

1 DR. SHELTON: I have a comment.

2 CHAIRMAN PATOW: Yes, Dr. Shelton.

3 DR. SHELTON: I'm still concerned that
4 these claims are difficult to read, particularly for
5 a lay person. If you look at the very first one, 82
6 percent of subject and environmental sounds, you know,
7 49 over 60, I assume that's 82 percent, and so that's
8 redundant. I'm wondering if it would make this
9 clearer to read by just stating someplace that there
10 were 60 subjects tested and then leave out all the
11 fractions and everything.

12 And you know, likewise I think on the next
13 page the sample size changes to 58. I don't think
14 that that would really matter that much to a lay
15 person if there's two fewer subjects there.

16 You know, likewise reporting what chance
17 is for this test, 43 percent, I'm not sure that that
18 number really adds to the clarity of this statement.

19 CHAIRMAN PATOW: How do the other panel
20 members feel about the specificity versus the -- the
21 specificity of having different numbers versus perhaps
22 a more general understanding of the claims?

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1 DR. WOODSON: I think a general
2 understanding is better.

3 CHAIRMAN PATOW: Dr. Hood?

4 DR. HOOD: Yeah, I think a lay person
5 trying to wade through this would find it much easier
6 if they could just get an idea of what their percent
7 chances are of benefitting.

8 CHAIRMAN PATOW: We mentioned before that
9 we felt there should be a claim that should state the
10 percent of those implanted that did not receive
11 stimulation. Is that enough to clarify for the
12 remaining claims?

13 For example, the first claim says 82
14 percent of the subjects, 49 out of 60. Does that need
15 to be modified to indicate that those are subjects who
16 had sound perception?

17 DR. HOOD: Yes.

18 DR. KILENY: In all the claims.

19 CHAIRMAN PATOW: In all the claims.

20 DR. KILENY: Yes.

21 CHAIRMAN PATOW: Is that the sense of the
22 other committee members?

1 Are there any other issues related to the
2 claims?

3 (No response.)

4 CHAIRMAN PATOW: I have to take a minute
5 to write this down or I'll forget it later. So bear
6 with me.

7 Are there any issues related to the user
8 manuals that we haven't discussed so far as far as the
9 user manual, the surgeon's guide, or any of the other
10 manuals that are provided that the members of the
11 panel would like to bring forward?

12 DR. KAHN: I thought we were going to
13 insert like the physiologic monitoring and the
14 surgeon's manual.

15 CHAIRMAN PATOW: Dr. Kahn, can you restate
16 that? I'm sorry.

17 DR. KAHN: Yeah, this is Dr. Kahn.

18 The electrophysiologic monitoring perhaps
19 should be inserted in the surgeon's manual so there's
20 more stress on that.

21 CHAIRMAN PATOW: There is a section on
22 electrophysiological monitoring. I think perhaps the

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1 question was whether that needed to be supplemented to
2 include more information on --

3 DR. KAHN: Whatever is there is very
4 minimal. It doesn't specify what Dr. Hitzelberger
5 said.

6 CHAIRMAN PATOW: Okay. So it needs to be
7 amplified.

8 No other issues there. Okay. Are there
9 then any other questions, comments, concerns of the
10 panel that haven't been addressed?

11 MS. BROGDON: May I ask one question?

12 CHAIRMAN PATOW: Certainly.

13 MS. BROGDON: Is it possible that patients
14 might ever be receiving two of these implants to
15 operating one? And is there anything the panel would
16 like to address in that case?

17 DR. HOOD: Well, I think based on our
18 experience yesterday we might recommend that the
19 efficacy data for bilateral implants have not been
20 collected or something like that.

21 CHAIRMAN PATOW: How do other panel
22 members feel about that? It came up as an issue with

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1 a different device yesterday. Is it a concern with
2 this device?

3 Is there a feeling that there should then
4 be a statement that there's no efficacy available
5 about simultaneous implantation?

6 Dr. Francis.

7 DR. FRANCIS: Could we gain maybe the
8 benefit of Dr. Brackmann's experience in this? I
9 could foresee where if one side did not work at all or
10 maybe didn't work very minimally, you might very well
11 want to give the benefit of a second chance.
12 Implanting the other side in that instance may be a
13 medical decision that's made by the physician, which
14 is a judgment of the physician and the relationship
15 with the patients becomes important, but could you
16 shed any light on that issue at all, Dr. Brackmann?

17 CHAIRMAN PATOW: If I could just clarify
18 from Nancy, are you talking about simultaneous or
19 asynchronous?

20 MS. BROGDON: Ever.

21 CHAIRMAN PATOW: Ever.

22 MS. BROGDON: Two operating devices. I

1 wasn't really addressing --

2 CHAIRMAN PATOW: Two operating devices.

3 MS. BROGDON: Yes. I wasn't really
4 addressing the question of if one failed might the
5 other side be implanted.

6 CHAIRMAN PATOW: Okay.

7 DR. BRACKMANN: Well, going back just a
8 little bit to binaural hearing aids, I think no
9 question that's efficacious. There's very little
10 risk.

11 Bilateral cochlear implants is one step
12 up. There are now studies being done about the
13 efficacy of bilateral cochlear implants, and there may
14 be some benefit.

15 If you have a -- let me say that all
16 decisions of the nature carrying the weight that Dr.
17 Francis has raised, I think it's going to be hard to
18 make a hard and fast rule and say you can't or can or
19 should or shouldn't because there are all degrees of
20 efficacy.

21 If you have a patient who has a device who
22 hears minimally, but yet by all or none classification

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1 does stimulate, if you have a rule that says they
2 can't have a second implant, I think you'll be
3 depriving them of a great deal of potential benefit.

4 On the other hand, I think that any
5 physician who had a patient that was functioning well
6 with an implant on one side -- I personally would not
7 offer the patient the second implant. We have not
8 done that.

9 On the other hand, we do have a patient
10 that you've all talked about that has a nonfunctioning
11 device on one side who benefits greatly from a
12 functioning device on the other.

13 So I think my opinion would be it's
14 cutting the hair too fine to really make hard and fast
15 rules. These are real clinical judgment questions.

16 CHAIRMAN PATOW: Dr. Brackmann, would it
17 be fair to say that at present there is not clinical
18 data regarding bilateral functioning cochlear
19 implantation?

20 DR. BRACKMANN: That's a true statement.
21 Yeah, they're being gathered.

22 I should ask -- no, I should decline. I

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1 should ask them.

2 (Laughter.)

3 CHAIRMAN PATOW: All right. Thank you.

4 Any other concerns of the panel members
5 regarding this PMA?

6 (No response.)

7 CHAIRMAN PATOW: At this time then we have
8 a period of 15 minutes for additional comments from
9 the sponsor -- no, let's see. No, we have 30 minutes.
10 I'm sorry. I'm looking at the wrong line. Thirty
11 minutes of open public hearing.

12 There's an opportunity for individuals to
13 come forward if they'd like to speak regarding this
14 device.

15 (No response.)

16 CHAIRMAN PATOW: Seeing none, then I'd
17 like to go to the next item on the agenda, which is
18 the FDA's closing comments.

19 MS. BROGDON: FDA staff have no additional
20 comments.

21 CHAIRMAN PATOW: No additional comments.

22 We have then a five minute opportunity for

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1 the sponsor to make closing comments.

2 MR. WEST: Ron West, and my comments will
3 be much shorter than five minutes.

4 I'd just like to once again thank FDA and
5 the panel for, I think, an excellent review and
6 displaying appropriate concerns that patients are
7 properly informed. So thank you for your time and
8 efforts today.

9 And just to provide a bit of context, as
10 you go forward in considering what additional
11 information we might need to follow on a post market
12 surveillance, I think it's important to understand
13 that auditory brain stem implants will represent
14 something less than one percent of the devices that we
15 sell in any given year going forward. So it's not a
16 big commercial issue for us.

17 And I think the real issue is we would
18 like to make sure that this device is available to
19 patients across the country so that they can get the
20 help that they need, and we would like to use what
21 additional resources that we have from a research and
22 development standpoint to try to improve the efficacy

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1 of the device in collaboration with Huntington Medical
2 Research Laboratories and the House Ear Institute.

3 CHAIRMAN PATOW: Thank you very much.

4 As we've learned from our experience
5 yesterday, the voting process can be somewhat lengthy.
6 So I would like to take a 15 minute break at this
7 point.

8 (Whereupon, the foregoing matter went off
9 the record at 2:26 p.m. and went back on
10 the record at 2:43 p.m.)

11 CHAIRMAN PATOW: Could I Sara Thornton now
12 to read the voting options to the panel, please?

13 MS. THORNTON: The medical device
14 amendments to the Federal Food, Drug, and Cosmetic
15 Act, as amended by the Safe Medical Devices Act of
16 1990, allows the Food and Drug Administration to
17 obtain a recommendation from an expert advisory panel
18 on designated medical device premarket approval
19 applications, or PMAs, that are filed with the agency.
20 The PMA must stand on its own merits, and your
21 recommendation must be supported by safety and
22 effectiveness data in the application or by applicable

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1 publicly available information.

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

11 Your recommendation options for the vote
12 are as follows:

13 One, approval if there are no conditions
14 attached.

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

20 Prior to voting, all of the conditions
21 should be discussed by the panel.

22 Three, not approvable. The panel may

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1 recommend that the PMA is not approvable if the data
2 do not provide a reasonable assurance that the device
3 is safe or if a reasonable assurance has not been
4 given that the device is effective under the
5 conditions of use prescribed, recommended, or
6 suggested in the proposed labeling.

7 Following the voting, the chair will ask
8 each panel member to present a brief statement
9 outlining the reasons for their vote.

10 Thank you, Dr. Patow.

11 CHAIRMAN PATOW: Thank you.

12 Do I have a motion with respect to
13 approval of the PMA P000015, nucleus 24 auditory brain
14 stem implant system?

15 Dr. Roeser.

16 DR. ROESER: I will make a motion that PMA
17 000015 be approvable with conditions.

18 CHAIRMAN PATOW: Is there a second to that
19 motion?

20 DR. SHELTON: Second.

21 CHAIRMAN PATOW: Discussion. Any
22 discussion by the panel regarding this motion to

1 approve with condition?

2 (No response.)

3 CHAIRMAN PATOW: All right. Can I have at
4 this point a -- then at this point we would add the
5 first condition.

6 DR. GULYA: Julie Gulya.

7 I would suggest that a claim be added as
8 the first claim regarding of the total number of
9 patients implanted, the percentage that actually
10 received stimulation, and I think the number there is
11 of the 90 that were available to be stimulated, it
12 would be some 82.8 percent, with 17.2 percent that
13 didn't stimulate. So you can put that in a -- I don't
14 know if my math is still any good at this hour of the
15 day, but I think it would be 82 percent essentially
16 received stimulation.

17 CHAIRMAN PATOW: Is there --

18 DR. SHELTON: I second.

19 CHAIRMAN PATOW: -- a second to that
20 motion?

21 DR. SHELTON: I so move or second.

22 CHAIRMAN PATOW: Discussion of this

1 motion?

2 DR. WOODSON: Do we really just want to
3 say can they be simulated? Because this is for
4 patient information, and what we want to get across is
5 that that percentage of patients actually had some
6 hearing. So some other word for auditory precept.
7 They had auditory perception on stimulation?

8 DR. GULYA: I will accept that amendment.
9 So it was amended that of the 90 patients stimulated,
10 82 percent received auditory precept upon stimulation.

11 CHAIRMAN PATOW: And this is --

12 DR. GULYA: A claim, the first claim.

13 CHAIRMAN PATOW: As a first claim.

14 DR. GULYA: Un-huh.

15 CHAIRMAN PATOW: Additional discussion?

16 Can we have a vote then on -- oh, I'm
17 sorry. Dr. Duffell.

18 DR. DUFFELL: I was just going to remark
19 I don't know if we should be transcribing this at this
20 point.

21 MS. THORNTON: No.

22 DR. DUFFELL: No?

1 MS. THORNTON: We're not going to do that
2 right now.

3 DR. DUFFELL: Okay. I was just trying to
4 save time. That's all.

5 CHAIRMAN PATOW: We've had extensive
6 discussion on that.

7 MS. THORNTON: Would you like to?

8 (Laughter.)

9 DR. DUFFELL: I'd be happy to.

10 CHAIRMAN PATOW: Do you type real fast?

11 DR. DUFFELL: I don't mind because I can't
12 vote anyway.

13 CHAIRMAN PATOW: Then prior to the vote,
14 could I ask that the motion be clearly stated?

15 DR. GULYA: I was afraid you'd say that.
16 The auditory brain stem implant, when implanted in a
17 population of 90 patients, 82 percent received
18 auditory precept upon stimulation.

19 DR. CANADY: Precept may not mean anything
20 to people. It didn't mean anything to me until today.

21 DR. GULYA: Okay. Gail, what word to you
22 want to use besides auditory precept?

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1 DR. WOODSON: I won't know. Of 90
2 patients implanted with the device, 82 percent --

3 DR. GULYA: Perceived sound?

4 DR. WOODSON: -- perceived sound when
5 stimulated.

6 DR. GULYA: Okay. Did you get that? I
7 don't think I can face the challenge of trying to
8 actually say that.

9 CHAIRMAN PATOW: Okay. We have that.

10 DR. WOODSON: This is just a
11 recommendation, right? Something you might buff it up
12 later anyway.

13 CHAIRMAN PATOW: Okay. We have that. We
14 have it recorded then. Okay, fine.

15 Can we then have a vote on this condition
16 as stated? Let me just go around -- no. All in favor
17 say aye.

18 (Chorus of ayes.)

19 CHAIRMAN PATOW: And opposed?

20 MS. THORNTON: One.

21 CHAIRMAN PATOW: And the condition passes.

22 Are there additional conditions? Dr.

1 Hood.

2 DR. HOOD: I have a minor revision to the
3 first claim stated under identification of
4 environmental sounds to say 82 percent of the
5 stimulable subjects scored significantly above chance
6 on a recorded closed set test of environmental sound
7 identification, dropping the extra numbers in the
8 chance percentages and designating those as stimulable
9 subjects.

10 CHAIRMAN PATOW: Do we have a second?

11 DR. SHELTON: I'd like to amend that to
12 include all the claims in that fashion. Eliminate the
13 extra numbers in all of the claims.

14 CHAIRMAN PATOW: There is a motion then to
15 amend all the claims, to simplify all of the claims.

16 DR. SHELTON: Yes.

17 CHAIRMAN PATOW: By eliminating
18 percentages or fractions.

19 DR. SHELTON: Fractions.

20 CHAIRMAN PATOW: Fractions.

21 DR. HOOD: And chance percentages.

22 CHAIRMAN PATOW: Do I have a second to

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1 that motion?

2 DR. GULYA: Second.

3 CHAIRMAN PATOW: Okay, and discussion?

4 Dr. Kileny.

5 DR. KILENY: I'm not sure whether the word
6 "who stimulated" was added in this motion.

7 DR. HOOD: Yes.

8 DR. KILENY: Okay.

9 CHAIRMAN PATOW: So it sounds to me like
10 there are two elements then of this motion. One is to
11 add the phrase "who stimulated," and the second is to
12 reduce the mathematical complexity of the statements
13 so that they will be more clear to consumers.

14 DR. HOOD: Correct.

15 CHAIRMAN PATOW: Now, can someone state
16 the motion clearly?

17 DR. HOOD: I move that we add "subjects
18 who stimulated" to each of the claims and delete the
19 fractions designating number of subjects, as well as
20 the percentage representing chance values.

21 CHAIRMAN PATOW: Thank you.

22 Additional comment? Dr. Duffell.

1 DR. DUFFELL: I saw that the sponsor had
2 some comment about this.

3 CHAIRMAN PATOW: Actually at this point we
4 can't entertain sponsor comments. Thank you though.

5 Having no further discussion, let's vote
6 then on this condition. All in favor say aye.

7 (Chorus of ayes.)

8 CHAIRMAN PATOW: Opposed?

9 (No response.)

10 CHAIRMAN PATOW: The motion passes
11 unanimously.

12 Any other conditions? Dr. Shelton.

13 DR. SHELTON: I move the device be
14 delivered without the magnet in place.

15 DR. GULYA: Second.

16 CHAIRMAN PATOW: I have a second.

17 Discussion regarding delivery of the
18 device without the magnet in place?

19 Then hearing none, a vote now --

20 DR. WOODSON: But then the labeling, the
21 product -- the surgeon's guide would have to be
22 modified, too, along with that.

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1 CHAIRMAN PATOW: So the motion then would
2 be to recommend that the device not only have delivery
3 with the magnet not in place, but there would be
4 appropriate modifications to the labeling--

5 DR. WOODSON: Yes.

6 CHAIRMAN PATOW: -- in the surgeon's
7 packet.

8 Further discussion?

9 (No response.)

10 CHAIRMAN PATOW: All in favor?

11 (Show of hands.)

12 CHAIRMAN PATOW: And opposed?

13 (No response.)

14 CHAIRMAN PATOW: The motion passes
15 unanimately.

16 Additional conditions? Dr. Canady.

17 DR. CANADY: That a statement be made that
18 bilateral efficacy has not been studied, the use of
19 bilateral.

20 DR. WOODSON: Simultaneous.

21 DR. CANADY: Simultaneously.

22 CHAIRMAN PATOW: Can you say --

1 DR. CANADY: Bilateral implantation has
2 not been studied; specifically excluding that.

3 CHAIRMAN PATOW: Okay. Do I have a
4 second?

5 PARTICIPANT: Second.

6 CHAIRMAN PATOW: Discussion of this
7 motion?

8 DR. WOODSON: We've have to say bilateral
9 simultaneous stimulation or something because we do
10 know that if one side doesn't work, then they want to
11 be able to do the other side.

12 CHAIRMAN PATOW: Would the phrase
13 "bilateral functioning implants" solve that?

14 DR. WOODSON: The efficacy of bilateral
15 functioning implants has not been studied.

16 DR. CANADY: That would be acceptable to
17 me.

18 CHAIRMAN PATOW: Further discussion?

19 DR. FRANCIS: Or the additional efficacy
20 because we already know that we're already stating
21 that we have efficacy for one. So I'm thinking if
22 it's an additional. The point is is there an

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1 improvement.

2 DR. CANADY: The point is there's no data.

3 CHAIRMAN PATOW: Improvement or not
4 improvement.

5 DR. CANADY: So we can't make a statement
6 one way or another. There's no data.

7 DR. WOODSON: And then the question is do
8 we have to bring it up.

9 CHAIRMAN PATOW: Well, that's for the
10 panel to decide. Is this an issue the panel would want
11 to have a condition regarding?

12 DR. SHELTON: Could you clarify the issue?
13 Can you elaborate?

14 DR. CANADY: I just want to -- the
15 question in my view is to say that we never reviewed
16 any data having to do with bilateral simultaneous
17 transfer. I think we ought to say that, and say it
18 neutrally. I mean it doesn't say it's good; it
19 doesn't say it's bad; it doesn't say you can't. It
20 just say that in this recommendation there was no data
21 presented.

22 CHAIRMAN PATOW: Additional discussion?

1 (No response.)

2 CHAIRMAN PATOW: Hearing none, then all in
3 favor say aye.

4 (Chorus of ayes.)

5 CHAIRMAN PATOW: It passes unanimously.
6 Additional conditions?

7 DR. KAHN: The condition would be to
8 amplify the information or neurophysiologic monitoring
9 in the information for surgeons.

10 CHAIRMAN PATOW: Do I have a second?

11 DR. CANADY: Second.

12 CHAIRMAN PATOW: And discussion? Dr.
13 Kileny.

14 DR. KILENY: This should be specified in
15 terms of inclusion in the surgeon's manual. Also
16 under Attachment 17(a) on the recommended training,
17 include more specific guidelines regarding the types
18 of neurophysiological monitoring and
19 neurophysiological events that may occur during ABI
20 placement.

21 CHAIRMAN PATOW: Additional comments?

22 (No response.)

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1 CHAIRMAN PATOW: Hearing none, all those
2 in favor say aye.

3 (Chorus of ayes.)

4 CHAIRMAN PATOW: Passes unanimously.

5 Okay. Thank you.

6 Any additional conditions?

7 DR. WOODSON: I think that
8 contraindication to the prior gamma knife surgery
9 should be modified. Instead of being an absolute
10 contraindication, an appropriate statement that --
11 whatever Dr. Brackmann said.

12 (Laughter.)

13 CHAIRMAN PATOW: Do you want me to state
14 what Dr. --

15 DR. GULYA: Gayle, can I help you out with
16 that? That's in Attachment No. 17, contraindications,
17 page 101, and I think the language used was that there
18 should be extreme caution used in the implantation of
19 patients who have undergone gamma therapy or, I
20 suppose, other types of radiation therapy.

21 DR. WOODSON: And there is a specific
22 reference to imaging studies to look at the integrity

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1 of the cochlear nucleus. I don't know if we need to
2 get that specific or if we can just say extreme
3 caution.

4 CHAIRMAN PATOW: So we have a motion then.
5 If we can get to what the language of the motion would
6 be then.

7 DR. GULYA: Gayle, you started off so
8 well, why don't you finish?

9 DR. WOODSON: Let me look at this page 101
10 again. It currently says the ABI is not indicated,
11 and it should say contraindications -- gosh, maybe it
12 should be instead of contraindications, it should be
13 precautions. Precautions should be used in
14 individuals who have undergone gamma knife radiation,
15 and preoperative evaluation of the cochlear nucleus is
16 recommended.

17 DR. CANADY: Can I make a recommendation
18 for wording?

19 DR. WOODSON: Okay.

20 DR. CANADY: Caution should be used in
21 patients who have undergone gamma knife because of
22 concern regarding possible injury to the cochlear

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1 nerve.

2 DR. WOODSON: Yes, okay.

3 DR. CANADY: Cochlear nucleus.

4 CHAIRMAN PATOW: Okay. Now, I'm going to
5 ask you to repeat that again so we can transcribe it.
6 So slowly.

7 DR. CANADY: That caution should be used
8 in patients who have undergone radiotherapy,
9 specifically gamma knife, because of concern about
10 possible injury to the cochlear nucleus.

11 CHAIRMAN PATOW: All right. Do I have a
12 second?

13 DR. GULYA: Second.

14 CHAIRMAN PATOW: Discussion?

15 (No response.)

16 CHAIRMAN PATOW: Hearing none then, all in
17 favor say aye.

18 (Chorus of ayes.)

19 CHAIRMAN PATOW: And it passes
20 unanimously.

21 Any additional conditions?

22 DR. GULYA: I have another one, and I'm

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1 not exactly clear where it would go, but in the
2 labeling there should be the language regarding it as
3 strongly recommended that the implanting surgeon
4 receive training regarding the appropriate techniques
5 to be used in implantation.

6 CHAIRMAN PATOW: Is there a second?

7 DR. SHELTON: I'd like to offer an
8 amendment. Make that instead of "surgeon" the
9 "implant team."

10 DR. GULYA: OH, thanks.

11 CHAIRMAN PATOW: Is there a second to
12 that? Let me make sure we have this transcribed.

13 MS. THORNTON: Can you say it again?

14 CHAIRMAN PATOW: Strongly recommend that
15 the implantation team should receive training.

16 DR. GULYA: Strongly recommend that the
17 implantation team receive training in the techniques
18 used for appropriate implantation. That covers
19 electrophysiologic monitoring, the whole gamut.

20 CHAIRMAN PATOW: Everything. Discussion?
**

21 (No response.)

22 CHAIRMAN PATOW: Hearing none, all in

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1 favor say aye.

2 (Chorus of ayes.)

3 CHAIRMAN PATOW: And that passes
4 unanimously.

5 Any additional conditions?

6 DR. FRANCIS: I have a motion that where
7 data is presented regarding efficacy in the patient
8 information packet that a statement be included in
9 that area regarding the percentage of patients that
10 were not stimulated. I know we've already talked
11 about a claim, but I'm thinking in terms of actually
12 placing it in the information packet, that it be also
13 placed next to that data.

14 CHAIRMAN PATOW: Do we have a second?

15 DR. SHELTON: Second.

16 CHAIRMAN PATOW: We have a second.

17 DR. KAHN: Second.

18 CHAIRMAN PATOW: Discussion?

19 It does appear twice in the user guide.
20 I earlier had a question about where it appears in the
21 user guide in that it appears two pages before the
22 clinical and then two pages after, but it doesn't

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1 actually appear in the --

2 DR. FRANCIS: Yeah, I agree with you that
3 it's there, but I think it ought to be -- that the
4 data that is provide ought to be looked at in the
5 context of the statistics and it ought to be placed
6 close, a little bit closer to --

7 CHAIRMAN PATOW: Are you suggesting a
8 specific place for this?

9 DR. FRANCIS: Possibly in the first
10 paragraph, before the data is actually presented.
11 Below clinical results.

12 CHAIRMAN PATOW: Under "Clinical Study
13 Results"?

14 DR. FRANCIS: Yeah.

15 CHAIRMAN PATOW: If I could ask you then
16 to repeat your motion.

17 DR. FRANCIS: The motion would be to
18 clearly indicate in the first paragraph of "Clinical
19 Study Results" the rate of nonauditory perception.

20 CHAIRMAN PATOW: Discussion?

21 DR. FRANCIS: ^{**} Not necessarily in those
22 words, but --

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1 MS. THORNTON: The rate of what?

2 DR. FRANCIS: The number of patients or
3 the percentage of patients who did not perceive sound.

4 DR. GULYA: Maybe would it serve your
5 intent to basically transcribe the same language that
6 we have for the first claim into that patient or user
7 manual? I mean we basically say to the effect of 90
8 patients implanted, 82 percent received sound or could
9 hear sound. Basically that's what we said.

10 If Sally has that transcribed, then we
11 could just insert it there, and then we've got it in
12 all places. Would that work for you?

13 DR. FRANCIS: Yeah, that would work.

14 CHAIRMAN PATOW: We have --

15 (Laughter.)

16 CHAIRMAN PATOW: We have a motion on the
17 table that says to clearly indicate in the "Clinical
18 Study Results" the percent of patients who did not
19 perceive sound. It seems to me that that's the same
20 information that you're suggesting.

21 DR. GULYA: It puts it in a little bit
22 more positive light, but it does -- by saying who did,

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1 it also gives you who did not.

2 CHAIRMAN PATOW: Do we have then --

3 DR. FRANCIS: So I would amend to the
4 previously stated, to Dr. Gulya's recommendations to
5 place the number of patients -- the percentage of
6 patients who actually perceived auditory perception.

7 CHAIRMAN PATOW: Who received.

8 DR. FRANCIS: Right.

9 CHAIRMAN PATOW: So changing the sense
10 from a negative to a positive statement.

11 DR. FRANCIS: Yeah, that would be fine.

12 CHAIRMAN PATOW: Okay.

13 MS. THORNTON: Was there an additional
14 part of that that said in all other places, something?

15 PARTICIPANT: In the claim.

16 MS. THORNTON: Okay.

17 CHAIRMAN PATOW: Okay. Further discussion
18 about this point?

19 (No response.)

20 CHAIRMAN PATOW: Hearing none, then all in
21 favor say aye.

22 (Chorus of ayes.)

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1 CHAIRMAN PATOW: And that carried
2 unanimously.

3 Any additional conditions? Dr. Kileny.

4 DR. KILENY: I would like to make a motion
5 that the sponsor carry out some limited scope post
6 market surveillance on the existing patients that may
7 consist of mailing of a questionnaire regarding
8 continued effective stimulation or continuing auditory
9 stimulation with the ABI over, say, a period of two
10 years.

11 CHAIRMAN PATOW: Do I have a second?

12 (No response.)

13 CHAIRMAN PATOW: Not having a second for
14 this motion, I can't carry it forward.

15 Are there any other conditions? Any other
16 conditions?

17 (No response.)

18 CHAIRMAN PATOW: Okay. Hearing none, we
19 are now ready to vote on the main motion, which is to
20 approve the PMA for the nucleus auditory brain stem
21 implant system with conditions, and the conditions --
22 do you want to read the conditions or -- no? Do we

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1 need to read the conditions?

2 (Laughter.)

3 CHAIRMAN PATOW: I think it's clear what
4 the conditions are. We've already gone through them.
5 So if it's okay with the members of the committee,
6 we'll dispense with that.

7 We can't. We have to read them. We must
8 read them, I'm told. We do have to read them. Okay.

9 Oh, we don't have to read them? That's
10 fine. Good.

11 So do we have a second?

12 PARTICIPANTS: Second.

13 CHAIRMAN PATOW: And is there discussion
14 regarding this main motion with the conditions as
15 previously approved?

16 (No response.)

17 CHAIRMAN PATOW: Hearing none then, all in
18 favor say aye.

19 (Chorus of ayes.)

20 MS. THORNTON: Raise your hand, please.

21 (Show of hands.)

22 MS. THORNTON: We have nine.

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1 CHAIRMAN PATOW: And it carries
2 unanimously.

3 At this time I'd like to go around the
4 table and poll each of the panelists as to their vote
5 and information regarding why they voted as they did.
6 I'd like to start with Dr. Francis, please.

7 DR. FRANCIS: NF2 is a devastating
8 disease. I think that this device has proven to be of
9 great value to those that have had the fortune to
10 participate in the clinical trial, and these patients
11 have been served well in terms of efficacy to some
12 limited extent, but to some extent, and I think that
13 the device has proven its safety.

14 So I felt that this was a reasonable thing
15 to vote for, and I congratulate the company.

16 DR. ROESER: Well, we heard first hand the
17 implications of NF2, and we were also given data on
18 safety and effectiveness that were easily
19 interpretable and convincing.

20 And as far as safety, there are some
21 issues. I think those were addressed quite
22 adequately. I think that over time those issues will

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1 be resolved.

2 And as far as effectiveness, I was very
3 impressed with what I saw relative to the potential
4 for this device, realizing that it's early in its
5 development, and of course, the hope is that over time
6 we'll see improvements which we're all hoping for.

7 And based on the presentations that we
8 had, which, again, I want to emphasize the
9 thoroughness of the information, the way it was
10 presented, in my opinion, convinced me very thoroughly
11 that this device should be approved.

12 CHAIRMAN PATOW: Dr. Woodson.

13 DR. WOODSON: I would concur. This is an
14 infrequent but very serious problem, and I'd like to
15 commend the Cochlear Corporation for their diligence
16 in pursuing this project and really putting together
17 very cohesive data that supports it.

18 I was also very glad to hear the two
19 patients come in. I know how much courage it takes
20 for them to come and present to a group like this, and
21 it really provided a perspective we wouldn't have
22 otherwise, and I know that they were motivating by

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1 wanting other patients to have the same opportunity.

2 CHAIRMAN PATOW: Dr. Kileny.

3 DR. KILENY: Well, I'd like to commend
4 Cochlear Corporation, the sponsor, for persisting with
5 this project. This device is equivalent to an orphan
6 drug. As Ron West mentioned, the volumes are not
7 going to be tremendously high, and they've done a
8 wonderful job in bringing along experts who spoke to
9 the benefits of this device.

10 It was also gratifying for me to see and
11 to hear Gail Umphrey speak. Some years back I've had
12 the privilege, along with the late Dr. John Kemink and
13 Buzz Hoff from Neurosurgery, to participate in her
14 care, and it's really nice to see how well she is
15 doing, and I'm looking forward to seeing this
16 technology available for all patients with this
17 devastating disease.

18 CHAIRMAN PATOW: Dr. Kahn.

19 DR. KAHN: I wanted to appreciate the good
20 work the sponsors did, and I personally felt today
21 that it would be very meaningful for a patient to have
22 this, and you guys did a good job of bringing somebody

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1 along to demonstrate that, and I think that's what I
2 casted my vote for.

3 CHAIRMAN PATOW: Dr. Shelton.

4 DR. SHELTON: I'd like to echo what
5 everyone else has said. The company has done a very
6 good job in proving safety and efficacy here, and
7 they've spent a lot of resources to bring out a device
8 that will make a large magnitude of change for a small
9 number of people.

10 And then also I think Bill Hitzelberger
11 and Derald Brackmann need to be congratulated as well
12 because this has been a long road to take this device
13 from a concept to a commercially viable device.

14 CHAIRMAN PATOW: Dr. Gulya.

15 DR. GULYA: I certainly think that the
16 Cochlear Corporation and the surgeons involved have
17 done an outstanding job in providing data that
18 supports the efficacy and safety of the device when
19 used as intended, and I think irrespective of the life
20 span left to individuals with NF2, I think this offers
21 an opportunity to give them a greatly enhanced quality
22 of life, besides quantity of life.

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1 CHAIRMAN PATOW: Dr. Hood.

2 DR. HOOD: I would like to congratulate
3 Cochlear Corporation and thank them for the quality of
4 their demonstration of the safety and effectiveness of
5 this device.

6 (Audio equipment accidentally disconnected
7 by participant.)

8 DR. HOOD: -- patients that obviously need
9 it and can benefit from it.

10 CHAIRMAN PATOW: Dr. Canady.

11 DR. CANADY: I, too, think it's been a
12 particularly clear panel discussion, and I've enjoyed
13 the opportunity to sit in and visit with my ear, nose,
14 and throat colleagues.

15 CHAIRMAN PATOW: And thank you.

16 I understand Dr. Duffell also has a few
17 words he'd like to add this afternoon.

18 DR. DUFFELL: Yeah. Just in closing,
19 actually first of all, I think the thanks also goes to
20 FDA. I mean, you all receive all this information,
21 these volumes of data. I mean, we've been thanking
22 Cochlear Corporation, and I well know from their

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1 standpoint what the work is, but there is as much work
2 and diligence involved on the part of the Food and
3 Drug Administration in wading through it and
4 challenging the thinking that the industry has in how
5 they put these things together and the labeling the
6 claims that we make. It is truly intended to be a
7 team effort, I think, is the way it should operate,
8 and it looks as though it has done that here. It
9 looked like a collegial effort.

10 So I compliment all of the review team
11 involved in this.

12 The other remark I wanted to make is also
13 we took time before we started these panel sessions to
14 talk about least burdensome approach to clinical trial
15 development and product approval process, and as kind
16 of the industry rep., I'd like to throw out this
17 comment as we draw to a close on these two days of
18 meetings: that least burdensome to industry, as well,
19 includes the wrap-up of these processes and the rapid
20 conclusion of the approval process, and I would just
21 hope that FDA will take the ^{**}comments that have come
22 forth at these meetings and quickly assimilate them,

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1 review them, and provide quick feedback to the
2 industry members that were here today and yesterday,
3 and hopefully bring it all to a quick conclusion.

4 Because if our interest collectively as a
5 panel, and as FDA and industry is to best serve the
6 interests of the patients that we're developing
7 products to help, then their best interests will be
8 served if we've decided today that this product should
9 be on the market to quickly get it there.

10 So and then also in closing, just thanks
11 a lot for the opportunity to serve on this panel. As
12 I draw to a close with my tenure on it, it's been
13 truly an honor and a privilege to do so, and I thank
14 everyone for the opportunity to be part of the panel.

15 Thank you.

16 CHAIRMAN PATOW: Well, thank you. We
17 really appreciate your service.

18 And I just would like to add my personal
19 thanks to everyone for making today go efficiently,
20 and I think a tremendous amount of knowledge was
21 shared here and an opportunity for experts and
22 industry to share regarding this particular device.

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1 I want to thank all of the panel members
2 for their excellent work in reviewing these documents
3 prior to the meeting, and then taking two days off to
4 come here and discuss the issues.

5 Also, the FDA has been, I think, truly
6 excellent in putting this meeting together, and I'd
7 just like to thank all of them for their efforts.

8 Nancy?

9 MS. BROGDON: Thank you.

10 I just wanted to let the panel know that
11 we have committed to bringing the review of this
12 document to a quick conclusion. So we've heard you,
13 and we've heard the public comments and the firm's
14 comments also.

15 CHAIRMAN PATOW: Excellent.

16 MS. BROGDON: I'd also like to thank the
17 panel for your deliberations.

18 CHAIRMAN PATOW: We have some closing
19 comments by Ms. Thornton.

20 MS. THORNTON: Yes. I'd like to add my
21 thanks to those who have gone before me today for all
22 of your hard work, and particularly to the panel that

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1 I am now meeting for the first time. I appreciate
2 your welcoming me and your pleasant cooperation with
3 me in planning the meeting. It's been much
4 appreciated.

5 Regarding the materials that you have, I'd
6 like to just ask you to leave them on the table.

7 Regarding the meetings, I'd like to just
8 make the announcement that I have put on the Web our
9 that our September 22nd meeting has been canceled.
10 Early in the fall I'll be coming out with a schedule
11 of meetings for this panel for 2001. So stay tuned.
12 Watch your Web sites.

13 Thank you again.

14 CHAIRMAN PATOW: The meeting is now
15 adjourned. Thank you very much.

16 (Whereupon, at 3:17 p.m., the panel
17 meeting was concluded.)

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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of: EAR, NOSE, AND THROAT DEVICES
 PANEL MEETING

Before: FOOD AND DRUG ADMINISTRATION
 MEDICAL DEVICES ADVISORY COMMITTEE

Date: JULY 21, 2000

Place: GAITHERSBURG, MARYLAND

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

Rebecca Davis