.

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1 CHAIRMAN PATOW: Do I have a second?

2 DR. KHAN: Second.

3 CHAIRMAN PATOW: Discussion? Okay, we'll
4 call that question then. All in favor, say Aye.
5 Again unanimous. Thank you.

6 Additional conditions?

7 DR. FRANCIS: A motion to include facial
8 nerve paralysis or injury, taste disturbances,
9 possible risks. In the patient packet, there is an
10 area where that needed to be included.

11 CHAIRMAN PATOW: We have a motion then to
12 add possibility of facial nerve paralysis and taste
13 disturbance in the patient product labeling, patient
14 information packet.

15 DR. FRANCIS: Page 8.

16 CHAIRMAN PATOW: A second?

17 DR. GULYA: Second.

18 CHAIRMAN PATOW: This is to add the
19 possibility of facial nerve paralysis and taste
20 disturbance to the patient information. Discussion?

21 Then a vote. All in favor? Again
22 unanimous.

1 Any additional conditions? Hearing none
2 then, I would like at this point to have a motion that
3 the PMA be approved with the conditions that we have
4 previously voted on.

5 DR. GULYA: So moved.

6 CHAIRMAN PATOW: I have a motion. Do I
7 have a second?

8 DR. FRANCIS: Second.

9 CHAIRMAN PATOW: Discussion? Hearing
10 none, then we have a vote then. All in favor? Again
11 a unanimous vote.

12 Now at this point I would like to poll
13 each of the panelists regarding their vote. It's an
14 opportunity for them to comment on their vote and any
15 of the conditions that they've taken. Dr. Gulya?

16 DR. GULYA: Well, I believe the
17 alterations that we've recommended reflect the data
18 that have been provided by the manufacturer and will
19 give the potential consumer adequate information on
20 which to make a informed decision.

21 CHAIRMAN PATOW: Thank you. Dr. Francis?

22 DR. FRANCIS: I totally agree with that.

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1 I think this represents an increased option for
2 patients and you've, I think, demonstrated its
3 efficacy to the extent that we've voted today, and
4 it's safe within what's reasonable in otologic devices
5 and surgery at this time.

6 CHAIRMAN PATOW: Thank you. Dr. Kahn?

7 DR. KAHN: I agree with what has been
8 said. I think this is a good alternative for the
9 patients who would have trouble with a conventional
10 one, and there is more progress to come in this area.

11 CHAIRMAN PATOW: Thank you. Dr. Kileny.

12 DR. KILENY: Well, I want to echo the
13 previous statements. I just want to add my
14 congratulations to the sponsor. They have brought --
15 This is the first time such a device has been brought
16 to the FDA and approved, and this is an important
17 development in the area of auditory prosthetics.

18 CHAIRMAN PATOW: Thank you. Dr. Woodson.

19 DR. WOODSON: I'd just agree that this is
20 also another very good option for patients, and it
21 will be interesting to see further progress in this
22 technology.

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1 CHAIRMAN PATOW: Thank you. Dr. Roeser.

2 DR. ROESER: I agree, and as I stated
3 earlier, this is an exciting new technology. Having
4 gone through this type of activity with cochlear
5 implants and seen where we are now, we can look at the
6 future and hope that the patients who need this type
7 of technology will benefit, which is our main concern.

8 I congratulate the sponsors also. I know
9 this is a very difficult thing to do, and we certainly
10 appreciate the thoroughness of the data and the
11 willingness to present the data in ways that were
12 understandable and interpretable.

13 CHAIRMAN PATOW: Thank you. Dr. Hood.

14 DR. HOOD: I'd just like to echo everyone
15 else, and thank you for bringing new technology to the
16 management of hearing loss.

17 CHAIRMAN PATOW: Thank you. Do you have
18 remarks?

19 MS. THORNTON: Yes. I just want to again
20 thank the sponsor for all their hard work, and for the
21 staff of the FDA for their ^{**}hard work as well. The
22 panel has completed a good job today.

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1 In conclusion for today's meeting, I would
2 like to ask all the panel members to please leave all
3 the documents pertaining to this submission on the
4 table for pick-up. Please take your folders for
5 tomorrow, and I will see you back here in this room
6 tomorrow morning at 8:30 for a closed session. That's
7 closed to the public, which will go from 8:30 to
8 approximately 9:15.

9 The open session for tomorrow will convene
10 at 9:15 in this room. Thank you all for a very long
11 day of very hard work. Thank you.

12 CHAIRMAN PATOW: Thank you.

13 (Whereupon, the foregoing matter went off
14 the record at 5:06 p.m.)
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CERTIFICATE

This is to certify that the foregoing transcript in the

matter of: EAR, NOSE, AND THROAT DEVICES
 PANEL MEETING

Before: FOOD AND DRUG ADMINISTRATION
 MEDICAL DEVICES ADVISORY COMMITTEE

Date: JULY 20, 2000

Place: GAITHERSBURG, MARYLAND

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

Rebecca Davis