

1 that's being used.

2 CHAIRMAN PATOW: Dr. Khan.

3 DR. KHAN: Angie Khan, for Dr. Fabry. You
4 showed us a slide about the hearing aid complaints.
5 Do you have something to show us in comparison what
6 happens when the Symphonix is in -- to all these
7 numbers?

8 DR. FABRY: Dave Fabry. The issue with
9 the slide specific to the participants in this study
10 on their complaints with their hearing aids -- Do you
11 have data to that effect?

12 MS. ARTHUR: Deborah Arthur. The closest
13 that would come to that, Dr. Khan, would be if we look
14 again at the satisfaction surveys and where we have
15 similar questions on quality of the effectiveness in
16 background noise. That's what we were showing you in
17 terms of our claims presentation where the patients
18 overwhelmingly were more satisfied with the
19 Soundbridge than with their hearing aids.

20 DR. FABRY: If we -- This is Dave Fabry
21 again. If we go to the issue of feedback, prior to
22 the participation, 67 percent had a complaint with

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1 feedback. Then as you recall, one out of 54 or 31 out
2 of 32 who had a concern with feedback. So that it's
3 not on a slide that I prepared that I could put up and
4 show, but it could be inferred from the data that
5 followed after that in terms of addressing each one of
6 those bullet items. That's the best I can do.

7 CHAIRMAN PATOW: This is Carl Patow. Can
8 I just clarify something that was said earlier. The
9 statement was made, I think, that 70 percent of the
10 users of the Symphonix device are also using binaural
11 aids at the same time?

12 MS. ARTHUR; No. I'm sorry. Seventy
13 percent of Soundbridge patients currently use an
14 acoustic hearing aids in the contralateral ear. In
15 other words, they are binaural users of amplification.

16 CHAIRMAN PATOW: Thank you.

17 DR. WOODSON: One more question.

18 CHAIRMAN PATOW: Yes, Dr. Woodson.

19 DR. WOODSON: Yes. First of all, I'm
20 wondering if you were surprised not to see a huge
21 difference between the analog and digital processors
22 and, based on your data, what kind of recommendations

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1 can you give patients and doctors in trying to select
2 what kind of processor to use?

3 MS. ARTHUR: Deborah Arthur. As in
4 conventional hearing aid fittings or traditional
5 hearing aid fittings, one of the advantages that one
6 might say of digital devices is in the increased
7 programmability that is offered. That would hold true
8 with the Audio Processor for the Soundbridge.

9 With the Vibrant D Audio Processor there
10 are more programming flexibility options that you have
11 than with the analog version. The patients -- It
12 would be a patient preference issue with respect to
13 fitting these patients.

14 CHAIRMAN PATOW: Yes, Dr. Hood.

15 DR. HOOD: Linda Hood. One other question,
16 following up on the binaural use with the Soundbridge
17 and hearing aid on the other ear. When the subjects
18 were completing the questionnaires, how were they
19 asked to do that? Were they asked to do that with
20 their binaural hearing aids versus Soundbridge alone
21 or binaural fittings both ways, monaural?

22 MS. ARTHUR: Of course, the questionnaires

1 -- Deborah Arthur. The self-assessments represented
2 what they were using in their real life listening
3 environment. So in effect, what they were reporting
4 in 70 percent of the cases was their hearing with the
5 Soundbridge and with a contralateral hearing aid, as
6 opposed to their preoperative condition, which was
7 hearing aid only.

8 CHAIRMAN PATOW: Other questions from the
9 panel? Carl Patow. I have two questions related to
10 the study methodology.

11 I understand from the slide that patients
12 were included in the protocol if they had bilateral
13 sensorineural hearing loss which was judged to be
14 moderate to severe. Were any implanted that were
15 judged to be mild?

16 MS. ARTHUR: Deborah Arthur. In the study
17 of the Vibrant P or the Vibrant D Audio Processors,
18 the criteria called for the patients to have a
19 moderate to severe bilateral sensorineural hearing
20 loss. We do have an IDE open that is looking at mild
21 hearing loss, but that's for a separate audio
22 processor.

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1 CHAIRMAN PATOW: And were any patients
2 implanted who had not been previous users of hearing
3 aids?

4 MS. ARTHUR: Deborah Arthur. No.

5 CHAIRMAN PATOW: Thank you. Any other
6 questions from the panel? Yes, Dr. Francis?

7 DR. FRANCIS: I heard mention that the
8 mean use of hearing aids was 3.2 years prior to
9 implantation. My question was: Do you know about how
10 long the individuals had their latest hearing aid?

11 MS. ARTHUR: Deborah Arthur, once again.
12 Retrospectively, we realized that on our questionnaire
13 where we asked about the previous usage of hearing
14 aids, by the respondents' information it was clear
15 that they were not sure whether they should respond
16 how long they had worn their current device or how
17 long they had worn hearing aids.

18 So that's why when I expressed a mean of
19 3.2 years, it's either with their current device or
20 hearing aid usage in general. So we don't have the
21 specific question, your current device. It was quite
22 obvious, based on the serialization of some of the

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1 hearing aids which usually includes the date of
2 manufacture, that we could determine the age of
3 putting in these devices.

4 CHAIRMAN PATOW: At this time then, we
5 would like to take a 15 minute break. We will come
6 back into session then at 12:15.

7 Again, I'd like to remind you about the
8 issue of confidentiality, particularly the panel
9 members, that they not engage in conversations that
10 might be misconstrued. Thank you very much. We'll
11 see you back in 15 minutes.

12 (Whereupon, the foregoing matter went off
13 the record at 12:02 p.m. and went back on the record
14 at 12:20 p.m.)

15 CHAIRMAN PATOW: If we could, would you
16 take your seats and reassemble, and we'll begin the
17 next set of presentations. Thank you.

18 I'd like now to introduce Dr. Morris
19 Waxler who will be leading the FDA presentation. Dr.
20 Waxler.

21 DR. WAXLER: ^{**} Good afternoon. I have only
22 to introduce Karen Baker who will -- She is the team

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1 leader for this PMA and doing an excellent job. Thank
2 you, Karen.

3 MS. BAKER: Thank you very much. Good
4 afternoon. As you know, I am Karen Baker. I'm the
5 Team Leader for the Symphonix devices premarket
6 application for the Vibrant Soundbridge system.

7 I'd like to thank my team members who have
8 worked long and hard throughout the investigational
9 device exemption review process and in the review of
10 this PMA. The contributions have been invaluable. Up
11 on the screen there is the list of our team. You can
12 see, it's quite comprehensive.

13 The team members are: Dr. Jaffee, who is
14 our medical-clinical reviewer; Teri Cygnarowicz, the
15 audiological reviewer; George Koustenis, our
16 biostatistician; Brian Beard, electrical -- excuse me,
17 biomedical engineer; Sandy Weininger, electrical
18 engineering; Paul Ruggera, electromagnetic
19 compatibility; Dan Chwirut, mechanical engineering;
20 Joseph Jorgens, software engineering; Victor
21 Krauthamer, neurophysiology; Vasant Malshet,
22 toxicology and biocompatibility; myself for the

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1 sterilization review; Ronald Swann, Office of
2 Compliance; Marian Linde, bioresearch monitoring; and
3 Carol Clayton and Phyllis Silberberg from OHIP, and
4 they were responsible for the patient labeling.

5 I would also like to express my thanks and
6 appreciation to the reviewers and scientists from
7 Health Canada. They have been a part of the IDE as
8 well as the PMA process. Their observations and
9 contributions have greatly enhanced the scope of our
10 review throughout this process.

11 Symphonix has already provided you with
12 the details of the device and the clinical
13 investigation. So at this time I would like to turn
14 the podium over to FDA's clinical and audiological
15 reviewers, Dr. Jaffee and Ms. Cygnarowicz. Thank you.
16 Dr. Jaffee.

17 DR. JAFFEE: Thank you. Mr. Chairman,
18 members of the panel, FDA-ers and guests, I'll just
19 give a clinical overview today from my perspective of
20 this device. Tom Balkany earlier eloquently described
21 the surgery. So that need^{**} not be repeated.

22 For the sake of brevity, I want to just

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1 really start right in with the Phase III study, which
2 was, of course, the original study for the approval.
3 During the course of the study, there was one device
4 that failed to activate, and then later on, mostly in
5 the six to nine month range, there were eight device
6 failures that were reported and occurred. Next.

7 Worldwide to that point, there were 351
8 subjects and six additional device failures were
9 noted, and that brought the total to 14. The company
10 halted production, went into analysis of the problems,
11 and found that there was a cyclical fatigue of the
12 bifilar wire in the VORP, in the conducting link of
13 the VORP, the Vibrating Ossicular Prosthesis. Next
14 slide.

15 This led to a revision of the device with
16 the insertion of the transition sleeve and start of
17 the Phase IIIa study, the one that is being reviewed
18 today.

19 There's 30 patients with six month data
20 from this study from North America. Twenty-five
21 subjects received the Vibrant D, six of whom were
22 reimplanted from earlier failures. Five subjects

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1 received the Vibrant HF, high frequency. European
2 data has 60 additional patients in this Phase IIIa
3 study. Next.

4 The question of residual hearing was
5 brought up earlier in the question period, and it
6 certainly is one of discussion. For the 53 patients
7 in the original Phase III study, there was an average
8 decrease of 3 decibels in the pure-tones.

9 As mentioned earlier, one subject has a
10 loss of 12, and another subject did have a loss of 18
11 decibels. In the current IIIa study of 30 subjects,
12 to date there have been no device failures. Next.

13 In discussing adverse events, I decided to
14 put together worldwide and the U.S. events to kind of
15 get -- sort of get a perspective of what has been
16 reported.

17 Facial nerve problems: There were two
18 worldwide and two from the U.S. -- of these, two are
19 from the U.S. Flap complications were four, one of
20 whom from the U.S. Skin irritation, three were
21 reported worldwide, none in the U.S. Infection, there
22 was one U.S. patient. The disconnection of the

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1 floating mass transducer was one U.S. patient.
2 Altered taste reports were that of eight subjects,
3 seven of whom were from the United States. Next.

4 Transient pain, as mentioned earlier, was
5 17, 13 U.S. subjects. Post-op dizziness, two, both
6 U.S. Transient intermittent signal, one; constant
7 noise, one, neither U.S. Increased tinnitus, one from
8 the United States. Residual hearing loss greater than
9 10 dB were six subjects, two from the United States.
10 A fullness sensation of 24 was reported worldwide, and
11 18 in the United States.

12 I think I'd like to discuss for a few
13 moments and editorialize on the adverse events. From
14 my knowledge of the investigators and the surgeons, I
15 feel that probably the finest surgeons in this country
16 have been doing this procedure, and from my attending
17 the meeting in Birmingham I met many of the foreign
18 surgeons and feel certainly of equal caliber.

19 To see that the results showed so many --
20 a certain disparity between adverse events between the
21 United States subjects and the foreign subjects is --
22 I've pondered over this quite a bit. I kind of feel

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1 that the surgeries are probably of equal caliber, and
2 there may be -- and this is my own editorializing --
3 that the reporting of these adverse events is not
4 quite as thorough from abroad.

5 Also, I would like to mention that I
6 really think that, you know, we talked before --
7 people who know me know I'm a great sports fan, and I
8 think I'm batting for the United States in this case,
9 because I think we really have -- Even though the
10 reports show more problems, I don't really think, if
11 we looked at it, that the surgeons were of any
12 different caliber to what has been reported. Next.

13 To compare to other procedures: Stapes
14 surgery has been mentioned, and certainly there are
15 some surgical similarities, but there is a difference;
16 because the surgeries are not equivalent. As we know,
17 in stapes surgery, tympanoplasty surgery, there is
18 pathology, and now we are dealing with a normal middle
19 ear to introduce a prosthesis.

20 There is a similarity, that both groups of
21 these patients can usually be helped with hearing
22 aids. Next.

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1 Cochlear implantation: Again, there's a
2 great deal of surgical similarities, but once again
3 for the practical usage, the patient receiving a
4 cochlear implant has no other option for his profound
5 deafness. Next.

6 The major issues I see is that very
7 important issue of MRI incompatibility. The
8 Soundbridge is an incredibly wonderful engineering
9 device, and certainly the MRI is also a wonderful
10 device. Over the years the MRI is beginning -- is not
11 beginning -- is being used for more and more purposes,
12 and more and more diagnostics. Right now the fact
13 that the Soundbridge is incompatible with this is a
14 major issue to me. Next.

15 The issue of binaurality has been
16 discussed before, and from my teaching and training,
17 of course, having two good ears is the ideal. If
18 there are two ears with hearing loss, it's been taught
19 that binaural hearing aids are certainly better than
20 monaural, and the issue of binaurality with middle ear
21 implants has not really been discussed.

22 It comes down to an issue with an implant

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1 in one ear and a conventional aid in the other ear.
2 There is, in my mind, some question about truly the
3 great benefit of the implant unless we can bypass that
4 hurdle. Next.

5 Again surgery: This is a surgical
6 procedure, as mentioned earlier, as we all know. If
7 it works in the long term, which we hope, this will
8 require further surgical revisions or surgical
9 procedures over the years, something that has to be
10 carefully discussed with patients. Next.

11 Advantages to the Soundbridge would be,
12 they mentioned earlier, the open ear canal; certainly,
13 less problem as far as wax accumulation with hearing
14 aid and external otitis due to or without the use of
15 hearing aids. It's easy for patient use. There is a
16 cosmesis factor, and an advantage to be listed that
17 the device, when working and in place, can last for a
18 long period of time. Next.

19 Disadvantage is that it is a technical
20 surgical procedure that involves entering a normal
21 mastoid and normal middle ear. It is MRI
22 incompatible, as mentioned earlier. Binaurality is an

1 issue. I have longevity down as a disadvantage,
2 because over time this will require replacement and/or
3 current improvements will come into place. It will
4 have its own life expectancy.

5 At this time, I would like to read the
6 questions for the panel.

7 The sponsor has provided evidence on the
8 effect of implantation of the device on residual
9 hearing, as measured by pure tone audiograms, speech
10 perception testing and impedance audiometry, for
11 example. The sponsor requests approval of the claim
12 (Claim #1), which reads: "The Vibrant soundbridge
13 does not adversely affect subjects' unaided hearing
14 when compared to their level of unaided hearing prior
15 to implantation of the device."

16 Question (a): Does the data support this
17 claim?

18 (b) Other than residual hearing, are
19 there other safety issues related to the physical
20 presence of the device in the middle ear that should
21 be addressed by the sponsor?

22 Second question: The second question has

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1 a typo in it, which I guess in these days we might
2 call a "word processoro," because we've mixed U.S.
3 percentages with worldwide. It reads as follows:

4 The most prevalent adverse events seen
5 were disruption or transection of the VIIth cranial
6 nerve, which if we use worldwide numbers was a .6
7 percent occurrence; transient post-operative dizziness
8 again would be .6 occurrence; fullness sensation of a
9 6.8 percent occurrence; and transient pain, 4.8
10 percent occurrence. Is the information provided to
11 the practitioner and the patient adequate to fully
12 inform them of these potential adverse effects?

13 Third question: Is the following warning
14 statement regarding MRI compatibility adequate to make
15 physicians and patients aware that they are excluded
16 from all types of MRI examinations and that the device
17 must be explanted prior to such examinations?

18 Quoting from the company: "Patients
19 implanted with the Vibrant Soundbridge should not be
20 subjected to MRI, and should not enter an MRI Suite or
21 come into close proximity to other sources of strong
22 magnetic fields."

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1 Question 4: The sponsor plans to follow
2 the Phase IIIa Safety Cohort subjects for a period of
3 18 months post-market. The data to be obtained during
4 this post-market follow-up will include, at a minimum,
5 the device status, cumulative months of use, and any
6 adverse events. In addition, the sponsor proposes to
7 report to FDA the following:

8 (1) clinically significant changes in
9 residual hearing to the implant ear;

10 (2) any alleged complications due to
11 incus erosion; and

12 (3) the failure rate of devices
13 incorporating the transition sleeve for the Phase IIIa
14 cohort.

15 Question (a): Is there any other data the
16 sponsor should collect during this post-market follow-
17 up period?

18 (b) Is there any other data the sponsor
19 should collect in an additional post-market follow-up
20 study?

21 At this time I'd like to introduce Ms.
22 Teri Cygnarowicz, clinical audiologist, who will

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1 proceed with the efficacy discussion of this device.

2 MS. CYGNAROWICZ: Thank you, Dr. Jaffee.
3 Mr. Chairman and distinguished panel, good afternoon.
4 I'm Teri Cygnarowicz, audiologist and scientific
5 reviewer in the ENT Devices Branch.

6 As the sponsor has already presented the
7 audiological data for this PMA, I will limit my
8 presentation to a couple of specific comments,
9 followed by a reading into the record the questions
10 that FDA requests that you discuss and address in your
11 panel deliberations.

12 The audiological data in this PMA address
13 both the safety and the effectiveness of the Vibrant
14 Soundbridge. As the safety of the device has already
15 been discussed by Dr. Jaffee, I will focus my comments
16 on the effectiveness data contained in the submission.

17 Both the objective and subjective
18 effectiveness data were reviewed for accuracy in order
19 to determine whether or not the data supports the
20 device effectiveness and the labeling claims the
21 sponsor intends to make. ** Next slide.

22 The control condition of a clinical trial

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1 for this device area is important, in that measuring
2 the true benefit of such a device is only possible
3 when it is compared to the best alternative available
4 to the patient.

5 It is well known that there are many
6 hearing impaired individuals in the U.S. who could
7 benefit from some form of amplification, though for
8 one reason or another, they do not utilize
9 conventional acoustic amplification. However, as we
10 enter a potentially new technological frontier, it is
11 important that we carefully define and measure the
12 true benefit of the device as compared to that of a
13 conventional hearing aid. Next slide.

14 At the beginning of, and throughout this
15 clinical trial, FDA has had numerous discussions with
16 the sponsor regarding the comparative control
17 condition of the subjects entering this study.

18 The firm was advised that conventional
19 hearing aids should be appropriately fit and optimized
20 for individual subjects. Also, variability of hearing
21 aid circuitry should be minimized. Next slide.

22 Further, the sponsor was advised that to

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1 help minimize variables and assist in determining,
2 quote, "real" benefit, signal processing of the
3 control hearing aid and of the implanted device should
4 ideally be similar to the same.

5 Symphonix chose not to fit patients,
6 subjects, with a hearing aid circuit similar to that
7 used in the audio processor of the Vibrant Soundbridge
8 device. Next slide.

9 Also, it selected a prescriptive formula
10 for real ear probe microphone testing of the patient's
11 existing hearing aid, or control, whereas it did not
12 incorporate a prescriptive formula to fit the audio
13 processor.

14 Conventional real ear testing is currently
15 not possible with the Vibrant Soundbridge, which I
16 view as a limitation of the device. Therefore, FDA
17 specifically requests your advice regarding the
18 labeling of the device as it pertains to the control
19 condition used in this clinical trial. Next slide.

20 Secondly, FDA is concerned that much of
21 the effectiveness data and resulting claims are based
22 upon subjective questionnaire data. FDA specifically

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1 seeks your input regarding the use of subjective
2 outcome measures as the basis of the effectiveness of
3 the Vibrant Soundbridge.

4 Now I will read into the record the
5 questions FDA would like the panel to address as it
6 discusses the effectiveness data for this device.

7 In the study the device was compared to
8 the preoperative aided control condition. As defined
9 in the study protocol, the subject must have met the
10 following minimum requirements to be entered into the
11 study:

12 "Persons who are currently users of
13 acoustic hearing aids and have used these aids for at
14 least four hours average per day for at least three
15 months prior to evaluation. The subject's hearing aid
16 in the ear to be implanted shall be capable of
17 achieving an NAL-R prescription at 500, 1000, 2000 and
18 3000 Hertz. Capable means that the aided threshold at
19 each frequency of the NAL-R prescription is within
20 plus or minus 15 dB."

21 (a) What are the implications of this
22 control condition upon the proposed intended use

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1 statement: "The Vibrant Soundbridge is indicated for
2 use in adults, 18 years of age and older, who have a
3 moderate to severe sensorineural hearing loss and
4 desire an alternative to an acoustic hearing aid."

5 (b) What are the implications of the
6 control condition on the following claims as stated in
7 the Phase III Safety and Effectiveness Data Section of
8 the PMA:

9 Claim #3: "The Vibrant Soundbridge
10 provides significant improvement in overall fit and
11 comfort."

12 Claim #5: "The Vibrant Soundbridge
13 provides equal or better functional gain compared to
14 a hearing aid."

15 Claim #6: "The Vibrant Soundbridge
16 significantly improves a patient's perceived benefit
17 in everyday listening situations."

18 Claim #7: "The Vibrant Soundbridge
19 significantly improves a patient's satisfaction and
20 perceived benefit in challenging listening
21 environments."

22 Claim #9: "When listening to speech, the

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1 Vibrant Soundbridge was significantly preferred over
2 the pre-surgery hearing aid in various listening
3 situations. Speech perception test results in a
4 controlled soundfield environment, such as NU-6 word
5 scores, SPIN - low predictability word scores, did not
6 demonstrate a significant mean change in scores
7 between the Vibrant Soundbridge and the hearing aid."

8 Number 6: What are the implications of
9 the subjective data collected by questionnaire versus
10 objective speech perception data as it pertains to
11 speech perception ability on the following claims:

12 I see we do not have this question up
13 there. I apologize for that. Let me read it.

14 It's pertaining to claims Number 6, 7 and
15 9, which read:

16 Claim #6: "The Vibrant Soundbridge
17 significantly improves a patient's perceived benefit
18 in everyday listening situations."

19 Claim #7: "The Vibrant Soundbridge
20 significantly improves a patient's satisfaction and
21 perceived benefit in ^{**}challenging listening
22 environments."

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1 Claim #9: "When listening to speech, the
2 Vibrant Soundbridge was significantly preferred over
3 the pre-surgery hearing aid in various listening
4 situations. Speech perception test results in a
5 controlled soundfield environment (NU-6 word scores,
6 SPIN) did not demonstrate a significant mean change in
7 scores between the Vibrant Soundbridge and the hearing
8 aid."

9 Thank you.

10 CHAIRMAN PATOW: At this time -- Thank
11 you. At this time, are there questions from the panel
12 for the FDA presenters? Dr. Duffell?

13 DR. DUFFELL: You all did not mention a
14 few of the claims. Would we take it from that then
15 there is no need for comment from the panel on the
16 claims not discussed as part of your presentation?

17 MS. CYGNAROWICZ: This is Teri
18 Cygnarowicz. We welcome your comments on any of the
19 other claims. It's just that our particular questions
20 for discussion, we speak these specific questions.

21 CHAIRMAN PATOW: Any other questions from
22 panel members?

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1 There's a question as to whether Question
2 7, which starts "In the clinical trial patients with
3 bilateral hearing loss were monaurally implanted" --
4 Was that question read? Was it read into the record?

5 MS. CYGNAROWICZ: You're correct, Dr.
6 Patow. This is Teri Cygnarowicz. That question was
7 not read into the record. Let me go ahead and read it
8 off of the overhead.

9 7. In the clinical trial patients with
10 bilateral hearing loss were monaurally implanted.

11 (a) Should the intended use statement
12 explicitly state that the device is intended only for
13 monaural implantation in patients with bilateral
14 hearing loss?

15 (b) What advice should be given to the
16 patient regarding the use of amplification in the
17 contralateral ear?

18 CHAIRMAN PATOW: Thank you, Teri. With no
19 further questions then from the panel, are there any
20 additional comments -- We have a 15 minute period here
21 for additional comments from the sponsor at this time.

22 I'd like to thank the FDA panel members.

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1 They can be excused, and then we'll hear the sponsor's
2 comments.

3 MR. CROMPTON: I've asked -- This is Mike
4 Crompton. I've asked Deborah Arthur, our Vice
5 President for Clinical Affairs, Dr. David Fabry from
6 the Mayo Clinic, and then also Dr. Martin Hyde just to
7 come up and offer a few comments.

8 CHAIRMAN PATOW: Thank you.

9 MS. ARTHUR: With respect to the question
10 regarding the control -- This is Deborah Arthur -- the
11 implications of the control condition upon the
12 proposed intended use statement: In the question as
13 posed by the agency, there was an issue raised about
14 the appropriateness of the control condition, i.e.,
15 the compliance with the NAL-R target plus or minus 15
16 dB at the state frequencies within the protocol.

17 We actually went back and looked at what
18 the compliance was on an individual patient by patient
19 basis to that NAL-R prescription target. What we
20 found is that 70 percent of the hearing aids were
21 within plus or minutes 5 dB average of the target, and
22 96 percent of those patients' hearing aids at the

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1 implant ear were plus or minus 10 dB average of the
2 target gain. So that is our response with regard to
3 that question.

4 DR. FABRY: And also -- This is David
5 Fabry -- the issue of the inability to use real ear
6 measurements for the Soundbridge versus the comparison
7 device. It's true that, short of somehow putting a
8 microphone into the middle ear space or beyond, you
9 cannot accurately assess by real ear measurement as
10 used for conventional devices.

11 Did anyone hear that tree falling?

12 The issue is that functional gain and real
13 ear measurements that have been evaluated in the
14 literature have shown that gain is gain, and that is
15 whether or not you are using functional or real ear
16 measurements, gain is equivalent across the two
17 measures when you control for presentation level of
18 the stimulus.

19 The issue then is whether or not the
20 target was met, as Deborah just showed, and also the
21 issue of circuit type, ** I guess, was the other
22 question. Regardless of digital or analog, as long as

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1 the gain is appropriate, held to a target measured by
2 either real ear or functional gain measurements, and
3 ensuring that maximum output is not uncomfortable for
4 the individual, the appropriateness of the fit can be
5 compared between the two devices for both digital or
6 analog devices.

7 Again, recent studies that have been
8 presented and published from the VA and others that
9 have looked at whether digital or wide dynamic range
10 or analog circuits are used, once a fitting target is
11 made, that's about the best comparison that you can
12 do. Now targets are widely regarded as the standard
13 for comparison of devices at a long term average
14 speech level of stimulus.

15 MS. ARTHUR: Further to the point with
16 regard to the control, the patients' appropriateness
17 of the hearing aid fit, as we talked about earlier,
18 was verified not only by the electroacoustic and real
19 ear measures, but also that verification was
20 clinically judged.

21 We looked at earphone scores, NU-6 as a
22 measure of word recognition at the implant ear, and

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1 then also compared it to their aided condition with
2 the hearing aid at the implant ear, with the
3 contralateral ear occluded, once again looking to see
4 was the performance what we would consider comparable,
5 and that the best hearing, so to speak, under earphone
6 at the appropriate hearing level intensity, as you can
7 see by this slide right here, certainly was comparable
8 between the implant ear and the soundfield aided
9 condition with their hearing aid at a pre-surgical
10 interval.

11 Other measures that were looked at to
12 determine that the device was appropriately fit: A
13 listening check, of course, to verify that there was
14 no obvious effect on the quality of the signal; and
15 then there were issues with the hearing device
16 satisfaction survey and the PHAP.

17 What we were looking for was to ensure
18 that these patients did not express gross
19 dissatisfaction with their hearing aid in a variety of
20 listening environments and conditions, once again
21 which would be reflective of an inappropriately fit
22 device.

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1 What we found on the hearing device
2 satisfaction survey was that, when you look at the
3 patient's performance -- this is on the five-point
4 scale we have up there -- we did a mean score for each
5 of the patients across the range of questions on the
6 HDSS, and then we plotted it.

7 What you see here is well within this
8 range of neutral that the majority of the patients
9 fell. They were not overtly dissatisfied or very
10 satisfied with their hearing aid. They hovered around
11 the mid-point, which is not inconsistent with what you
12 would see in the general hearing impaired population.

13 DR. HYDE: This is Martin Hyde. I'd just
14 like to comment on the subjective versus objective
15 outcome measures.

16 I'm sure many of you are aware that, not
17 just in audiology but in many areas of health
18 assessment, there is a worldwide trend toward the
19 integration of subjective measures that are real world
20 measures into the panoply of measures that is used to
21 assess a patient.

22 So there is a general trend toward the

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1 acceptance of psychometrically valid subjective real
2 world measures, and these two things should be seen as
3 complementary aspects of patient assessment.

4 The tools that we used, the PHAP, to
5 remind you, is probably an exemplary questionnaire in
6 terms of the standard of psychometric validation
7 normative data that has been made available by Robin
8 Cos and her colleagues. So I think, of any of the
9 subjective tools that we use in audiology, I would not
10 criticize the PHAP. It wouldn't be one of them that
11 I would pick upon.

12 Both the PHAP and, more commonly, its
13 derivative, the APHAP, have become fairly widespread
14 measures of clinical benefit from hearing aids. In
15 fact, the conversion, I think, is such that in my
16 clinic, if we had clear benefit on a PHAP and the
17 conventional speech tests did not concord with that
18 assessment, then we would be asking ourselves not what
19 was wrong with the PHAP but what was wrong with the
20 speech tests. Thank you.

21 MS. ARTHUR: Deborah Arthur. With the
22 concern or the question regarding binaurality and

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1 whether or not the patients were fully enjoying the
2 opportunity for binaural listening, Symphonix has
3 always recommended binaural use of amplification.

4 In the course of the clinical trial, as
5 would be expected, it was only recommended to be
6 implanted monaurally at the poorer ear. There is no
7 indication from the patients' reports that the use of
8 a conventional hearing aid at the contralateral ear in
9 any way is not an appropriate way for them to listen
10 or that the quality or the other advantages we see in
11 binaural listening compromised by having a direct
12 drive system at one ear and an acoustic device at the
13 other ear.

14 The only questions we get to that effect
15 are when can we have a Soundbridge at the
16 contralateral ear.

17 DR. FABRY: This is Dave Fabry, and I'll
18 return just for a moment again to the issue of
19 subjective and objective measures, and returning to
20 the SPIN test used in the study, the objective
21 measure.

22 If the worry from using subjective

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1 measures is that in some way the participants in the
2 study were exaggerating the benefit because of the
3 fact of their participation in the study, objective
4 measures certainly are less prone to that type of an
5 evaluation. In fact, it would be more likely to be
6 experimenter error in recording the responses.

7 When we showed equivalent performance on
8 the SPIN measure, that, to me, reflects that adequate
9 audibility occurs without discomfort for the device
10 using a prescriptive method. In fact, many of the
11 comparisons, if not all of the comparisons, with state
12 of the art hearing aids that are comparing digital and
13 analog find equivalent performance between existing
14 devices that are properly fit and the new device.

15 It is, in fact, an entry point. Then, in
16 my opinion and in clinical settings, the subjective
17 data provide the additional benefit not related to
18 speech understanding and noise that contribute to
19 overall satisfaction with the hearing aid.

20 As I indicated, one of the issues for me
21 that was relevant and important was that, of the data
22 that exists long term in the 44 patients at the time

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1 the PMA was submitted, all of them are still wearing
2 the device.

3 Another issue could be, is that if somehow
4 there were a sham surgery or control items on a
5 subjective measure that related to something where you
6 didn't expect to see benefit and did not see it in the
7 data, that would point to an issue of a lack of a
8 Hawthorn effect.

9 Upon review of the data, the subjective
10 data, all of the measures use the PHAP, which does not
11 have control questions like that, and the SHACQ, which
12 is up on the screen now. The listening preference for
13 speech, which showed a marked preference on the basis
14 of participants for the Soundbridge versus their
15 appropriately fit conventional amplification.

16 If you look over to the right for
17 telephone usage, recall that the participants in the
18 study all had the Soundbridge implanted in the poorer
19 ear, if there was an asymmetry between the two, and
20 were likely, given that this was a moderate to severe
21 degree of hearing loss for all the participants in the
22 study, to have used the hearing aid in their better

1 ear, the non-implanted ear.

2 Therefore, on the SHACQ the closest thing
3 that we could come to in terms of a control question
4 or one that you would not expect to see any inherent
5 benefit of the Soundbridge is included on this slide,
6 and shows indeed no preference for the Soundbridge
7 versus their preexisting conventional device.

8 It's as close as anything that can come
9 that will show on this preference based subjective
10 study that the Hawthorn effects were minimal and that
11 subjects were not inherently biased toward giving a
12 favorable response to the Soundbridge under conditions
13 where we would not expect a favorable result on the
14 basis of the study design.

15 CHAIRMAN PATOW: Thank you very much for
16 your comments.

17 We will now take a break for lunch and
18 resume the committee deliberations at 2:15 p.m. Thank
19 you.

20 (Whereupon, the foregoing matter went off
21 the record at 1:00 p.m.)

22

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1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (2:18 p.m.)

3 CHAIRMAN PATOW: If I could ask you to
4 come to order, please. Before we start this
5 afternoon's committee deliberations, I would just like
6 to mention that we were able to get some information
7 about the consumer representative. Unfortunately, Dr.
8 Garcia has come down with an ear, nose and throat
9 malady which has prevented her from flying. So she
10 will not be able to join us today and, hopefully, she
11 will be able to be at some of our other meetings.

12 There are two primary panel reviewers for
13 this device, Dr. Julianna Gulya and Dr. Ross Roeser.
14 I have asked that they each briefly present a summary
15 of their findings on review of the materials that were
16 submitted. Dr. Gulya.

17 DR. GULYA: Again, this is a very brief
18 summary. I have more detailed comments, and we can
19 slog through those as it becomes appropriate.

20 I think, first, I think the PMA should be
21 approved, but that is going to be with conditions. I
22 had some question in my mind what exactly the intended

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1 use statement was going to be, but that has been
2 sufficiently described to this point in time. I know
3 what the situation is.

4 I thought, with regard to claim number 1 -
5 - that's the one about effects on residual hearing --
6 I think that we need to be sure that there are
7 additional longer term follow-up performed, as I would
8 anticipate be done in a post-marketing surveillance.

9 Regarding claims 2 and 3, I think it would
10 be very important to have the wording reflect that
11 this net data is of a subjective nature, to be sure
12 that any consumer be appropriate advised.

13 Regarding claims 4 through 6 and also
14 number 8, I believe the data support these claims as
15 they are, and I won't deal with those any further.

16 Regarding claim number 7, I did not feel
17 that the data supported this claim, and in my original
18 review I suggested the claim will need to be modified.
19 The manufacturer has incorporated a modification, and
20 we as a panel will need to look at those modifications
21 to see if they are sufficient.

22 Regarding claim number 9, I believe the

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1 data did not support this claim. Regarding claim
2 number 10, I thought the wording should be modified,
3 as it could be potentially misleading.

4 I think the plan is for, after our
5 summary, we will go through each one of the questions
6 posed by the FDA, and then we can address some of
7 these other issues as they arise.

8 CHAIRMAN PATOW: Thank you. Dr. Roeser.

9 DR. ROESER: Overall, I also feel that
10 this is a new, exciting technology that has tremendous
11 potential for future development. I think the
12 application was clear, and I want to thank the
13 manufacturer and consultants for providing the data in
14 a way that was interpretable.

15 The intended use was modified.
16 Originally, a concern I had -- Originally, it was
17 stated that it was for patients who do not perceive a
18 benefit from acoustic hearing aids. The way it's been
19 modified as an alternative to an acoustic hearing aid,
20 in my opinion, represents a much different question,
21 because I think what we are being asked to determine
22 is not alternative but equivalence. Is this device

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1 equivalent to existing hearing aids?

2 Well, it's a low number of subjects. I
3 think we're dealing with a little over 50 patients.
4 We're dealing with primarily subjective data,
5 especially when we are looking at speech perception,
6 speech intelligibility, which is a primary concern, as
7 we heard.

8 So I would like to visit the issue of the
9 intended use. I'd like for us to talk that one
10 through, because I'm uncomfortable with the way that
11 it's currently worded.

12 The use of subjective effectiveness data -
13 - I'd like to comment on that, because it is a primary
14 issue with this PMA. Those of us in audiology are
15 getting more and more familiar and used to the concept
16 of using subjective rating scales. A key here is
17 standardized. We like to see data that are based on
18 rigorously developed and standardized subjective
19 rating scales, and I think that the whole concept of
20 using that kind of data -- we're becoming more
21 comfortable.

22 Here, the issue is mainly what claims can

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1 be made from the data. That's overall what we are
2 being asked to do. So that when we look at the
3 claims, which we will be doing, we have to represent
4 the claims as the data tells us or as the data were
5 collected. That tends to be more of a wording issue.
6 I think that we need to -- As we go through the
7 claims, we can address that issue.

8 On claim number 1: Claim number 1 had to
9 do with significant shift in residual hearing. I
10 don't accept that claim as it's currently worded,
11 because I think the criteria of 10 dB is too lenient.
12 We'll get down to that, but just for the record, I
13 would like to raise a question about claim number 1.

14 Claim number 2: Again, it's a wording
15 issue. Because it was based on subjective data, we
16 should consider rewording it, so that it's clear that
17 it is subjective information.

18 Claim 3 should include a comparison with
19 the current device and hearing aids.

20 Claim 5: The issue of how functional gain
21 reflects on clinical performance. I think that was
22 well enough addressed the presentation that I feel

1 comfortable with claim number 5.

2 Claim 4, 6 and 8, I think, are supported
3 by the data, and I think claim 7, 9 and 10 are not
4 supported by the data. That's all.

5 CHAIRMAN PATOW: Thank you. As far as
6 process for the panel, I'd like to have us go through
7 the seven questions for panel discussion one at a
8 time. I think that, by doing so, we will be able to
9 address many of the remaining questions.

10 There may be, after we finish with the
11 seven questions for panel discussion, some needed
12 discussion on some of the other claims that aren't
13 addressed by the questions, and we can certainly look
14 at those after we finish with the questions for panel
15 discussion.

16 The first question then: The sponsor has
17 provided evidence of the effect of implantation of the
18 device on residual hearing, as measured by pure tone
19 audiograms, speech perception testing and impedance
20 audiometry, for example. The sponsor requests
21 approval of the claim (Claim #1): "The Vibrant
22 Soundbridge does not adversely affect subjects'

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1 unaided hearing when compared to their level of
2 unaided hearing prior to implantation of the device."

3 The question that is asked is: Do the
4 data support this claim? Do I have comment from the
5 committee members?

6 DR. ROESER: I think I'm on record.

7 CHAIRMAN PATOW: Dr. Roeser is on record
8 that he has, I guess, a question about whether it
9 should be a 5 or 10 decibel gradation that should be
10 considered as the significant point. Other comments
11 by the panel? Dr. Hood?

12 DR. HOOD: Linda Hood. Yes. I am
13 wondering about the 10 dB cutoff. If we use 10 dB to
14 signify a permanent threshold shift in noise areas and
15 such, is 10 dB here to be considered, yes, within an
16 acceptable limit of not having a significant shift?
17 I'm kind of wrestling with the different definitions
18 with that.

19 DR. GULYA: Well, it seems that in a
20 previous panel meeting to which I was not part, there
21 was some discussion about the 10 dB threshold shift.
22 I know in clinical trials a clinical trial I'm

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1 involved in, again, is a different purpose than for
2 this implant, but the threshold of a hearing change
3 there is 10 dB threshold shift, and two contiguous
4 frequencies were 15 decibels in one frequency.

5 So how one defines a clinically
6 significant hearing loss is certainly a matter that is
7 being discussed here, and I don't know if there is 100
8 percent agreement for every venue what an appropriate
9 definition is. You've heard that there is one
10 definition for noise induced hearing loss in hearing
11 conservation programs and so on.

12 As I recall from some of the data that the
13 manufacturer presented, it looked, eyeballing it, that
14 if you took the 5 decibel criterion, that seemed like
15 70 percent or so of their subjects had less than a 5
16 dB or up to a 5 dB hearing loss, and it looked like,
17 again roughly eyeballing it, somewhere around 20
18 percent or so had between 6 and 10 dB with those two
19 individuals beyond that.

20 So I thought that, if the data were to
21 support the claim that there was no further hearing
22 loss and they were told to use the definition of 10

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1 dB, then the data shows that. If the new bar is going
2 to be 5 decibels, then they showed it for -- and I'm
3 not sure what the FDA adjective would be, but
4 certainly for many patients it would appear to be, if
5 70 percent had that. It may be adequate to reflect
6 that nuance with appropriate changed wording.

7 So that's sort of my take on it.

8 CHAIRMAN PATOW: Dr. Woodson.

9 DR. WOODSON: Yes. We can look at kind of
10 how we want to define what's a significant shift or
11 what we think might be a statistical thing that we
12 could support. But I think what really happens on the
13 labeling is what is it that we need to tell people so
14 they can make an intelligent decision about whether or
15 not they want to have an implantation.

16 To tell somebody there's an average dB
17 shift or something may not mean too much to them. The
18 fact is, it doesn't matter what percentage of people
19 have a hearing loss. If you're in the group that has
20 a significant hearing loss, then that's the issue.

21 So to say that it doesn't affect it at all
22 ignores the fact that maybe there is a small

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1 percentage that would have some threshold shift. So
2 I'm just thinking, the way it's worded maybe doesn't
3 give the patient the information they need to make a
4 decision.

5 It doesn't seem to -- For the vast
6 majority of patients, it doesn't cause any -- How much
7 is a patient going to notice with it? Would they
8 notice 10 dB? Would they notice 5 dB? It's more what
9 the patient would notice in their living than what we
10 would define, and also what is the chance -- Do we
11 think there's a chance still that someone could have
12 a significant hearing loss, even though most people
13 don't?

14 CHAIRMAN PATOW: Dr. Kileny.

15 DR. KILENY: Well, I think that it depends
16 where you start. If your threshold was 30 dB and you
17 have a 10 dB change, that's perhaps less noticeable
18 than going from 80 to 90 dB, given the nature of the
19 dB scale.

20 My recollection is that at the June '99
21 panel meeting we did discuss ranges, and my
22 recollection is we discussed changes of between 5 and

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1 10 dB. I'm not sure that we actually nailed down 10
2 dB as the upper acceptable range.

3 What I would suggest in this situation is
4 that, rather than talking about means and standard
5 deviation, especially given this single subject
6 design, the claim should basically include the range
7 of threshold shift incurred in this patient population
8 and just leave it at that.

9 Perhaps it could be added that a certain
10 percent of the patients incurred 5 dB or less and so
11 forth and so on, but I think that what should be
12 included in this claim is what was the range of
13 threshold shift in this patient population, from 3 to
14 18 dB or whatever the range. I think that's about the
15 range that it was.

16 A minority of the patients have the higher
17 threshold shift, but it's undeniable that the range
18 went from a very low 3 to a high of 18 decibels.

19 DR. DUFFELL: A comment, and then maybe a
20 question for FDA, since they will probably be more
21 familiar than I am right now with what the
22 manufacturer submitted. But at least I know a lot of

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1 industry, they typically have phraseology like this in
2 there that sometimes is a little ambiguous and
3 difficult to interpret, but then FDA requires that the
4 clinical section of the labeling provide the detail
5 that supported that statement, such as in the graphic
6 form that was displayed here today.

7 Is that present, already in there? Is
8 that data in the labeling or proposed to be in the
9 labeling such that it would clarify what we mean by
10 significant and, therefore, kind of addresses the
11 panel's comments, is what I'm leading to? I mean,
12 that's where the difficulty is: What is significant;
13 where are the numbers. if the numbers were in the
14 clinical section, then you can interpret there,
15 physician, for your patient.

16 MS. BROGDON: Dr. Duffell, I don't
17 personally know how these numbers were included in the
18 labeling. But if the panel believes that certain
19 breakouts of the data should be presented, if this
20 application is eventually approved -- If you believe
21 that certain breakouts are necessary, then you should
22 include that in your recommendation.

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1 DR. DUFFELL: Thank you.

2 CHAIRMAN PATOW: One piece of this that I
3 find troubling is that we have a relatively small
4 sample size, and yet within that small sample size we
5 have two patients that had greater than even the 10 dB
6 standard, and yet the claim is made that the Vibrant
7 Soundbridge does not adversely affect subjects'
8 unaided hearing, where clearly we have some people who
9 are affected.

10 I would wonder if the claim could be
11 modified to say, for example, "for most subjects the
12 Vibrant Soundbridge does not adversely affect
13 subjects' unaided hearing." That would -- While it
14 obscures the 5 or 10 dB dispute or consideration, it,
15 I think, more accurately reflects the fact that there
16 will be a small percent of patients who, it sounds
17 like, will have a larger degree of hearing loss,
18 although that's a very small percent, presumably.

19 Dr. Hood?

20 DR. HOOD: Yes. I would agree with that.
21 I think that the idea is just to convey the message to
22 the potential patients that there is a chance that

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1 hearing might shift, that the majority of the data say
2 that it wouldn't, but that that could happen.

3 CHAIRMAN PATOW: Dr. Roeser.

4 DR. ROESER: And I think that adequately
5 reflects the concern that I had, because -- I mean, 5
6 dB, 10 dB, we could sit here for the next three hours
7 and debate statistical variability. The point that I
8 was making is that virtually all subjects had poor
9 thresholds.

10 I mean, thresholds vary both ways, and
11 what I heard this morning was that all subjects
12 shifted to poorer hearing. There were no -- There was
13 no improvement, which in threshold variability we see
14 improvement as well as decreases. So to say that
15 there was no change in hearing, I think, is an
16 overstatement.

17 If we temper it in ways that the other
18 panel members have suggested, I think that adequately
19 represents the data, which is what we are expected to
20 be doing. Do the data support the claims?

21 CHAIRMAN PATOW: I have a suggestion, I
22 think, from Dr. Kileny. The Vibrant -- suggested

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1 claim would be: The Vibrant Soundbridge may adversely
2 affect residual unaided hearing, in the range of
3 threshold shift in the study population of 3 to 18
4 decibels. Another approach.

5 DR. WOODSON: Carl, I know that you want
6 to be specific in stating what data supports it, but
7 you can't predict that that's what's going to happen
8 for the next 100 patients, that nobody is ever going
9 to be worse than 18 or that anybody will ever be that
10 bad again.

11 So I think the labeling has to be, you
12 know, specific enough but if we nail ourselves down to
13 that prediction, then somebody comes back with a 20 dB
14 loss and they weren't made -- say, gee, you told me I
15 could only lose as much as 18, and now I've lost 20.

16 CHAIRMAN PATOW: I would agree. Do we
17 feel comfortable enough to go on to 1(b)?

18 Other than residual hearing, are there
19 other safety issues related to the physical presence
20 of the device in the middle ear that should be
21 addressed by the sponsor?

22 DR. GULYA: They mentioned in their

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1 literature that extrusion was something they thought
2 about, and I didn't see any instances of that. But
3 again, if it's a very low percentage issue, you may
4 need to follow several thousand patients.

5 So I think an additional factor that
6 should be monitored is the extrusion of the device in
7 the post-marketing surveillance studies.

8 CHAIRMAN PATOW: Any comment from the
9 panel about the transition sleeve modification? Is
10 that something that we feel should continue to be
11 monitored or are we comfortable with that? This is
12 the change that was made to the wiring.

13 DR. WOODSON: So that the wires wouldn't
14 snap.

15 DR. GULYA: I thought that's something
16 that they are going to be following.

17 DR. WOODSON: They plan to do that, right?

18 CHAIRMAN PATOW: They plan to do that?

19 DR. GULYA: Yes.

20 CHAIRMAN PATOW: Earlier today we talked
21 about the corti tympani issue. Is that something that
22 we should consider?

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1 DR. FRANCIS: Well, yes, I think that
2 future changes in tastes function should be monitored.
3 One other question that I had, if I could, Dr. Patow,
4 is a question of any potential for changes in baseline
5 residual hearing over time, if that shouldn't also be
6 monitored.

7 We have a three-month residual hearing
8 assessment, but is there any -- you know, that should
9 maybe be looked at. There may already be data that
10 haven't been presented today on that.

11 CHAIRMAN PATOW: Dr. Duffell, do you have
12 a comment?

13 DR. DUFFELL: Yes. I was going to say,
14 the manufacturer is here. Maybe they can comment on
15 that, whether or not they have got a long term follow-
16 up plan on that that's already been committed to.

17 CHAIRMAN PATOW: Can someone from the
18 sponsor --

19 MS. ARTHUR: Deborah Arthur.

20 CHAIRMAN PATOW: Thank you. The
21 transcribers tell me they've now identified our
22 voices, and we no longer have to identify them each

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1 time.

2 MS. ARTHUR: All right. Thank you very
3 much. Yes, with regard to the patient data, we do
4 have up to 12-month data, as has been mentioned here
5 before, on more than 50 percent of the patients. We
6 do have air conduction thresholds graphically
7 represented compared to the presurgical, and those are
8 comparable measures.

9 I right this second don't have the graphic
10 in front of me and can look at it, but I think, more
11 importantly, what we have done is by our post-market
12 surveillance we have committed to monitoring changes
13 in residual hearing through the term of the post-
14 market surveillance of those patients.

15 CHAIRMAN PATOW: Yes, Dr. Khan?

16 DR. KHAN: Although it wasn't mentioned as
17 ossicular necrosis concern over a period of time.

18 CHAIRMAN PATOW: Any other comments
19 regarding safety issues and the physical presence of
20 the device in the middle ear?

21 Let's go on to question 2: The most
22 prevalent adverse events seen were disruption or

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1 transection of the VIIth cranial nerve; transient
2 post-operative dizziness; fullness; and transient
3 pain. Is the information provided to the practitioner
4 and the patient adequate to fully inform them of these
5 potential adverse effects?

6 Dr. Gulya?

7 DR. GULYA: To my read of the patient
8 information guide, as it was on page 8 of that guide,
9 it listed many possible adverse effects. But unless
10 I was really asleep at the switch, I didn't see facial
11 nerve injury listed in there.

12 So I thought that's pretty standard risk
13 with the approach used. It is a low percentage risk,
14 and can be, I guess, so cited, but I think it needs to
15 be mentioned that it is a potential risk of the
16 implantation procedure. But it is included in the
17 package insert, I saw, on age 3. So there are a
18 little bit discrepancies of what information is
19 included where.

20 CHAIRMAN PATOW: Perhaps there just needs
21 to be then consistency between the two.

22 DR. GULYA: Exactly.

1 CHAIRMAN PATOW: Dr. Woodson.

2 DR. WOODSON: I had a couple of points.
3 One is: When you first look at this, you say, gee,
4 2.5 percent had the nerve cut. It's not really
5 disruption. They're really describing like a
6 neurapraxia.

7 The other thing is it's not really
8 complication of the implant per se, but it's a
9 complication of putting it in, and this has been in a
10 controlled trial where you have the best possible
11 people doing the surgery. There may be a concern
12 that, if you have a lot more people, more surgeons,
13 and each one is going to have their own learning
14 curve, it's hard to predict what the real incidence of
15 that would be.

16 This also brings up something that was
17 brought up earlier about, gee, is there something that
18 general otolaryngologists are going to use or are we
19 going to have restrictions or just label it.

20 The other things were, when I looked
21 through the facial paresis cases as they were detailed
22 -- I forget which one of the presenters gave that, but

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1 it's substantiated in the data here -- they were quite
2 long term after the surgery, three or four weeks.

3 One was -- You could always say, well,
4 maybe it's wishful thinking that they thought it was
5 Bell's palsy, but there was a coincident other cranial
6 neuropathy currently ongoing. so that makes you
7 think, well, maybe it really wasn't maybe a late
8 reaction to heating of the nerve.

9 The other one was, similarly, even very
10 dubious it was related to surgery. I think the
11 number, if you use -- Depending on which denominator
12 you use, it may be an 0.6 percentage incidence of
13 facial nerve dysfunction.

14 CHAIRMAN PATOW: What the question, I
15 think, refers to, though, is the patient and operator
16 literature. Actually, in there, I don't see that
17 there are specific numbers given.

18 DR. GULYA: Right.

19 CHAIRMAN PATOW: So that probably isn't an
20 issue in the literature themselves. One of the
21 reviewers, and now I can't remember which panel
22 reviewer, had a question about moving a sentence or a

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1 paragraph from the operators to the patients or vice
2 versa. It seemed like it was misplaced. Does anyone
3 remember that comment? No?

4 I made a note of it as I was going
5 through, but I'm not sure I could find it right now.

6 DR. GULYA: Was that in Dr. Jaffee's? I
7 think there was something in Dr. Jaffee's review.
8 Then when I looked through the paperwork that was
9 provided to us, the offending passage was gone. So I
10 think they had taken care of it.

11 CHAIRMAN PATOW: Yes, it was in Dr.
12 Jaffee's review under the user manual. So it's been
13 corrected.

14 DR. GULYA: I think that's been resolved,
15 yes. I looked at that.

16 CHAIRMAN PATOW: Thank you very much.
17 Great.

18 So it sounds as if the addition of
19 possibility of facial nerve damage to the patient's
20 information is the only issue that is a concern
21 regarding labeling to the panel. Okay. Let's go on
22 then to question 3:

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1 In the study the device is compared to the
2 preoperative aided controlled condition. As defined
3 in the study protocol, the subject must have met the
4 following minimal requirements to be entered in the
5 study. They had to be current users of acoustic
6 hearing aids and have used the aids for at least four
7 hours average per day for at least three months prior
8 to evaluation.

9 DR. GULYA: You're doing a different one
10 from Number 3.

11 CHAIRMAN PATOW: Oh, we've got new
12 numbers. Excuse me, I'm on the old numbers. Thank
13 you. Apparently, there were two editions of the
14 questions for panel discussion, and I'm on the wrong
15 edition.

16 DR. GULYA: This is the one about the MRI.

17 CHAIRMAN PATOW: Sorry. So now question
18 3: is the following warning statement regarding MRI
19 compatibility adequate to make physicians and patients
20 aware that they are excluded from all types of MRI
21 examinations and that the device must be explanted
22 prior to such examinations?

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1 It gives the passage: "Patients implanted
2 with the Vibrant Soundbridge should not be subjected
3 to MRI, and should not enter an MRI Suite or come into
4 close proximity to other sources of strong magnetic
5 fields."

6 Comments from the panel? Dr. Gulya?

7 DR. GULYA: I think it also should be note
8 that they have bolded in their patient information the
9 "not." They make it stand out. So I think, to my
10 mind, I guess that always can be emphasized more by
11 the practitioner who is evaluating the patient.

12 The issue I had was: In their literature
13 they also mentioned that patients should stay clear of
14 things such as cellular phones. Since cellular phones
15 are almost a ubiquitous part of life, if not on the
16 Beltway when you're behind somebody that's driving
17 slow, at least in life in general, I think that should
18 probably be emphasized also to the patient, that that
19 can be something that can disrupt function of the
20 device.

21 **
22 CHAIRMAN PATOW: And I can't remember. Is
that in the patient information material?

1 DR. GULYA: It is, but it's -- I can give
2 you the citation. It's Patient Information Guide,
3 page 9. It's kind of the bottom paragraph. It says,
4 "Cellular phones and strong magnetic sources such as
5 high voltage power lines or transformers may interfere
6 with the operation of the audio processor."

7 I think it's there, but I would posit that
8 with the prominence of these devices, it should be a
9 little bit more emphasized, either moved up the list
10 or bolded or something, so it's not something somebody
11 just slides by as they are reading through something.

12 CHAIRMAN PATOW: Dr. Duffell?

13 DR. DUFFELL: I've got a kind of a
14 question, and it's probably going to have to be
15 answered by the manufacturer. Since our consumer rep
16 is not here, thinking about the consumer, I know
17 oftentimes with some of the products I've been
18 involved with, consumers get very concerned when they
19 read a statement like this in there, and they think
20 it's absolutely categorical that they cannot have such
21 a thing done. Sometimes there are emergency
22 situations that arise.

1 The question for the manufacturer is: Is
2 there actually objective data that says this is indeed
3 hazardous or is this an absence of data and, since in
4 the absence of that data, we have to presume that
5 there may be a risk? So what is the answer? Is it
6 absolute or just thought to be so?

7 CHAIRMAN PATOW: Can we get clarification
8 from the sponsor?

9 MR. KATZ: Bob Katz, Vice President of
10 Research and Development. We did perform cellular
11 phone compatibility testing, in accordance with the
12 ANSI proposed standard, the American National
13 Standards Institute, for wireless device compatibility
14 with hearing aids.

15 In many cases we found that there was no
16 measurable interference with the audio processor
17 device, but with some cellular phones, some types, and
18 some orientations, we did find an audible level which
19 was typically around 65 decibels of audible level.

20 DR. DUFFELL: And with MRI? Was there
21 testing done with actual MRI?

22 MR. KATZ: There's been no conclusive

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1 testing done with MRI to date.

2 DR. DUFFELL: So then it's an absence of
3 knowledge that leads you to say that it may be unsafe.
4 We don't know.

5 MR. KATZ: That's correct.

6 CHAIRMAN PATOW: Thank you. Other
7 comments from the panel?

8 Question 4 then: The sponsor plans to
9 follow the Phase IIIa Safety Cohort subjects for a
10 period of 18 months post-market. The data to be
11 obtained during this post-market follow-up will
12 include, at a minimum, the device status, cumulative
13 months of use and any adverse events. In addition,
14 the sponsor proposes to report to FDA the following:

15 (1) clinically significant changes in
16 residual hearing to the implant ear;

17 (2) any alleged complications due to
18 incus erosion; and

19 (3) the failure rate of devices
20 incorporating the transition sleeve for the Phase IIIa
21 cohort.

22 Questions posed are: Are there any other

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1 data the sponsor should collect during this post-
2 market follow-up period?

3 A suggestion was made earlier related to
4 changes in baseline residual hearing.

5 DR. GULYA: That's part of their plan.

6 CHAIRMAN PATOW: That's part of the plan.
7 Any extrusion?

8 DR. GULYA: No. That's the only -- As I
9 mentioned before, extrusion would be something I'd
10 like to make sure they keep track of.

11 CHAIRMAN PATOW: Any other data that the
12 panel would suggest be included?

13 The second question: Are there any other
14 data the sponsor should collect in an additional post-
15 market follow-up study?

16 DR. ROESER: We are talking only about
17 safety now? I want to clarify that, because this is
18 qualified by "sponsor plans to follow the Phase III
19 Safety Cohort subjects." All of these relate to
20 safety. So are we only talking about post-market
21 surveillance for safety?

22 CHAIRMAN PATOW: I'd have to ask the FDA,

1 I guess. Does this -- Is this necessarily related
2 only to safety or could it include efficacy data?

3 MS. BROGDON: I think we would like to
4 hear the panel's recommendation on that.

5 CHAIRMAN PATOW: Dr. Roeser, are there
6 issues related to efficacy of the device you would
7 like to raise?

8 DR. ROESER: I think we still have the
9 issue of trying to get some objective evidence on this
10 device. We have some objective evidence on gain, no
11 question, on feedback -- well, feedback is not
12 necessarily on other characteristics. But as we heard
13 today, one of the primary difficulties with current
14 technology is speech intelligibility and specifically
15 speech intelligibility and noise.

16 I would like to see some objective data
17 for this device to show its performance in that area,
18 specifically in speech intelligibility; because right
19 now, the data we have shows equivalency. Is that
20 right? Yes, equivalency. We don't show that the
21 device is superior or inferior. It seems to be an
22 equivalent device.

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1 I just think that -- and we've talked
2 about the issue of subjective questionnaires. If
3 we're going to be talking about post-market
4 surveillance, it would be helpful to have some
5 information, some objective information that we can
6 look at in the future and see if this device does, in
7 fact, have -- if there is an advantage or see what it
8 does in noise and speech intelligibility.

9 MS. BROGDON: Dr. Patow, I may have misled
10 you a moment ago. Apparently, the Phase IIIa study of
11 the new modified device is only a safety study, and
12 this post-market study would be continuing follow-up
13 of those patients who have already been enrolled.

14 If you want a post-market study of safety
15 and/or effectiveness, you would need to be requesting
16 another post-market study. That's the reason for the
17 next part of the question that we have asked you.

18 DR. ROESER: You can strike my comments.

19 CHAIRMAN PATOW: So during this post-
20 market follow-up period, it sounds like the data that
21 they are proposing to gather is acceptable to the
22 panel. I don't hear that there are any other elements

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1 that the panel would like to have collected.

2 The question then would be, should they
3 have an additional post-market follow-up to look at
4 either new issues or concerns?

5 DR. ROESER: And maybe we could get to
6 this when we get into the claims, because some of
7 this, I think, as we talk through the claims, can be
8 spelled out in ways that might be more helpful for
9 everybody to understand.

10 CHAIRMAN PATOW: Fine. Any other comments
11 on question 4?

12 Question 5 then: In the study the device
13 was compared to the preoperative aided control
14 condition. As defined in the study protocol, the
15 subject must have met the following minimum
16 requirements to be entered into the study:

17 "Persons who are currently users of
18 acoustic hearing aids and have used these aids for at
19 least four hours average per day for at least three
20 months prior to evaluation. The subject's hearing aid
21 in the ear to be implanted shall be capable of
22 achieving a NAL-R prescription at 500, 1000, 2000 and

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1 3000 Hz. Capable means that the aided threshold at
2 each frequency of the NAL-R prescription is within
3 plus or minus 15 dB."

4 The question is then: What are the
5 implications of this control condition upon the
6 proposed intended use statement? That statement
7 reads: "The Vibrant Soundbridge is indicated for use
8 in adults, 18 years of age and older, who have a
9 moderate to severe sensorineural hearing loss and
10 desire an alternative to an acoustic hearing aid."

11 Comments of the panel?

12 DR. GULYA: I'll let Ross go first.

13 CHAIRMAN PATOW: Dr. Roeser?

14 DR. ROESER: I've already raised the
15 question about the modified intended use statement.
16 The previous statement that we were presented with
17 before this morning was that this device is for
18 patients who have sensorineural hearing loss and do
19 not perceive a benefit from acoustic hearing aids,
20 which is really -- To me, it's a different issue.

21 I might be misperceiving it, but now we're
22 talking about an alternative which, to my mind, what

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1 we're being asked is do the data provide equivalency?
2 Can we compare this data to a current, existing
3 technology?

4 I'd like the panel's input on this
5 alternative intended use statement.

6 CHAIRMAN PATOW: Dr. Woodson?

7 DR. WOODSON: I kind of reacted
8 differently to the change in the intended use than you
9 did, because to me, if you're only going to use it for
10 people who are not satisfied with the hearing aid,
11 then you really have to prove that this is a lot
12 better.

13 On the other hand, if they desire an
14 alternative because they are getting external otitis
15 or they don't want to have to fool with an external
16 device, then it is just an alternative, then I think
17 you have much less stringent requirements for showing
18 that it's better.

19 CHAIRMAN PATOW: I read this a little bit
20 differently. It says that they desire an alternative,
21 but it doesn't say that they have actually ever put on
22 a hearing aid. In fact, it makes no suggestion that

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1 they would have had to have had any experience with a
2 hearing aid. They just need to desire an alternative.

3 I was concerned that we were going from a
4 nonsurgical approach directly into a surgical approach
5 without any experience with a conservative option.
6 Dr. Hood?

7 DR. HOOD: This is something that I
8 thought about also. I wasn't sure where to bring that
9 up. That's whether or not there would be any kind of
10 use of a hearing aid prior to this. For someone who
11 is a complete nonuser, should they have an experience
12 with a nonsurgically implanted hearing aid prior to
13 the procedure?

14 CHAIRMAN PATOW: Yes, Dr. Roeser?

15 DR. ROESER: That relates back to the
16 comment that I was trying to address, which is
17 equivalency. What we would say is that this device is
18 an equivalent device to a hearing aid. So the fact
19 that a new hearing aid, potential new -- or a hearing
20 impaired individual who is seeking benefit might look
21 at this as the equivalent -- this device as being
22 equivalent to existing hearing aids.

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1 Quite frankly, I don't think we have the
2 data to be able to say that, based on 50-some-odd
3 subjects with somewhat limited subjective reports.

4 CHAIRMAN PATOW: Dr. Duffell.

5 DR. DUFFELL: Since it's unclear for
6 different panel members what was intended by the
7 statement, can we ask the manufacturer what their
8 actual market intent was behind the statement? Also,
9 I would just add while they are getting ready for
10 that, that I don't -- You know, in dealing with
11 patients over the years that I've encountered, a lot
12 of them have a lot of different motivating factors for
13 why they want an alternative.

14 I would think, considering the cost of
15 these devices, to force them to have experienced a
16 hearing aid first might be considered burdensome to
17 some. I think it's, you know, a decision that needs
18 to be made with, as we would say, full disclosure in
19 the labeling of what the known facts are, the pros and
20 the cons, and then with that learned intermediary
21 explain that to the patient. Then they make an
22 informed decision and decide, and not be forced, like

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1 I said, to possibly have the hearing aids first.

2 Again, I would like to hear from the
3 manufacturer what their intended market goal was with
4 the statement.

5 CHAIRMAN PATOW: Would the manufacturer
6 like to comment?

7 MS. ARTHUR: Deborah Arthur. Actually,
8 within the package inserts for the individual
9 components of the device, under the "Indicated For
10 Use" statement under the specific section called
11 "Individualization of Treatment," it does state that
12 the population will be experienced with an
13 appropriately fit acoustic hearing aid.

14 Therefore, we do address that these
15 individuals should have hearing aid experience prior
16 to consideration for implantation with the
17 Soundbridge.

18 CHAIRMAN PATOW: Thank you. Personally,
19 I would then feel more comfortable if the intended use
20 statement would be modified so that it would read that
21 "The Vibrant Soundbridge^{**} is indicted for use in
22 adults, 18 years of age and older, who have a moderate

1 to severe sensorineural hearing loss and who desire an
2 alternative to an acoustic hearing aid who have had
3 experience with a professionally fitted and adjusted
4 hearing aid," something to that effect that they would
5 have had at least some experience of a nonsurgical
6 modality.

7 Now I'm not an audiologist. So I'm going
8 to need some help here to relate -- In question 5 here
9 the preamble talks about the relationship of the
10 intended use statement and the data, the NAL-4
11 prescription at these various frequencies and how --
12 Do the minimum requirements to enter the study relate
13 appropriately to the indicated use?

14 So maybe I could have Dr. Roeser or others
15 comment about that.

16 DR. ROESER: Maybe we need clarification,
17 because I'm not quite sure. What are the implications
18 of the control condition relative to the following
19 claims? I don't know if the question being asked is
20 that we only have three months of prior hearing aid
21 wearing for four hours^{**} a day or if it relates
22 specifically to the NAL. I'm unclear on that. Maybe

1 we could get clarification from the FDA.

2 DR. GULYA: I similarly had questions as
3 to what they were trying to get at.

4 MS. BROGDON: I'd like to ask Ms.
5 Cygnarowicz to answer the question.

6 CHAIRMAN PATOW: Thank you.

7 MS. CYGNAROWICZ: Teri Cygnarowicz. I
8 think the intent was understanding what the control
9 condition overall was in this study. Does the
10 intended use reflect what took place in that clinical
11 trial? So that a patient going in to be evaluated for
12 this device may want to know what took place in the
13 clinical trial.

14 Based upon the intended use statement,
15 does the rewording that you suggested accurately
16 reflect what took place in the clinical trial?

17 DR. ROESER: From what I heard this
18 morning -- and I don't have any specific -- Let me say
19 it different. What I heard this morning is that we
20 were dealing with a population of 50-some-odd hearing
21 aid wearers who were wearing their instruments
22 significantly more than four hours a day and who had

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1 significantly more experience than three months.

2 So as a minimum criteria, I would say that
3 we would not accept the claims based on that
4 information. But I heard also that the minimum
5 criteria were exceeded, that we were dealing with
6 patients who had worn their instruments longer than
7 the minimum criteria.

8 So if I were going to design a study and
9 I said these criteria, I would be very concerned;
10 because I don't think they are stringent enough to be
11 able to base claims like this. But if my recollection
12 serves me right, we heard that these were just minimum
13 criteria that were exceeded. Is that the essence of
14 what the question is?

15 MS. CYGNAROWICZ: To put it another way,
16 knowing what took place, what was actual regarding the
17 control group, the fact that they exceeded these
18 measures, does the intended use statement accurately
19 reflect what took place in the clinical trial?

20 DR. ROESER: The revised intended use or
21 the new intended use? **

22 MS. CYGNAROWICZ: Revised.

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1 DR. ROESER: Revised. I'm more
2 comfortable with the revised intended use statement
3 than the original intended use statement.

4 CHAIRMAN PATOW: The second part of this
5 question, the 5(b), then is: What are the
6 implications of the control condition on the following
7 claims as stated in the Phase III Safety and
8 Effectiveness Data Section of the PMA:

9 Claim #3: "The Vibrant Soundbridge
10 provides significant improvement in overall fit and
11 comfort."

12 Comments from the committee?

13 DR. GULYA: I'm trying to reorient myself
14 to this.

15 CHAIRMAN PATOW: Okay. One of the
16 questions that I think came up in one of the reviews
17 was significant improvement compared to what, and
18 should there be a statement relating to what the
19 comparison group is. Dr. Roeser?

20 DR. ROESER: In the review that I
21 submitted, I suggested that the wording of this claim
22 be modified to reflect the actual procedures. My

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1 suggestion was "Compared to conventional hearing aids,
2 patients report that the Vibrant Soundbridge provides
3 significant improvement in overall fit and comfort,"
4 because it is based on subjective reports, and it is
5 being compared to a conventional hearing aid.

6 DR. GULYA: I think I'm a little bit more
7 oriented now. Let's see. With regard to claim Number
8 3, what my suggestion was, they needed to alter the
9 wording of the claim to reflect the subjective nature
10 of the data, which I think is what I just heard you
11 say also.

12 DR. ROESER: I can't hear you.

13 DR. GULYA: For claim number 3, they need
14 to alter the wording to reflect the subjective nature
15 of the data. For number 5, I thought that was okay.
16 For number 6, that was okay. For claim number 7, I
17 thought the claim would need to be modified, and for
18 claim number 9 I did not think that the data supported
19 that claim.

20 CHAIRMAN PATOW: Let's go back, if we
21 could, to claim number 3. Are we comfortable then
22 with the addition of the words "compared to

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1 conventional hearing aids, patients report that the
2 Vibrant Soundbridge provides significant improvement
3 in overall fit and comfort"? Other suggestions or
4 comments?

5 DR. GULYA: Well, again, it's subjective
6 data. That needs to be pointed out. Some of this --
7 You're stuck with subjective data, because it's
8 subjective types of things that you're looking at.
9 But to be perfectly fair to the potential consumer,
10 they should be made aware that there is no way to give
11 a hard, solid objective measure of something like
12 this.

13 CHAIRMAN PATOW: With the words "patients
14 report that," which would imply a subjective report.

15 DR. GULYA: Yes. That would probably
16 work.

17 CHAIRMAN PATOW: Then claim number 5 has
18 been modified by the sponsor already, if I remember
19 correctly from this morning.

20 DR. GULYA: Well, they changed "better" to
21 "increased."

22 CHAIRMAN PATOW: "Better" to "increased."

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1 So with that modification in mind, it now reads: "The
2 Vibrant Soundbridge provides equal or increased
3 functional gain compared to a hearing aid."

4 DR. GULYA: That's fine.

5 CHAIRMAN PATOW: Other comments?

6 Claim number 6: "The Vibrant Soundbridge
7 significantly improves a patient's perceived benefit
8 in everyday listening situations." Any implications
9 of the control condition related to this particular
10 claim? Is the panel comfortable with the control
11 condition that was used and now this claim is being
12 made, based on that? Okay.

13 Then claim number 7: "The Vibrant
14 Soundbridge significantly improves a patient's
15 satisfaction and perceived benefit in challenging
16 listening environments."

17 DR. GULYA: And they modified that. They
18 added the "for many patients" at the end.

19 CHAIRMAN PATOW: "for many patients." I
20 would have a comment. Maybe I'm just being picky, but
21 I don't see that there was actually a test done for
22 challenging listening environment. There was, in

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1 fact, a test done for background noise, but individual
2 patients may come to what they perceive as a
3 challenging listening environment and not necessarily
4 believe that's background noise. For them, the
5 challenge may be something quite different.

6 This presumes that everyone has the same
7 challenge, which is background noise. I don't know if
8 that's an issue in general for the panel or not.

9 DR. ROESER: For me, it is, because we're
10 looking at, again, subjective data. We don't have a
11 direct comparison between what isn't and what is a
12 challenging listening environment. It's undefined, as
13 you pointed out.

14 I think this is an area that is
15 particularly sensitive for those with hearing
16 impairment, and it's something that is the most
17 difficult. I would like to see a comparison between -
18 - Since we've all agreed that we're going to be
19 looking at this device with respect to current,
20 available technology, I'd like to see some comparison
21 between the available technology and this device in
22 order to be able to make this claim -- a direct

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1 comparison.

2 CHAIRMAN PATOW: Are there other comments?

3 Dr. Kileny.

4 DR. KILENY: In the same trend, I'm just
5 a little uncomfortable with this statement, because in
6 spite of previous discussions on whether a challenging
7 environment means noise, signal-to-noise ratio, that
8 may very well be so. But the comparison was made to
9 the patient's own existing hearing aids at the time,
10 as opposed to optimizing amplification and comparing
11 it to that.

12 So somehow the statement should reflect
13 the fact that this was not necessarily compared to the
14 best and most up-to-date, current technology such as
15 digital programmable hearing aids, directional
16 microphones and so forth and so on that are known to
17 be very helpful in certain listening environments.

18 CHAIRMAN PATOW: Are you suggesting then
19 perhaps a phrase like "compared to conventional
20 hearing aids"? No? How might you -- How could the
21 claim reflect that?

22 DR. KILENY: Well, maybe "compared to an

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1 average acoustic hearing aid," something like that.
2 I don't know how else to express it. You could say to
3 the patient's own hearing aid at the time, but you
4 know, some of them may have had very high tech hearing
5 aids, and some may have had the lower end type
6 acoustic amplification.

7 So because the comparison to a standard
8 hearing aid wasn't standardized or optimized across
9 these study patients, across these subjects, I think
10 that claim needs to be made with regard to this that
11 the condition in which the study was carried out, so
12 that the consumer and the future clinicians looking at
13 this as an option can make an educated decision.

14 CHAIRMAN PATOW: Dr. Roeser.

15 DR. ROESER: Well, I will be a little bit
16 more extreme and say that -- or maybe a lot more
17 extreme and say that, because we couldn't define a
18 challenging listening environment, we can't make this
19 claim. This claim can't be made, because there is no
20 definition. It was based on a field trial, subjective
21 questionnaire, and I'm uncomfortable being able to say
22 that we had a comparison, a direct comparison or even

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1 an acceptable comparison between available technology
2 and this device, because we didn't put them in the
3 same "whatever we want to call it, challenging
4 listening environment."

5 CHAIRMAN PATOW: Let me run a possibility
6 by you and see if this solves that question for you or
7 not. If one were to say, "For many patients the
8 Vibrant Soundbridge significantly improves a patient's
9 satisfaction and perceived benefit in listening
10 environments with background noise," does that --

11 DR. ROESER: I don't know that we have the
12 data to be able to say that.

13 CHAIRMAN PATOW: Dr. Duffell.

14 DR. DUFFELL: And that's actually the
15 lead-in to my question. What other data does the
16 manufacturer have that would support this? Perhaps
17 there is something more than what we were given.
18 Could they elaborate where they were getting that
19 from?

20 DR. FABRY: David Fabry. The issue with
21 the PHAP is that it is a subjective measure, albeit
22 one for which normative data have been gathered on

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1 hard of hearing patients. There are seven subscales,
2 some that deal with reverberant conditions, some with
3 background noise conditions, some with ease of
4 communication under well lit, low reverberant
5 conditions, low background noise conditions.

6 So those data do span a variety of
7 listening environments, albeit it is in a subjective
8 index. But data do exist from a variety of studies
9 that have looked at populations of hard of hearing
10 patients who are successfully wearing hearing aids,
11 and their performance on that is well chronicled by
12 Cox and colleagues.

13 DR. DUFFELL: So it's one test instrument
14 that covers a range of different types of hearing
15 challenges.

16 DR. FABRY: Different situations, albeit
17 it is a subjective measure, and what Dr. Roeser is
18 saying, it wasn't an objective measure in those
19 conditions, but presurgery data with their existing
20 device and post-implant data were collected on all
21 subjects related to that issue.

22 May I comment on the other issue that Dr.

1 Kileny raised regarding the comparison device, the
2 control device?

3 CHAIRMAN PATOW: Yes.

4 DR. FABRY: I think that to limit to
5 digital or analog devices is going to put a timeline
6 on whenever another one of these devices come to
7 market in terms of the current, latest whiz-bang
8 gadget being digital. I would argue that technology
9 is going to change, but the fitting measurements
10 remain constant.

11 If you look at the NAL formula, it was
12 developed initially 25 years ago and was really based
13 on technology from 50 years ago. As long as adequate
14 audibility without discomfort occurs, the device under
15 comparison to the Soundbridge was appropriately fit.
16 So that perhaps a modification that says
17 "appropriately fit conventional amplification,"
18 regardless of whether it's digital or analog, would
19 capture the essence, just for your consideration.

20 CHAIRMAN PATOW: Although we can't predict
21 the future and what will be the possible technology
22 for hearing aids in the future, so to say

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1 "appropriately fit" ten years from now may, in fact,
2 be quite different than what it is now. And to make
3 a comparison with a possible future technology and say
4 that the Vibrant Soundbridge significantly improves a
5 patient's satisfaction -- Who knows?

6 I'm a little uncomfortable with that,
7 although I understand your point. Dr. Woodson?

8 DR. WOODSON: Maybe it's better for the
9 claim to just say what we know, that in this study
10 patients felt that it improved their hearing.

11 I think in audiology and in hearing, it's
12 a field that's kind of blessed by being able to have
13 a whole lot of numbers, more than other fields. But
14 I think it may be a curse, too, in that you put too
15 much into the numbers and not rely on subjective
16 things, because we all know patients who -- you know,
17 you can look at the numbers, and they say you should
18 get great benefit from this hearing aid, and he leaves
19 it in his drawer, or we know patients who've got a
20 central auditory problem and their pure tone average
21 looks great, but they don't hear.

22 We know old people who have presbycusis

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1 and their perception is worse compared to what you
2 predict. So there's more going on than exactly what
3 we can measure, and that's one of the benefits of a
4 subjective thing. It's that you can measure all these
5 things, but they are only -- the subjective things are
6 only significant in how they relate to how much
7 benefit the patient gets from the hearing aid.

8 So they are kind of getting at the problem
9 from two ends. I don't think we should discount
10 subjective measures. I think they are very valuable.

11 CHAIRMAN PATOW: While I wouldn't discount
12 the subjective measures, what concerns me about this
13 statement here is that it refers to challenging
14 listening environments. Yet as I said, I'm not an
15 audiologist, but what I see in the PHAP results are
16 seven measures, one, for example, "familiar talkers,"
17 another "ease of communication," "reverberation."

18 Reverberation could be a challenging
19 listening environment. "Reduced cues" -- perhaps that
20 is one. "Background noise" might be one.
21 "Aversiveness sounds" -- I don't know. "Distortion of
22 sounds" -- I don't know.

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1 Some of these seem to be potentially
2 challenging. Others I'm not so sure about, but I'm
3 not sure that the phrase "challenging listening
4 environment" would correctly be interpreted by
5 consumers of the product. That's what bothers me.
6 Dr. Hood?

7 DR. HOOD: Linda Hood. Yes. One of the
8 things that I was concerned about with this was just
9 the phrasing "in challenging listening environments"
10 suggested to me that it might encompass all
11 challenging environments or it might be interpreted
12 that way.

13 I'm wondering if that should be qualified
14 of certain environments or something like that.

15 DR. GULYA: Well, perhaps a little bit
16 more wordsmithing here is eliminating the
17 "challenging" and "in a variety of listening
18 environments, as defined in the PHAP." There you have
19 the reverberation, the loss of background cues, and
20 what have you. You've specified what the source of
21 the different environments is and if they did better
22 in those. Ross has got a counter.

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1 DR. ROESER: Claim Number 6 really covers
2 all the listening situations that are in the PHAP. It
3 states that it significantly improves the patient's
4 perceived benefits in everyday listening situations,
5 and that's something we agreed to accept.

6 I think accepting that would cover claim
7 number 7.

8 CHAIRMAN PATOW: Dr. Duffell?

9 DR. DUFFELL: Yes. Actually, my comment
10 was a take-off on yours. I think the change that
11 you're recommending is appropriate, although what I
12 would have said is just leave the statement as it is,
13 and then after "challenging," just put "(as defined
14 by)." Then that's up to the clinician to explain to
15 the patient what that test instrument is all about,
16 what it covers, and what it does not cover, as they
17 interpret a challenging -- I mean, then you're letting
18 the data speak for itself. Okay?

19 Now you've defined what that data is, and
20 it's clear in the labeling, and that's up to the
21 clinician to explain it.

22 CHAIRMAN PATOW: Dr. Kileny.

1 DR. KILENY: Well, maybe then claim 6
2 covers it all, and if claim 7 is no longer there, then
3 there's not -- The issue of what in particular was
4 this reference to or what type of acoustic
5 amplification was this compared to then is not an
6 issue anymore. In fact, there is some redundancy
7 between claim 6 and 7.

8 CHAIRMAN PATOW: Dr. Hood.

9 DR. HOOD: In looking back, it looks like
10 claim 6 is also based on the PHAP. So if we qualify
11 one, then we have to qualify the other, and if
12 "challenging" isn't there, they really do seem the
13 same.

14 CHAIRMAN PATOW: Are you suggesting that
15 we should modify claim 6 or suggest a modification for
16 claim 6 that would say "as in the PHAP"? Maybe I'm
17 not understanding exactly what you are suggesting.

18 DR. HOOD: What I was saying is that claim
19 6 talks about everyday listening situations. That's
20 what the PHAP covers. So in claim 7, if we aren't
21 using the word "challenging," then they really are
22 addressing the same issues.

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1 CHAIRMAN PATOW: You're suggesting that
2 perhaps we don't need claim 7, that we wouldn't
3 support claim 7, and that claim 6 would -- we're more
4 comfortable with that.

5 DR. HOOD: Yes.

6 CHAIRMAN PATOW: It does seem like there's
7 several problems with claim 7, as far as the testing
8 environment and also exactly what the claim means.

9 MS. BROGDON: Dr. Patow, I'd like to just
10 mention to the panel that you're potentially talking
11 here not just about statements in labeling, but also
12 potential advertising claims. So if you're discussing
13 caveats and additional descriptive wording, you might
14 want to consider how those would also be said in
15 advertising.

16 CHAIRMAN PATOW: Thank you. Is there a
17 feeling then amongst the members of the panel that
18 claim 6, in fact, could be used and that claim 7 not
19 be used? Is there more discussion related to that?

20 DR. ROESER: Should we take a vote? Are
21 we ready?

22 CHAIRMAN PATOW: We will do that later.

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1 We can certainly take a consensus.

2 DR. WOODSON: Well, if you think, you
3 know, about how it gets applied to advertising, let's
4 think how you would have an ad, you know. Everyday
5 listening situation -- that's just having conversation
6 with somebody. You could have the commercial with a
7 lady talking to her friend across the fence, and we
8 all know what claim 7 is talking about. If you're at
9 a cocktail party and there's all this noise and one
10 person on one side of you, you can picture the
11 scenario.

12 So that's the difference between claim 6
13 and claim 7. So what does the data support?

14 CHAIRMAN PATOW: Dr. Duffell?

15 DR. DUFFELL: I was just going to ask
16 again. I mean, there's where I would say to the
17 manufacturer what is your intent. I mean, what is the
18 marketing intent behind this claim?

19 MS. ARTHUR: What the manufacturer would
20 propose -- Deborah Arthur. What the manufacturer
21 would propose is that actually we consolidate claims
22 6 and 7 and say that in many listening conditions --

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1 and then list the PHAP subscales with familiar
2 talkers, with reduced cues, in background noise or
3 distortion of sounds, etcetera.

4 CHAIRMAN PATOW: I think that's a very
5 good approach. If someone could actually write that
6 down, that would be very helpful, and then I could
7 have the panel address it. That would be great.

8 MS. ARTHUR: Thank you very much.

9 CHAIRMAN PATOW: Dr. Francis, did you have
10 a comment?

11 Let's move on to claim number 9, and we'll
12 come back to the combined 6 and 7 concept in just a
13 minute.

14 Claim number 9 says: "When listening to
15 speech, the Vibrant Soundbridge was significantly
16 preferred over the presurgery hearing aid in various
17 listening situations. Speech perception test results
18 in a controlled soundfield environment (e.g., 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."

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1 It will make for an interesting radio
2 advertisement or television advertisement, whenever it
3 gets to the marketing stage. Comments by the panel?
4 Okay.

5 Before we move on -- Well, actually, we
6 deal with claim 6 and 7 again in question 6. So why
7 don't we move to question 6, and then we'll catch that
8 issue again.

9 Question 6 says: What are the
10 implications of the subjective data collected by
11 questionnaire versus objective speech perception test
12 data as it pertains to speech perception ability on
13 the following claims:

14 Let's just jump down to claim 9, and then
15 we'll come back up to 6 and 7. So I'm not going to
16 read claim 9 again. Are there any comments related to
17 subjective data and claim 9? That is speech
18 perception test results in a controlled soundfield
19 environment.

20 DR. GULYA: I agree with Dr. Woodson.
21 This is Julia Gulya. I agree that there is an
22 important dimension to be added in the evaluation of

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1 these devices by the subjective data. In fact, this
2 is data that you can't get objectively. So you're
3 going to have to come to grips with the fact that some
4 of it is just going to have to be subjective.

5 I think what they did in this claim number
6 9 is they clarified it over the initial claim, as I
7 recall, that stopped with the first sentence. What
8 they are saying is that was preferred, despite the
9 fact that in objective testing you didn't see any
10 difference, and that was where they got backed into
11 using the SHACQ, whatever that acronym stands for. I
12 never will remember it.

13 That was what they tried to address with
14 the SHACQ, was the fact that, despite objective
15 measures not showing any difference of performance
16 between the hearing aid and the Symphonix device,
17 nonetheless, patients preferred this.

18 Now the one thing that I was looking for
19 and still am looking for is validation of that SHACQ
20 questionnaire, and that's an issue that remains on the
21 table, is that whether or not -- I mean, subjective
22 data is subjective data, and yes, you have to rely on

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1 it; but by the same token, you would like to make sure
2 that the questionnaires you are using to assess that
3 subjective response are validated to be, in fact,
4 measuring what they are supposed to be measuring, be
5 able to validate that they can measure a difference
6 between different situations, and a whole slew of
7 other things.

8 I haven't gotten information to that
9 effect that makes me feel real solid that I feel that
10 this thing has been validated.

11 DR. ROESER: I would like to also raise
12 concerns. What we are being asked to do is base our
13 opinion on a test that was developed by the
14 manufacturer to test the manufacturer's device. On
15 the surface, that seems inappropriate.

16 The fact that we use subjective data has
17 already been addressed, and I think we feel very
18 comfortable with that, but to use a device that was
19 developed that's not been standardized, that we don't
20 know the face validity, to make a claim, especially a
21 claim as important as this one, because it relates to
22 speech perception, I think we need to consider very

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1 carefully. I'm very uncomfortable with that.

2 The fact that the objective tests are
3 included in the claim, I think, is favorable in that
4 it does say that, even though we couldn't show it
5 objectively, we have subjective information that this
6 device does improve speech perception, but it's based
7 on an unstandardized, nonvalidated subjective test
8 that -- I guess I've already said it -- I'm not real
9 comfortable with.

10 CHAIRMAN PATOW: I think part of our
11 charge is to be sure that we feel that there is
12 scientific basis for the claims that are being made.
13 If we're not comfortable with the science, that's an
14 important factor.

15 I would ask the manufacturer, besides the
16 SHACQ, are there any other validated tests that would
17 support this claim or is the SHACQ the one test on
18 which this claim is based?

19 MS. ARTHUR: Deborah Arthur. Claim number
20 9 was specifically just using the SHACQ as its basis
21 for the claim, but it is a simple preference test, and
22 it's really not a test with respect to speech

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1 perception. I'd like to make that clarification.

2 What it is, is a preference, and the
3 preference is always requested in each of the
4 questions to the patients with the hearing aid listed
5 first followed by the Soundbridge. The preference
6 test just says, when listening to speech in the
7 following situations, which device do you prefer, the
8 hearing aid or the Soundbridge?

9 The question or the statements about
10 speech perception are really not what is intended to
11 be reflected, and I don't believe the wording actually
12 says that. This second part of the claim deals with
13 the speech perception as measured by the standardized
14 -- or the objective measures in the controlled
15 soundfield dealing with the SPIN, but the first part
16 was just varying preference.

17 CHAIRMAN PATOW: Thank you. Dr. Roeser,
18 comment?

19 DR. ROESER: Well, if it's not speech
20 perception, then why were speech perception tests used
21 to measure the claim? I mean, the SPIN test -- it's
22 a speech perception and noise test. So maybe we're

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1 mixing intent here.

2 MS. ARTHUR: Excuse me for coming right
3 back up, but I felt like you were asking me that
4 question.

5 DR. ROESER: Yes.

6 MS. ARTHUR: The fact is I believe, as one
7 of the other panel members mentioned a moment ago, the
8 original claim stated, when listening to speech, the
9 Vibrant Soundbridge was significantly preferred over
10 the presurgery hearing aid in various listening
11 situations.

12 That was specifically taken from the
13 SHACQ. Based on comments from the agency and the
14 primary panel reviewers, Symphonix amended that claim
15 to include the second statement, because the
16 information that Symphonix got in the reviewer's
17 comments and the panel comments were that we needed to
18 make sure that all of the information was prepared or
19 provided to the patients indicating how they did also
20 in terms of speech, other controlled or objective
21 speech measures.

22 The sponsor then put in the results of the

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1 SPIN test. It wasn't that the original claim sought
2 to get objective speech measures via the SPIN and then
3 patient preference via the SHACQ, but it was a vehicle
4 in claim 9 to put in the wording that we felt that the
5 panel and the FDA requested.

6 CHAIRMAN PATOW: Dr. Francis.

7 DR. FRANCIS: Yes. I think I'm
8 uncomfortable with the term significantly, because it
9 implies that we have a standardized test where
10 statistics could truly demonstrate a difference which,
11 as we have already said, we have not validated exactly
12 what difference in this test really means.

13 Since you clarified it nicely what the
14 actual questionnaire question was, maybe simply
15 indicating that the Vibrant Soundbridge was chosen
16 over the individual's current hearing aid or preferred
17 relative to their current hearing aid, indicating
18 something along that line might be a little bit -- may
19 be more accurate.

20 CHAIRMAN PATOW: Dr. Roeser.

21 DR. ROESER: I don't know that I can say
22 more.

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1 CHAIRMAN PATOW: Okay. I just would want
2 to query the panel as to whether the use of -- If we
3 were to not use the word significantly, which to me
4 implies a statistical basis and validation, does the
5 panel still feel comfortable with using a preference
6 survey as the basis for a claim? Dr. Hood?

7 DR. HOOD: I'm still uncomfortable with a
8 preference survey, and I feel like almost having the
9 speech perception test in the same paragraph or in the
10 sentence next to the results of the instrument
11 preference is misleading as to what the other
12 instrument may be testing, what the SHACQ may be
13 testing.

14 CHAIRMAN PATOW: Dr. Roeser.

15 DR. ROESER: I think you said it for me.
16 You said we are being asked, on the basis of
17 scientific information, whether we can accept this
18 claim, and there is no scientific basis for the
19 instrument that was used to base the claim on.

20 So your statement, to me, solidified my
21 feeling that I'm uncomfortable with this claim.

22 CHAIRMAN PATOW: Dr. Duffell.

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