

1 DR. SHELTON: Well, no. Like cochlear implants,  
2 you should wear a helmet when you are doing activities that  
3 might involve some type of head trauma, to prevent damage to  
4 the device or to the head. Can you foresee any kind of  
5 limitations? I mean, scuba diving would be one, perhaps.  
6 It is certainly true for any kind of ear surgery. Would it  
7 apply to this? I am not sure. But, I mean, is there  
8 anything else that you could consider?

9 DR. CAMPBELL: Dr. Campbell. I think the same  
10 could be for a cochlear implant, like you suggested. That  
11 is all, though. The microphone placement in the ear canal  
12 might be a problem in diving. I think it is a minimal  
13 problem, though.

14 DR. SHELTON: Okay. Any other comments? That  
15 concludes my part of the questions, then.

16 DR. PATOW: We were going to take a break at 3  
17 o'clock. I wonder if we could take our break now, before we  
18 start deliberating the second set of questions, and then  
19 come back fresh? So let's take a 15-minute break now, and  
20 we will resume again at 3:00.

21 [Recess.]

22 DR. PATOW: If we could resume, 1(d) in the  
23 questions asked the question, "What pre-clinical data would  
24 be most beneficial in predicting safety and effectiveness of  
25 these devices in humans?" And over the break there was some

1 clarification of what kind of information was being asked.  
2 And I wonder, I asked if Dr. Shelton could return to this  
3 important question before we go on to the second set of  
4 questions.

5 DR. SHELTON: Okay, so the question here is, for  
6 pre-clinical studies, some of the things that we heard about  
7 in the presentations this morning, is it animal data, is it  
8 laser doppler, computer, human cadaver bone data, what types  
9 of studies should be done before these devices are  
10 implanted? Any comments from the panelists? Paul?

11 DR. KILENY: So what you are referring to is  
12 substantiating device performance pre-clinically, doing some  
13 type of measurements that substantiate what the device in  
14 fact is going to do once it is implanted, and that could  
15 include to some extent animal studies or the various laser  
16 doppler vibrometry or other type of mechanical measurement  
17 to look at the device. And in fact that could also answer  
18 some questions about maximum output, whether the device  
19 generates energy beyond what is considered to be safe for  
20 the cochlea.

21 DR. MIDDLETON: Taking a different approach, I  
22 think it would good to have baseline data regarding client  
23 expectations, both in terms of what benefits they believe  
24 they are achieving from, let's say, air conduction hearing  
25 aids; some type of self-reporting, self-assessment

1 perception of where they think they are, what their  
2 expectations are for the new device, the middle ear  
3 amplification device, what are their expectations; and then  
4 have some type of orientation about what can be reasonably  
5 expected. All of that information at the outset, I think,  
6 in terms of baseline data would be important, and then a  
7 post-evaluation along those same lines in terms of self-  
8 evaluation, self-perception.

9 DR. SHELTON: Carl?

10 DR. PATOW: Carl Patow. I think that is  
11 addressing--what you are saying is perfectly valid and very  
12 important, but I think the question is addressing not the  
13 actual clinical implantation time for a patient but actually  
14 what studies should we require be done prior to introduction  
15 of this technology in humans. Should we be looking at  
16 temporal bone anatomy and insertion of this in the temporal  
17 bones, and what kind of testing do we want there? Do we  
18 want animal testing?

19 So what you are suggesting is very important and I  
20 believe should be done. I think the question is looking at  
21 something different.

22 DR. SHELTON: Yvonne?

23 DR. SININGER: Yes. Yvonne Sininger. Along the  
24 line of what Paul said related to safety and the maximum  
25 levels is--I think you could use--the cadaver studies would

1 be important, and especially looking at something like the  
2 laser doppler to determine that you can get adequate  
3 amplification from these devices in the ranges that we would  
4 expect. We know how much motion of the stapes we should be  
5 able to expect for certain degrees of hearing loss, and I  
6 think that any of these devices should be able to  
7 characterize how much power they can actually apply, how  
8 much gain we should expect to be able to see, before they  
9 ever put them in a patient. So I would like to see some  
10 data along that line.

11 DR. SHELTON: Gayle?

12 DR. MIDDLETON: Yes. I think that from what was  
13 presented today and what was in the packet, it seems pretty  
14 clear that what you want to know about how the device  
15 performs mechanically can't really be determined in animals  
16 because they are not shaped like us, and if we want to know  
17 how it works in a human, that the temporal bone seems to be  
18 the best model for measuring the performance of the device.

19 Now, then, the question is, do we use laser  
20 doppler? Well, there is a lot of different things of laser  
21 doppler. There is the point laser doppler that you can buy,  
22 but then we saw some presentations today about three-  
23 dimensional laser doppler. And it is not just enough to  
24 say, well, you need to use a laser doppler. I think we need  
25 to specify what information do we want them to get.

1 Do we want them to tell us, you know, what is  
2 your--you know, to specify the output ranges and make sure  
3 that it doesn't go beyond a certain level, and then they  
4 might use different technologies to measure that? Would  
5 that be acceptable?

6 DR. SHELTON: So if I understand, then, as far as  
7 animal versus temporal bone, you are happy with temporal  
8 bone, human temporal bone data, and it sounds like everyone  
9 else who has commented is happy with that as well. Carl,  
10 am I--

11 DR. PATOW: Carl Patow. I think for assessing the  
12 adequacy of amplification and looking at the mechanics, that  
13 is true. There may be times when in a new system you will  
14 want to look at biocompatibility or tissue reaction, and  
15 that would not be appropriate. You would want an animal  
16 study to look at those kinds of questions.

17 DR. WOODSON: Right. Right. I think that it has  
18 been established that we can't look at the mechanical  
19 aspects in the animal.

20 DR. PATOW: Right. I would agree.

21 DR. WOODSON: Okay.

22 DR. SHELTON: So everyone is happy with human  
23 temporal bone data, it sounds like. Peter?

24 DR. UHTHOFF: You just have to tailor the risks of  
25 that particular device to what you want to have, and that is

1 where animal studies come in. I mean, you are actually  
2 right, it is more of the mechanical interaction that you are  
3 looking for in animal studies than the acoustic qualities.  
4 So what are the effects on the bones, what are you doing to  
5 the bones, and you can study that in an animal study.

6 DR. SHELTON: Any other comments?

7 Okay, I will turn it over to Paul.

8 DR. KILENY: Thank you very much. I was asked to  
9 moderate this section of the discussion involving a  
10 discussion of the risk versus benefit of these devices, and  
11 we certainly need to remember that when we refer to risk  
12 associated with these devices, the comparison should be the  
13 other alternative, of course, which are the standard  
14 amplification devices that are currently used, and there are  
15 a variety of risks out there. We have discussed most of  
16 them in the previous discussion, so I am not going to repeat  
17 those.

18 In terms of the benefit, there are a number of  
19 questions, and the first question is: What is an optimal  
20 control for assessing the performance of these devices? And  
21 there are obviously a number of options. The control could  
22 be pre-operative unaided hearing, it could be hearing with  
23 the patient's own hearing aid, it could be hearing with an  
24 optimal fitting after a certain length of trial.

25 So I would like to open this to the panel and get

1 some feedback regarding the type of control that the panel  
2 would see fit for these devices.

3 DR. WOODSON: Gayle Woodson. If you use the  
4 patient's own hearing aid, that is going to be something  
5 extremely variable because people come in with varying  
6 levels. I heard a lot of consensus in the presentations  
7 today that you have to compare it to the best that is  
8 possible with given technology, and I didn't hear anybody  
9 argue the opposite, so I would--that would be my feeling, is  
10 that you have to compare it to what is the best possible.

11 DR. KILENY: Carl?

12 DR. PATOW: Carl Patow. I am not an audiologist.  
13 Is there a set standard for determining what is the best  
14 possible?

15 DR. KILENY: I will let Dr. Sininger answer this  
16 question.

17 DR. SININGER: There are some very good ways of  
18 assessing aided performance, but no, there is no  
19 standardized, accepted battery of tests that say this is the  
20 way we have optimized performance. And one of the things I  
21 would just like to throw out is, we keep saying digital  
22 hearing aids. I mean, digital is just one way of processing  
23 the signal, and in and of itself doesn't ensure that a  
24 patient has been properly fit with amplification.

25 But we do have certainly batteries of tests that

1 we could suggest, that show that certain amplification is  
2 better than others. There is patients that need  
3 compression, that aren't being fit with compression, and  
4 that sort of thing. I think to say that we should compare  
5 the hearing aids that a patient walks in with is not fair,  
6 but to say that we should--it is the same with cochlear  
7 implants that we do with children especially. Before we  
8 assume that they are not getting maximum benefit, we make  
9 sure that their amplification has been optimized.

10 So I would definitely go with a reassessment of  
11 binaural amplification and with a certain test battery, and  
12 we can talk about what the test battery might be, and have  
13 the patient have some usable time with that amplification.  
14 That is the other issue, is you can't simply change hearing  
15 aids and expect to see what the potential performance with  
16 those hearing aids will be.

17 But I would definitely say optimized binaural  
18 amplification should be the baseline against which we would  
19 assess performance of these devices. That sets a pretty  
20 high standard for the devices, and it doesn't take into  
21 consideration some of the other benefits that these devices  
22 might provide, like the loss of the occlusion effect and  
23 some of the cosmetic issues.

24 MR. SAUBERMAN: This is Harry Sauberman. Can you  
25 give us an estimation, Dr. Sininger, how long binaural

1 amplification should be worn before a patient chooses this  
2 option?

3 DR. SININGER: Maybe we can get some input from  
4 the group, as well, but I would think a minimum of a month  
5 of use with refit amplification, binaural amplification. In  
6 order to have any kind of leveling off of performance, a  
7 minimum of a month would be reasonable.

8 DR. KILENY: Well--sorry, go ahead.

9 DR. ROSENTHAL: You said because you want  
10 reproducibility, is that right? You want to be sure that it  
11 is stable, it is at the same level.

12 DR. SININGER: There is a significant amount of  
13 learning that goes on with a new signal.

14 DR. ROSENTHAL: So they can get better?

15 DR. SININGER: So they can get better, exactly.  
16 The system is still somewhat plastic, and the performance on  
17 a speech battery, for example, isn't going to be--doesn't  
18 achieve that level immediately.

19 DR. ROSENTHAL: I am just curious why, I know this  
20 might be heresy, but why do you not just want to use their  
21 unaided situation and look at the potential difference that  
22 the hearing aid can make? Is that--

23 DR. SININGER: My personal feeling would be that  
24 if I wanted to tell a patient what the possible benefits of  
25 this device would be, I would have to compare that not to--

1 you know, if someone is deciding which new car to buy, you  
2 are not going to compare it to their old clunker, you are  
3 going to compare it to the other cars on the market, so it  
4 is the same sort of thing. We have--I would think, just to  
5 be fair to patients, that they need to understand how much--  
6 how these devices compare to what is out there that is  
7 available without surgery.

8 DR. KILENY: Dr. Shelton?

9 DR. SHELTON: I think also, to expand on that, by  
10 convention with cochlear implants we tend to do the same  
11 type of analysis. We take the patient's existing hearing  
12 aids and then predict if we can do better with a cochlear  
13 implant. I mean, here we are doing that same analysis, only  
14 we are trying to see if we can do it as good as their  
15 current hearing aids, and so it is something that we are  
16 comfortable with.

17 DR. KILENY: I think another comment I would like  
18 to make regarding this question is that we should  
19 distinguish between experienced hearing aid users, and in  
20 those cases I would think that a month with improved  
21 amplification or best aided condition would be sufficient to  
22 obtain a baseline, but there would be also patients that  
23 will come in to see their physician or their audiologist who  
24 have not had amplification before, who have been brought  
25 into the office by the prospect of these implantable

1 devices. And in my opinion, they too should--obviously,  
2 they too should be compared to an aided condition, but  
3 should be for longer than one month in those cases of the  
4 inexperienced or non-experienced patient.

5 Any thoughts about that, Dr. Campbell or Dr. Khan?

6 DR. KHAN: Dr. Khan. The question is, what is  
7 that time frame for those people who are not experienced,  
8 that you would watch them, how long?

9 DR. KILENY: Well, I think at least about three  
10 months.

11 DR. SININGER: This is Yvonne Sininger again.  
12 Would it not be reasonable to, in clinical trials on these  
13 devices, to limit them to experienced hearing aid users to  
14 avoid that variance in the data?

15 DR. DUFFELL: But then what defines "experienced,"  
16 and at what point are you just grabbing a number out of the  
17 air versus having an objective reason for the number?

18 DR. ROSENTHAL: Rosenthal. Well, experience I  
19 think we can define. I have no problem with defining it. I  
20 am concerned about the issue of the baseline, because you  
21 are going to want to show an improvement. If after--and we  
22 can make, I think we can make a decision whether we can use  
23 experienced or inexperienced. We appreciate that. But I  
24 want to know when are you sure they are reproducible at that  
25 best level.

1           It is like--I am sorry to harp back to refractive,  
2 but you know with refractive they had to have the same  
3 refraction six months to a year apart, the exact same,  
4 before they were allowed to be entered into the trial. You  
5 are talking about entering people into a trial and you want  
6 to get them--you want to find out where they are and how  
7 much better you can make them, and if they are still in a  
8 learning situation, some go on learning for three months, I  
9 am worried that one month may be too soon.

10           DR. MIDDLETON: I think one--

11           DR. ROSENTHAL: I just don't know. I mean, I am  
12 asking.

13           DR. MIDDLETON: This is Renee Middleton. I mean,  
14 for a lot of older adults, one month is not always  
15 necessarily enough time even with a hearing aid, and so I  
16 would feel--I don't feel comfortable with saying, you know,  
17 only experienced hearing aid users. I think you need both  
18 in the group, those who had never been amplified before but  
19 for whom this, using this device would be a first time event  
20 for them, that they need to be included in that sample. And  
21 one month, I don't--I am not sure is long enough to  
22 establish some stability over time with adjusting to it.  
23 Maybe three to six months. Six months may be too long, but  
24 three months, maybe?

25           DR. KILENY: Well, I think--I don't know, Yvonne,

1 if the one month came from this background or not, but  
2 currently when somebody purchases a hearing aid, they have a  
3 30-day trial period, and if they miss that by one day, that  
4 is it. So--and that is actually for the experienced and the  
5 inexperienced user, as well. They have the same trial  
6 period allowable by the hearing aid dispensers.

7           So I agree that in some cases it depends upon the  
8 patient and its cognitive, a patient's cognitive abilities.  
9 It may take longer than that. In some cases, some patients  
10 maybe would be--two weeks would be maybe sufficient.

11           But we still need to come up with some kind of a  
12 reasonable number here that would be reasonable for patients  
13 and for clinicians and for manufacturers, that would be  
14 acceptable. Maybe we could say they should have two years'  
15 worth of hearing aid trials, but that is probably not<sup>2</sup>  
16 practical.

17           DR. SININGER: The one month--Sininger again--the  
18 one month figure came from my recollection of similar kinds  
19 of studies on hearing aid performance, and we do know that  
20 it is not immediate but it doesn't take forever, either.  
21 And if you have got an experienced hearing aid user, I would  
22 think one month is an adequate period of time with them  
23 using the hearing aid during that period of time, to reach  
24 the level of performance that we are going to expect in  
25 adults. Perhaps in children it might even be longer, but in

1 adults that would be reasonable.

2 DR. ROSENTHAL: So you are talking about a  
3 baseline and then one month?

4 DR. SININGER: Yes, but they won't achieve the  
5 same performance out of those two times, but--

6 DR. ROSENTHAL: Well, if they do, then I would  
7 feel more comfortable, because then they are level, they are  
8 stable.

9 DR. SININGER: But I would believe a month of  
10 experience with well-fit hearing aids and then to look at  
11 the performance at that point is a reasonable place in which  
12 to say this is where we are going to--what we are going to  
13 judge against their implant performance.

14 DR. KILENY: And then how about the new user?  
15 This is for the experienced patient, correct? You are  
16 recommending one month for somebody who has had hearing aids  
17 before, or for anyone? And older patients, adults.

18 DR. SININGER: If you remember, I am the one that  
19 thinks we should look at experienced users at this point.

20 DR. KILENY: Right.

21 DR. SININGER: I would like to be able to tell the  
22 inexperienced user what an experienced user felt about this,  
23 how they could compare it, you know, against hearing aids.  
24 And I think we get--it gets a little bit--again, it just  
25 simply adds noise to the data when we have very different

1 patients looking at these devices. But that is--and I don't  
2 know what the answer to the other question is.

3 DR. KILENY: So it looks like we do have consensus  
4 on using aided results, best aided results, as a baseline as  
5 opposed to unaided. And it looks like we are gravitating  
6 towards the experienced hearing aid user and currently we  
7 would not consider somebody who has not been a hearing aid  
8 user. And we also seem to have some consensus on a one-  
9 month trial baseline and then like a 30-day evaluation with  
10 standard hearing aids. Does anybody have any other comments  
11 on this question?

12 DR. CAMPBELL: Yes.

13 DR. KILENY: Dr. Campbell?

14 DR. CAMPBELL: Dr. Campbell. I wouldn't like to  
15 see the people who have never worn be left out of this. Why  
16 can't we set a criteria for fitting them with the best aids  
17 binaurally for say three months, for some period of time,  
18 instead of eliminating them out of the study? This makes it  
19 more complicated. It is purer if we have only experienced  
20 users, but we could come up with something.

21 DR. WOODSON: Gayle Woodson. Maybe the  
22 manufacturers could make that, if they wanted to--we would  
23 recommend that you get the cleanest data if you just limit  
24 it to experienced users, and that if they wanted to include  
25 inexperienced in there, that they would have to have them

1 have experience over a certain period of time with the  
2 binaural aids. Does that sound reasonable?

3 DR. SININGER: This is Yvonne Sininger again. One  
4 of the considerations is going to be cost. For a non-user  
5 who walks in wondering if they are looking for  
6 amplification, binaural digital amplification is not  
7 inconsequential in terms of the cost, and so we would have  
8 to keep that in mind. It has to be kept in mind in either  
9 case, but--

10 DR. ROSENTHAL: Rosenthal. They may also be so  
11 happy with the binaural amplification that they would not  
12 want to be entered into the trial, so I don't know. You  
13 know, companies can certainly propose arms to a study. I  
14 get the feeling we should possibly start with the  
15 experienced user and then, as things progress, potentially  
16 have another arm in which they looked at inexperienced  
17 users.

18 DR. KILENY: Peter?

19 DR. UHTHOFF: Peter Uththoff, Health Canada. I  
20 think it all goes back to the company. What do they want to  
21 market this product for? What are the indications, and to  
22 whom do they want to market this product towards? And I  
23 strongly feel that the patients enrolled in the study must  
24 correctly and adequately reflect the market share they want  
25 to go after.

1 DR. KILENY: Well, are there any other comments on  
2 this question? If not, we will move on to the next  
3 question. Any other comments?

4 DR. SININGER: The only other comment might be--  
5 Sininger again--how do we compare optimized hearing aid use?  
6 I mean, we have to have a test battery with which to do  
7 that, and that is not straightforward. Is this the right  
8 time to talk about what specific data we should be sampling?

9 DR. ROSENTHAL: Doesn't the next question address  
10 that?

11 DR. KILENY: Well, the next question relates to  
12 changes seen in unaided hearing. I suppose this is a good  
13 time to address the test battery, maybe at least in general  
14 terms, i.e. to include speech recognition measures as well  
15 as functional gain measures.

16 And since you mentioned this, there is another  
17 issue here, and that is to have some kind of a modality, to  
18 have an ability to evaluate the implanted or partially  
19 implanted hearing aid itself, as we are able to do now with  
20 a hearing aid in order to troubleshoot or determine whether  
21 something has happened to the hearing aid separate from the  
22 patient's auditory system. So some kind of an objective way  
23 to measure hearing aid output, in addition to functional  
24 measures.

25 DR. SININGER: I am wondering how you might do

1 that. I mean, we are in the same situation we are in with  
2 cochlear implants, in that you can't access the part of the  
3 device that is actually--

4 DR. KILENY: Well, there are some ways to do that  
5 in cochlear implants.

6 Go ahead.

7 DR. DUFFELL: Maybe I could--Bill Duffell--I could  
8 refer the people, the panel, back to the SoundTec  
9 presentation and their slide entitled "Baseline Control."  
10 It is a bit over my head about the specifics of the type  
11 test, but I know they have outlined here at least two tests  
12 and some sort of a checklist that appear to be addressing  
13 that question you asked, which I think is important for the  
14 panel to consider and for FDA to consider for a guidance  
15 document, because that is what industry will be looking to  
16 to set up their trials, so I think it is a very good  
17 question you posed, Yvonne. It needs to be addressed in the  
18 guidance document.

19 But, anyway, they have tossed something out here.  
20 So, I mean, are these two measurements, the NAL-R and the  
21 APHAB, are they appropriate measures? And I don't know  
22 myself. I am not an expert in the area, so--

23 DR. SININGER: The NAL-R is simply a target gain  
24 measure for the hearing aids. It is a way of determining,  
25 based on the threshold of hearing, how much gain you might

1 expect to see at individual frequencies, and so that in and  
2 of itself is not a test. I think what they--and I don't  
3 have that in front of me--yes, that is a way of determining  
4 whether or not your hearing aid has been optimally fit, and  
5 that is an important issue, but NAL-R is one of a grouping  
6 of formulae that are used to determine how much gain is  
7 appropriate.

8 I would suggest that we do have some sort of maybe  
9 not specific recommendation on which target gain performance  
10 measure to use, but that there is a series of two or three  
11 that are appropriate.

12 The APHAB is a checklist. It is a questionnaire  
13 that the patient fills out related to satisfaction with the  
14 hearing aid, and that is probably one of the more accepted  
15 of that sort and would be worthwhile data.

16 I think it would be helpful for the manufacturers  
17 if we do have some sort of listing, though, of expected  
18 baseline information and then test information, which I  
19 would assume would include APHAB and then, as Paul  
20 mentioned, simple measures like sound field amplified  
21 thresholds.

22 Now, again, we would have to have these measures  
23 probably with no amplification, with adequate amplification,  
24 conventional amplification, and with this implant device.  
25 So you need an unaided, an aided threshold for pure tones

1 across the speech range, probably 250 to 10,000, I would  
2 think.

3           We need a speech recognition measure that includes  
4 speech recognition or speech intelligibility, and which is  
5 for the most part the patient's ability to repeat words.  
6 That goes from those patients who have very poor speech  
7 recognition ability through patients who have, you know, a  
8 better degree of that, so we need more than one test, and  
9 the test that is used probably with the most acceptance  
10 right now is the HINT test, the Hearing In Noise Test that  
11 not only assesses how well a patient can hear but how well  
12 they can hear in noise, which is very important. Hearing in  
13 quiet may not be nearly as predictive of general performance  
14 as a hearing in noise test.

15           But then we might also need a simple--I think one  
16 of the other ones they mentioned using was--or that Dr. Soli  
17 mentioned using was a simple CNC measure, so it is a word  
18 repeatability kind of test.

19           So sort of as a basic battery, I would like to see  
20 those bits of information.

21           DR. DUFFELL: And what frequency do you think is  
22 appropriate for repeating those measures? Is it--do you do  
23 it monthly for the first three months after it is turned on?  
24 I mean, when is enough enough, of the testing, of those  
25 instruments?

1 DR. SININGER: I think monthly might be overkill,  
2 and you can't repeat--I mean, if you have enough different  
3 lists of these tests, you can repeat them, but you run out  
4 of those after a while. I know for children we go every  
5 three months for looking at performance changes. Three to  
6 six months I would think might be a reasonable time. I  
7 don't know what you think, Paul, about--

8 DR. KILENY: In an adult population? Probably for  
9 at least--post-implant, post-implantation? I think you have  
10 got to follow them for at least six months, if not longer  
11 than that.

12 DR. SININGER: But how often for administering the  
13 test battery?

14 DR. KILENY: Oh, every three months.

15 I think that what we should do at this point is at  
16 least agree on some principles regarding what type of test  
17 procedures, because there are so many different kinds of  
18 ways to tests, the many different kinds of speech  
19 recognition tests and other types of tests that are out  
20 there. I think there is consensus that we need to look at  
21 speech recognition as well as some type of pure tone gain  
22 measure, that we should look at speech in quiet as well as  
23 in noise.

24 Any other comments? Anybody from the  
25 manufacturers wants to make a very brief comment about tests

1 and these kinds of issues? Okay, Sig and then--

2 DR. SOLI: Sig Soli from House Ear Institute. I  
3 am not speaking in behalf of any manufacturer at the moment.  
4 But if you are concerned about binaural hearing performance,  
5 I would suggest that you include in the assessment battery,  
6 in a minimum assessment battery, something that will measure  
7 binaural function as opposed to monaural function.

8 In our experience, a good way to do that is to  
9 measure directional hearing in noise, the ability to benefit  
10 from the spatial separation of speech and noise when they  
11 are both present and you are trying to understand sentences.  
12 The HINT test, as Yvonne mentioned, is designed in part to  
13 enable you to do that.

14 Another way of doing it is to test sound  
15 localization. That is a little more difficult to do  
16 reliably, but I would encourage you to consider as part of  
17 the evaluation, especially since you have advocated the use  
18 of binaural amplification, some measures that explicitly  
19 engage the functions of the binaural system, to inform you  
20 about the benefit of the device in that regard.

21 DR. KILENY: Thank you. Just one more comment,  
22 because time is running out.

23 MS. MATTHEWS: We are currently using the--I am  
24 Pam Matthews with SoundTec--we are currently using the SPIN  
25 low predictability sentences as an option to the HINT. The

1 HINT is a wonderful test, it is more mid- and low-frequency  
2 weighted, and we wanted something that showed more of the  
3 high-frequency benefit of the extra gain, since we don't  
4 have the feedback problem of acoustic hearing devices. So  
5 that is another test that I would like to have considered.

6 Directionality, our median age of the population  
7 is like 65 to 70 years old. I don't think directionality  
8 and localization is going to be the most important things to  
9 these people in their lifestyle. And when you talk about  
10 testing them in quiet and testing them in noise, testing  
11 their thresholds, you are talking about a large segment of  
12 time, and if you want to do it all in the same time period  
13 so you have good unaided scores for the same day and the  
14 same condition, you can only tax these people so much. So I  
15 would implore you that you really consider the length of the  
16 test battery for the segment of population we are talking  
17 about, as well. Thank you.

18 DR. KILENY: Thank you. I think we will move on  
19 to the next question, so make sure that we can at least  
20 touch upon the rest of the questions. This is only the  
21 second one we are discussing, and this relates to a  
22 clinically significant change in unaided hearing post-op,  
23 what is a clinically significant change in residual hearing  
24 post-op.

25 And we have heard different figures here today, 9

1 dB, 10 to 12 dB. Should we look at bone conduction  
2 threshold? Should we look at air conduction threshold?  
3 Should we look at both?

4 And then another comment that Teri made, of  
5 course, is that step size when you test hearing makes a big  
6 difference in what can be considered a significant change.  
7 If you test in 5 dB steps, that is the smallest change that  
8 you are going to see. If you use 2 dB steps, that could be  
9 the smallest step that you can see. And whatever is  
10 practical and informative. So let me open this question to  
11 the panel right now. Is a change, is a 10 dB change  
12 acceptable, for instance?

13 DR. SININGER: This is Yvonne Sininger again. I  
14 think a 10 dB change, average change throughout the  
15 frequencies by air conduction might be acceptable. I think  
16 we should test it by bone conduction as well, because there  
17 is where that issue of are we doing any sensory damage  
18 possibly isn't going to show up without a bone conduction  
19 test, and perhaps speech intelligibility as well. I think  
20 more than say 6, 8 percent change in speech intelligibility  
21 should be noted, as well.

22 DR. KILENY: Okay. Clough?

23 DR. SHELTON: I would certainly agree. I think  
24 that the change in post-operative hearing should be air  
25 conduction and bone conduction, because we are looking at

1 two different mechanisms here. I think it is important to  
2 separate out the effects of perhaps surgical trauma on bone  
3 conduction versus the effects of the device load on the  
4 ossicular chain on the air conduction. And I think also  
5 change in speech discrimination is important, as well.

6 This is where you get fairly arbitrary, and we can  
7 look at other reporting schemes that people have used in the  
8 past for change in hearing. You know, some would say a 10  
9 dB change in the average or a 15 dB change in the average is  
10 significant; also a 15 dB speech discrimination score is  
11 significant, as well. We use these types of reporting  
12 criteria for acoustic tumor surgery, and that is a model  
13 that could be used.

14 DR. KILENY: Okay. Other comments?

15 DR. ROSENTHAL: Rosenthal. Do you think a quality  
16 of life--are there standard quality of life questionnaires  
17 for hearing, and should they be incorporated into this?

18 DR. KILENY: Well, there are some general quality  
19 of life questionnaires that can be used for hearing  
20 purposes. There have been studies, quality of life studies  
21 conducted. These are multi-center studies, but conducted by  
22 the Johns Hopkins group in patients with cochlear implants,  
23 and use some standardized quality of life measures. And  
24 since there is a lot of data on that now, perhaps we should  
25 look at that data and maybe use the same questionnaires and

1 the same concepts that have been used for patients with  
2 implants.

3 Any other comments on this question?

4 DR. UHTHOFF: Peter Uhthoff, Health Canada. They  
5 must be statistically significant, as well.

6 DR. KILENY: What must be statistically  
7 significant? The change?

8 DR. UHTHOFF: The change, yes.

9 DR. KILENY: Well, that then opens the question of  
10 whether we are talking about group statistics or single  
11 subject measures.

12 DR. UHTHOFF: I would think it would be group  
13 statistics.

14 DR. SININGER: In that case--Sininger again--  
15 whether or not a 10 dB change is a change depends upon the  
16 number of subjects that you have measured it in, and so--and  
17 I would think that average numbers might not be what we want  
18 to look at.

19 What we want to look at is in any one subject, I  
20 mean, if you have 10 subjects with no change and one subject  
21 with a 50 dB change, I want to know that even if it averages  
22 out, that sort of thing. But we may have to look at what is  
23 clinically significant in terms of a change and look at  
24 individual subjects from that standpoint. Otherwise--

25 DR. KILENY: In hearing, at times what may be

1 statistically significant is not clinically significant. If  
2 you establish a change in hearing, either improvement or  
3 deterioration, of, say for argument's sake 5 dB, if you have  
4 a very large sample and there is very little variability,  
5 that could be a statistically significant change, but we all  
6 know that it is clinically irrelevant.

7 DR. UHTHOFF: But the other way around is what I  
8 was saying.

9 DR. KILENY: Right.

10 DR. UHTHOFF: That is the only comment.

11 DR. KILENY: Okay.

12 DR. DUFFELL: Bill Duffell. I would offer just  
13 one other comment for the panel to consider. Quality of  
14 life is certainly an important assessment in any technology,  
15 but from an industry standpoint one of the things that we  
16 often run into is, there are a lot of test instruments out  
17 there. They haven't always been validated in the population  
18 that is being studied, and when they are not, then their  
19 applicability to a product approval application can be  
20 called into question.

21 And sometimes those tests are very costly and  
22 time-consuming to administer, and ultimately you may not end  
23 up with anything better than an overall global assessment  
24 that we often see in clinical trials, of investigator  
25 assessment of change or patient assessment of change, which

1 usually can be, you know, summarized in just whether or not  
2 you would undergo this procedure again, if given the choice  
3 today, realizing the benefits you have had to date.

4 I mean, that is what it is, bottom line, all  
5 about. Would you do it all over again? Would you tell your  
6 neighbor to do this, based on what you have had so far to  
7 date? And I realize that is very crude, but in the end it  
8 may not be any more valid or less valid than an assessment.

9 DR. ROSENTHAL: Excuse me. Rosenthal. That is a  
10 satisfaction questionnaire. I am talking about a quality of  
11 life.

12 DR. DUFFELL: But a quality of life that is  
13 validated in this population of patients.

14 DR. ROSENTHAL: Well, that is what I was asking.  
15 I think if there is one, I think it is very valuable to use  
16 it, because you can then inform ultimately the prospective  
17 candidates for these implants what are some of the issues  
18 they may be particularly happy with and what are some of the  
19 issues they may not be particularly happy with. It depends,  
20 I guess, on their lifestyle and on what they want, and there  
21 may be things that--I mean, I just don't know. I know  
22 certainly in the eye it is very valuable to use a quality of  
23 life questionnaire for a practicing surgeon.

24 DR. KILENY: There are mathematical  
25 transformations or statistical transformations that you can

1 obtain some figures of quality, and which have been used in  
2 these cochlear implantations, and so you can actually have  
3 some--you change the sort of subjective measure into a  
4 quasi-objective measure that you can at least quantify, at  
5 least a quantifiable measure of changing quality of life.  
6 And, as I said, we probably ought to look at these studies  
7 that have been conducted by the Hopkins group.

8 Yes, Carl?

9 DR. PATOW: Carl Patow. I would agree we would  
10 have to look carefully at this study, because I think the  
11 motivation may be very different in this patient population  
12 than the cochlear implant population. If the, for example,  
13 the motivation is cosmetic, in that if they had the same  
14 degree of hearing post-implant that they had before implant,  
15 their functional capabilities may be in fact identical but  
16 they may feel better about themselves. And whether the  
17 questionnaire would get that information or whether a more  
18 simple questionnaire would get to the same information would  
19 have to be looked at carefully.

20 DR. KILENY: But I think that is valid, too. I  
21 think that somebody feeling better about himself or herself  
22 because of cosmesis is a relevant issue for the individual.

23 DR. PATOW: Then it gets down to the question of  
24 the cost and time involved, and whether to get to that piece  
25 of information is valuable enough to be part of--

1 DR. DUFFELL: A requirement, yes. Exactly.

2 DR. PATOW: So I think it just needs to be  
3 carefully looked at, that is all.

4 DR. KILENY: Yvonne?

5 DR. SININGER: Sininger again. I also am  
6 concerned that we get too carried away with how much data  
7 has to be acquired. I think some of these tests that were  
8 suggested, like the APHAB talks not necessarily about  
9 general quality of life but about communication ability in  
10 real life situations, and that is what I am concerned about.  
11 How can this patient hear in a variety of situations, and  
12 how can they communicate? And I personally believe that  
13 that is what is important. That is what I would counsel  
14 patients about. And so without overburdening the  
15 manufacturers, we can get a lot of that information from  
16 some of those questionnaires.

17 DR. KILENY: Okay. I propose that we move to on  
18 the next question: Should the device be restricted to  
19 patients who demonstrate certain types or degrees of hearing  
20 loss? And some of the issues here would be stable versus  
21 fluctuating hearing loss; a certain threshold for speech  
22 recognition; pre-operative speech recognition, should it be  
23 limited to patients who have 60 percent or better or 70  
24 percent or better speech recognition?

25 And there is another related question here. If we

1 do not restrict it to a certain range of speech recognition,  
2 but to a wider range, should we do studies where we stratify  
3 for pre-operative speech recognition? So I would like the  
4 panel to address this question now. Clough?

5 DR. SHELTON: Well, a basic thing. I think that  
6 it should be for patients that have a sensorineural loss  
7 only, rather than a conductive loss. I would be concerned  
8 that just the mechanism of these devices, the way they work,  
9 that it wouldn't work well with a conductive loss, so we  
10 would again have data that wasn't clean.

11 DR. KILENY: Any concerns about stability of  
12 hearing over what length of time?

13 DR. CAMPBELL: Dr. Campbell. It should be stable.  
14 I can't tell you the length of time, though. In case you  
15 have a fluctuating hearing loss, as in Meniere's disease,  
16 until it stabilizes out. I don't know what time period, but  
17 they shouldn't have any fluctuation of hearing.

18 DR. KILENY: Clough?

19 DR. SHELTON: I would certainly agree. I would  
20 think you would want to exclude patients that have things  
21 like Meniere's disease pre-operatively, because I think all  
22 of us that do Meniere's surgery will do a shunt operation,  
23 the patient will come back in post-operatively, and if their  
24 hearing is worse after surgery, we get credit for it. Of  
25 course, every once in a while they come back in, their

1 hearing is better. I always take credit for that, too. But  
2 we again--

3 DR. SININGER: What was that second?

4 DR. SHELTON: Their hearing is better.

5 DR. SININGER: When their hearing gets better, you  
6 take credit?

7 DR. SHELTON: If it is worse, I always get credit  
8 for it, but I always take credit when it gets better, even  
9 though it probably had nothing to do with the surgery per  
10 se. But I think we want to have a stable population that we  
11 are studying so, again, those kinds of things don't mask the  
12 effect of the surgery or of the device.

13 DR. KILENY: I believe one of the manufacturers  
14 recommended two years, stable hearing over a two-year  
15 period? Is that a reasonable length of time?

16 DR. CAMPBELL: I would think so, two years, and no  
17 conductive hearing loss patients. And the mild category,  
18 also, limited.

19 DR. KILENY: Any restriction in terms of amount of  
20 hearing loss? I mean, are we talking about moderate,  
21 moderate plus, severe? What sort of range of hearing loss  
22 should we look at?

23 DR. SININGER: Yvonne Sininger. Again, going back  
24 to some estimate of how much power the device can actually  
25 apply to the middle ear, that should go into what patients

1 are appropriate. I mean, if you can't get enough gain to  
2 fit a severe hearing loss, then those patients should be  
3 restricted. But mild gain--I mean mild losses I don't think  
4 should--should be restricted, but I would believe that the  
5 range of hearing should be related to the device and what it  
6 can--what it can purport to do.

7 DR. KILENY: Yes, Peter.

8 DR. UHTHOFF: Peter Uthhoff, Health Canada. I  
9 don't think you should be restrictive. I think you should  
10 allow the manufacturer to tell you what--or they should, you  
11 know, clearly indicate the indications for use and then just  
12 make sure that the data they provide is adequate to  
13 substantiate the safety and efficacy according to those  
14 indications. But having a priori, you know, cutoff is not  
15 appropriate. If the manufacturers wants to put the high bar  
16 up here, let them. If they want to put them down here, let  
17 them. I mean, I don't see the issue.

18 DR. WOODSON: Gayle Woodson. Again, I think we  
19 need to make sure we distinguish between ultimate labeling  
20 of the product versus the study, and I guess if you want to  
21 recommend to the industry what is the best way of designing  
22 the study, we can say, you know, you are going to have your  
23 best--you are going to get your best figures and have an  
24 optimal study if you restrict it to patients who have a  
25 moderate hearing loss. Now, if they want to study it in

1 another population, I don't think we should necessarily  
2 restrict them from that.

3 DR. KILENY: Yes, Dr. Rosenthal?

4 DR. ROSENTHAL: Well, there you do have to take  
5 the risk versus the benefit. If they have very mild hearing  
6 loss, I am not sure, certainly in the first part of this  
7 adventure that we are entering into, one would like to enter  
8 them into studies. Even if that is the indication they  
9 want, one might feel, well, maybe we better just make sure  
10 everything is--I don't know.

11 DR. SININGER: Sininger. I am going to disagree  
12 with that. You have patients who have significant  
13 difficulty with--problems with earmolds, problems with  
14 allergy to those materials, and there are a lot of reasons  
15 why someone with a mild hearing loss might very well want to  
16 pursue one of these devices.

17 DR. KILENY: Any thoughts regarding speech  
18 recognition, speech intelligibility, speech recognition  
19 scores? Should that be a criteria? I mean, would you want  
20 to include patients with 28 percent speech recognition? Is  
21 that realistic, and if not, why not?

22 DR. SININGER: Again, one of the things we haven't  
23 talked about is how are we measuring speech recognition. If  
24 you simply apply a 60 dB sound pressure level signal, then  
25 it is going to relate very much to how much hearing loss

1 they have. So what does 60 percent speech recognition  
2 ability mean? I think we have to get a little more clear  
3 about that.

4 But I am not particularly in favor of limiting the  
5 unaided speech recognition score that should be included,  
6 patients with only 60 percent or better only being included,  
7 because that is not realistic. That is not who we are  
8 seeing walk into the clinic necessarily.

9 DR. KILENY: Any other comments? Clough?

10 DR. SHELTON: Clough Shelton. I would agree. I  
11 am not sure that we need a floor on the speech  
12 discrimination either. I mean, I think that if you implant  
13 patients with poor discrimination, if that is what they have  
14 got, you would put a hearing aid on them anyway, and you are  
15 comparing them to their hearing aid condition, so I am not  
16 sure there is any form for it. I think if you had someone  
17 with bad speech discrimination, you put a hearing aid on  
18 them, you might lower your expectations, but again you are  
19 comparing them to themselves.

20 DR. CAMPBELL: Dr. Campbell. Then, again, how far  
21 do you go down before you put the cochlear implant in?

22 DR. SHELTON: Right.

23 DR. KILENY: Well, at some point these indications  
24 might cross over, and there may end up being some kind of a  
25 gray zone. We all know that the criteria for implantation

1 are very different today than they were even three years  
2 ago, let alone 15 years ago. So I think the criteria are  
3 going to continue to change for cochlear implants, and for  
4 these devices eventually, so at some point maybe the patient  
5 might actually have an option of one or the other, and  
6 hopefully we will be able to give them the risk-benefit  
7 account for both and let them decide.

8           Okay, I think we can--anything else about this  
9 question, other comments? Let's move on to the next  
10 question, then. This is--relates to the proposed benefit  
11 being improvement in the fidelity of sound. We have heard  
12 this term today a number of times, and we have heard the  
13 occlusion effect and feedback mentioned, perhaps indicating  
14 that these devices will be free of both. Obviously, they  
15 will be free of the occlusion effect. I am not so sure that  
16 there cannot be any feedback in a device such as these.

17           But the main question here is, how are we going to  
18 determine an improvement in fidelity of sound or quality of  
19 sound in these patients? Are we going to use, again, some  
20 type of qualitative questionnaires, maybe some type of  
21 adaptive measurement, some type of scaling? How are we  
22 going to take into account the placebo effect, which may not  
23 be necessarily negative but it is going to be there, and we  
24 need to account for that, too, perhaps.

25           MR. SAUBERMAN: This is Harry Sauberman. When we

1 designed this question and discussed it internally, we  
2 thought of fidelity not only as gain or functional gain but  
3 also as a function of bandwidth, so as both a gain and a  
4 bandwidth product. So in assessing and discussing this  
5 question, could you do it in the context of both gain and  
6 bandwidth?

7 DR. KILENY: Okay, so the implication being that  
8 one of the advantages of these implantable hearing aids  
9 would be a wider operating bandwidth, less restrictive  
10 bandwidth?

11 MR. SAUBERMAN: Yes, that is correct.

12 DR. KILENY: Okay. Well, I guess one way to  
13 assess bandwidth is--one of the simplest ways to do it is  
14 just looking at functional gain, I suppose. If they get  
15 better gain in the higher frequency range than with a  
16 standard hearing aid, that in itself proves that the  
17 operating range of these hearing aids is going to be  
18 improved in the high frequency end of the scale. But there  
19 maybe some other measures. Maybe this could be  
20 substantiated by improved speech recognition scores, as  
21 well.

22 DR. SININGER: Yvonne Sininger. I don't know what  
23 the term "fidelity" means. I don't have an internal feeling  
24 for what it is. I do have a feeling that it is a subjective  
25 judgment, a human subjective judgment like loudness, and

1 therefore may or may not be related to bandwidth and/or high  
2 frequency and/or other--I don't know what it is related to.  
3 Unless we had some sort of definition for what we mean by  
4 fidelity, I am still very uncomfortable with it.

5 MR. SAUBERMAN: Harry Sauberman. I know generally  
6 that in the engineering community that fidelity is defined  
7 as a bandwidth consideration of, again, bandwidth product,  
8 and among engineers fidelity does imply a wide bandwidth.  
9 Whether it is to 16 kHz or 20 kHz, that is a matter of what  
10 particular group you are speaking with, but fidelity does  
11 inherit the term "bandwidth".

12 DR. KILENY: So that this actually gets back,  
13 perhaps, to some of the pre-clinical measures that we have  
14 discussed earlier, and if we talk about fidelity in the  
15 engineering sense as opposed to the subjective sense, then  
16 some of this can be substantiated pre-clinically by doing a  
17 variety of electromechanical or laser vibrometry  
18 measurements that would substantiate the bandwidth of these  
19 devices. Isn't that so? Cough?

20 DR. SHELTON: Are you talking about the quality of  
21 the sound, "I like the way it sounds," is that what you are  
22 getting at? I mean, because it sounds like an analogy with  
23 picking out a stereo. Did you like stereo A or stereo B, if  
24 it sounds better? You can put it to the speakers and  
25 measure their output, and the outputs may be very similar,

1 but some will like the way A sounds versus B, and it is a  
2 very subjective thing.

3           And I don't know if there needs to be some type of  
4 measure like the music example Dr. Maniglia showed us today,  
5 the quality of those kinds of things, because if you talk  
6 about a quality of life type issue, this may be one of those  
7 quality of life type issues that these devices can provide.

8           MR. SAUBERMAN: Well, there are two aspects here.  
9 It is the quality of the device, which is the, you could  
10 call it the physical bandwidth or the physical  
11 characteristics of the system, and then you have the  
12 physiological bandwidth of the anatomy of the middle ear  
13 itself. And what you really have is a system effect of--you  
14 could model it. You have the device and the physiological  
15 anatomy, and it is really the product of the two, I would  
16 imagine, if you were to model it. That would be your  
17 fidelity or your gain bandwidth, which would be the transfer  
18 function of the system.

19           DR. KILENY: Carl?

20           DR. PATOW: Carl Patow. I guess the concept of  
21 fidelity, it sounds like there are several different  
22 definitions, but there are some qualities of sound that may  
23 change, having the device implanted. One aspect may be new  
24 feedback, a new source of feedback, or perhaps it is  
25 slipping somehow, or if it has an articulation and there is

1 a squeak in it. I mean, the device itself could potentially  
2 promote some kind of sound, which I think would be something  
3 to at least note. I don't know how one would assess it,  
4 but--

5 DR. KILENY: Well, you are talking about  
6 distortion, I guess.

7 DR. PATOW: Distortion, feedback, extra sounds.

8 DR. KILENY: But both of these can be determined  
9 psychophysically or very subjectively, as well as physically  
10 and physiologically, so those are two different things. And  
11 as Clough has mentioned, you know, you can do an engineering  
12 measurement on the specs of a stereo system, and in terms of  
13 the engineering specs A is much better than B, but maybe you  
14 like the second one better for whatever reason. That is  
15 subjective.

16 Dr. Campbell?

17 DR. CAMPBELL: The question is--is a patient  
18 criteria, isn't it? Candidacy, rather than after the  
19 implant is in? Pre-implantation?

20 DR. KILENY: Well, my understanding of this was  
21 that that related to--the comparison was again to pre-  
22 implantation, and pre-implantation with amplification.

23 DR. CAMPBELL: I don't know if it can be measured.

24 DR. KILENY: Any other comments? Go ahead.

25 MS. MATTHEWS: Pam Matthews, again, with SoundTec.

1 With the direct drive mechanism, I have heard several middle  
2 ear companies talk about the first time their patients are  
3 hooked up, the patient goes, "Wow, that sounds so much more  
4 natural than my hearing aid did." The sound quality  
5 mechanism of the direct drive may provide a different  
6 perception of sound for the patient, and I do feel like it  
7 is more of a subjective measure that may be partly related  
8 to the extended bandwidth.

9           We tried testing our patients out to 8,000 Hz, and  
10 boy, we ran into a problem with standing waves. You can go  
11 out to 4,000 pretty reliably in the sound field, but if you  
12 go up to 6,000, you have an 85 dB limit for your audiometer.  
13 You go to 8,000, you have a 70 dB limit with the audiometer,  
14 and it is very tough to get unaided to aided, to get  
15 functional gain measures above there.

16           I think you can use engineering voltage boxes or  
17 something to get readouts further, but even hearing aid  
18 boxes roll off after 4,000 Hz. You don't get adequate  
19 representation of what an acoustic hearing aid can do on a  
20 hearing aid test box, either. So it requires some  
21 specialized equipment and has to be done more on a bench  
22 model, from my understanding, that in actual live testing.

23           DR. KILENY: So perhaps, as we mentioned earlier,  
24 some bench, pre-clinical bench testing could substantiate  
25 the electromechanical characteristics, but there should be

1 some measure of quality or fidelity, some subjective  
2 psychophysical measure that could be used to determine that.

3 Did you want to make a comment?

4 DR. SOLI: Could I make a comment, please?

5 DR. KILENY: There was a gentleman in the back, I  
6 think, from--go ahead, and then Sig.

7 DR. LEYSIEFFER: Hans Leysieffer from Implex  
8 again. I think I would make a suggestion for fidelity,  
9 because this is one of our main goals of the whole TICA  
10 design. I would say fidelity is the absence of distortion,  
11 and our personal belief is that you can maybe reduce  
12 stimulation level if you increase fidelity.

13 And our feeling is that we help patients not only  
14 by loudness level, for a sensorineural hearing loss, but by  
15 undistorted sound presentation, not only increase the  
16 bandwidth but decrease non-linear distortions, and on the  
17 other hand linear distortions. So our belief is, you  
18 present a flat frequency response and a broad frequency  
19 range up to maybe 10 kHz, and then bring down the non-linear  
20 distortion compared to conventional hearing aids about 1  
21 dekate, and then our belief is that you can also reduce the  
22 stimulation level that presents speech material to the  
23 patients, and then you can preserve residual hearing again  
24 over a long time.

25 So our belief is that fidelity is really an

1 important criteria, and you can measure it physically on the  
2 device.

3 DR. KILENY: Right. Do you have any suggestions  
4 how to measure it psychophysically? Perhaps Dr. Soli?

5 DR. SOLI: I would agree with what this gentleman  
6 just said. Fidelity is a property of sound, it is not a  
7 property of perception, so I don't see it as being a patient  
8 candidacy criterion at all. It is a property of the device.

9 You can, I believe, get some indirect measures of  
10 fidelity when you measure speech intelligibility in noise.  
11 The presence of even a small amount of distortion or  
12 bandwidth limitation will degrade performance, speech  
13 intelligibility performance in noise, so that gives you an  
14 indirect indication of fidelity. And as this gentleman just  
15 suggested, with a good linear non-distorting system, speech  
16 intelligibility is actually somewhat better.

17 DR. KILENY: Okay. Any other comments? Dr.  
18 Maniglia?

19 DR. MANIGLIA: I believe this is an engineering  
20 problem, and the engineers defined the fidelity very well,  
21 about distortion. And every device can be measured in a  
22 bench test, and I think the best way to do it is probably to  
23 use the fresh human temporal bone, which simulates the human  
24 ear the best.

25 If you gather a human temporal bone within eight

1 hours after death, you really can get excellent testing.  
2 And then you can hook up the device to the fresh human  
3 temporal bone with an insert microphone in the ear canal and  
4 measure the device to see if the device is good.

5           Some people like it. Most people should--several  
6 observers should listen to it and see. Like my son, he buys  
7 a stereo which costs \$2,000 and I buy one that cost \$300. I  
8 like mine, I don't see much difference with him, and he  
9 hates mine. So it is a matter of temporal lobe perception.  
10 It is hard to say.

11           DR. KILENY: So it seems to me that maybe this  
12 question was placed sort of not quite in the right context.  
13 Maybe candidacy should not come in here. Maybe we need to  
14 talk about fidelity in engineering terms that will be done--  
15 that will be measured through some type of bench testing,  
16 and maybe this should not be some type of a candidacy  
17 criterion. Is that sort of--is that a perception, is that a  
18 correct perception that I have here?

19           DR. SININGER: My confusion has been coming in  
20 related to claims that are sort of filtering in. You know,  
21 the whole idea that patients claim that it sounds better,  
22 but what does that mean, and is that related to the  
23 fidelity? I would like to see some comparison between the  
24 fidelity of the device and the quality estimates that the  
25 patients are making.

1 DR. KILENY: Well, you know, we have talked about  
2 speech and speech in noise, and it has been confirmed that  
3 that might be a good measure for this purpose as well, so  
4 perhaps just establishing some criteria in terms of speech  
5 in noise performance would fulfill this requirement.

6 DR. PATOW: We have just 25 minutes or so, and we  
7 have got two questions left, so I wonder if we could move on  
8 from this question.

9 DR. KILENY: Okay. Next question: What are your  
10 concerns for patients going from binaural conventional  
11 hearing aids to monaural implants?

12 Here we have some issues regarding directional  
13 hearing. Some comments were made earlier today about using  
14 the implanted hearing aid in tandem with a standard hearing  
15 aid in the contralateral ear. Are there any concerns--and I  
16 am just, I would like to restrict the discussion now to the  
17 first part of the question--regarding going from binaural  
18 amplification to a monaural implant, or maybe monaural  
19 implant with a contralateral standard amplification, any  
20 concerns of the panel? Does anybody on the panel believe  
21 that once a patient has received an implant that does  
22 function well and is cosmetically appealing, will continue  
23 wearing a contralateral standard hearing aid?

24 DR. SHELTON: Clough Shelton. I think there might  
25 be situations where someone would wear just their implant

1 around the house, and if they are going to a situation like  
2 a meeting or a restaurant with background noise, they may  
3 put a contralateral hearing aid in for the sound direction  
4 use.

5 I mean, I think we are also making an assumption  
6 here that everyone is going to come in with binaural hearing  
7 aids, which is certainly not my experience. I have lots of  
8 patients that have unilateral fittings. I have older  
9 patients with limited hearing needs that have dexterity  
10 problems, say. They just have one hearing aid, and that is  
11 all they want to deal with. So I think that we may see  
12 various situations with binaural versus monaural hearing  
13 aids today.

14 DR. KILENY: Well, there are some economic issues  
15 at play here. Many of the patients that I see who really  
16 should be wearing binaural amplification, use monaural  
17 amplification because they pay out of pocket, and so--which  
18 raises the economic issues associated with these particular  
19 devices as well, the cost aspect as well.

20 Yvonne?

21 DR. SININGER: Another point I see is that--there  
22 is really two things I see as the benefits of binaural  
23 amplification or binaural hearing, one being localization  
24 and the other being hearing in noise, and so we are going to  
25 assess hearing in noise, speech perception ability in noise.

1 And so if there is a substantial reduction because of the  
2 monaural nature of this, then we will see that.

3 But I don't know how to--necessarily how to  
4 address the localization issue. I think it is something  
5 that, if we test it as Sig has suggested, I can't imagine  
6 that with the monaural situation you are not going to see a  
7 significant decrease in the ability to localize. That is  
8 just--should happen.

9 DR. KILENY: Well, it is a matter of providing  
10 adequate counseling to the patient and of patient  
11 preference. You can always recommend to the patient to  
12 continue wearing a hearing aid on the contralateral side. I  
13 mean, that is always available. We are not taking away,  
14 this device doesn't take away that ability.

15 DR. PATOW: Carl Patow. For the purpose of the  
16 study, there are patients who are profoundly deaf in one  
17 ear, and would we have any recommendations about putting an  
18 implant on the only hearing ear

19 DR. KILENY: Not doing it. That is the other  
20 question. Would any of the otologists operate on a normally  
21 hearing ear that can receive a standard hearing aid?

22 DR. MANIGLIA: We only operate on the hearing ear  
23 if the patient has a disease that is threatening their  
24 hearing or something like that. But it took a long time  
25 before a stapedectomy was done bilaterally. It took a while

1 to prove that the operation was really good.

2           So going back to cost, this operation is going to  
3 cost probably \$15,000, if you add the device cost,  
4 anesthesia cost, facility cost, the surgeon's fees, and  
5 maintenance of the device itself, so it is expensive. So  
6 any patient who has \$15,000 to have this operation, because  
7 the insurance companies are not going to pay for it, managed  
8 care doesn't pay for it, they should have \$5,000 or \$6,000  
9 to get the best hearing aid binaurally--which nature gave us  
10 two ears to hear, that is why we have two ears, stereophonic  
11 hearing--and compare binaural with the unilateral  
12 implantation.

13           Dr. Maniglia from Cleveland, Ohio

14           DR. KILENY: Would anyone under any circumstances  
15 recommend binaural implantation? I think there is a simple  
16 answer to that.

17           DR. CAMPBELL: Dr. Campbell

18           DR. KILENY: Dr. Hough?

19           DR. HOUGH: Jack Hough from Oklahoma City. I  
20 think that if a patient has had an implant in one ear, we  
21 are looking down the road in the future a long ways, but if  
22 we had an acceptable result in one ear and it stayed stable  
23 for at least a year, then I think we are probably at liberty  
24 to operate on the other ear.

25           DR. KILENY: Thank you.

1 Dr. Campbell?

2 DR. CAMPBELL: I totally agree. Why not? If the  
3 patient wants it and can afford it, why not, down the line,  
4 after this has been proven successful

5 DR. KILENY: Okay. Other thoughts?

6 DR. ROSENTHAL: Is that the consensus of the  
7 panel?

8 DR. KILENY: Well, you know, my feeling is that  
9 initially, I mean, we are talking about clinical trials  
10 right now. We are not talking about an approved device.  
11 Once a device is approved, you know, the sky is the limit,  
12 but under a clinical trial situation I think that we should  
13 limit it to one ear within the clinical trials. I don't see  
14 any situation where we would do binaural implantation under  
15 any type of clinical trial.

16 DR. ROSENTHAL: Can I get a sense of the panel on  
17 that, because there has obviously been two opinions  
18 expressed.

19 DR. MIDDLETON: Renee Middleton. I think for the  
20 purpose of the trials, without getting into the other areas,  
21 that it should be strictly used for the monaural, not  
22 binaural.

23 DR. PATOW: Carl Patow. I would agree.

24 DR. CAMPBELL: I agree. Just don't lock it out in  
25 the future.

1 DR. KILENY: No. I think these questions relate  
2 not to the future, not to an approved device, but to the  
3 immediate short term question.

4 DR. CAMPBELL: Absolutely. We are still there

5 DR. KILENY: And we are down to the last listed  
6 question. It is: How should these devices accommodate for  
7 hearing changes?

8 We talked about the necessity to implant patients  
9 with stable hearing, at least for a two-year period. We do  
10 not want to implant somebody with a fluctuating hearing  
11 loss. But we all know that the nature of sensorineural  
12 hearing loss is such that it is not going to remain stable  
13 forever. It might progress slowly over 10 years or 15 or 20  
14 years. How should this device accommodate for these kinds  
15 of changes that are part of the natural history of  
16 sensorineural hearing loss?

17 DR. PATOW: Carl Patow. It strikes me that that  
18 is a question that the manufacturer will need to consider as  
19 they design the device and looking into the future, but not  
20 something that we would be able to put into a guidance  
21 document, saying that specifically this is how you should  
22 accommodate for hearing changes

23 DR. KILENY: Maybe the question is, should these  
24 devices accommodate for hearing changes, not now. We don't  
25 know how. So if I posed the question that way, should these

1 devices accommodate for changes in hearing?

2 DR. WOODSON: Gayle Woodson. I think, you know,  
3 if you are doing a--I don't think we should have to require  
4 them to do that, because if we are looking at a short term  
5 study where they are going to be studying things for a year  
6 anyway and they are supposed to be stable for two years, you  
7 wouldn't necessarily expect that you are going to be seeing  
8 a lot of changes in the short term anyway.

9 But you would think that they should consider that  
10 in designing it. They are not going to--you know, in that  
11 period of time that they do the study, they are not going to  
12 be able to document that they can accommodate for the  
13 changes, but I think in considering a design, presumably it  
14 is going to be a change in the way of adjusting the gain of  
15 the device or the compression or whatever, and that  
16 certainly they are going to design something that you can  
17 adjust for the patient's hearing, so presumably that could  
18 be changed over time.

19 DR. SININGER: Yvonne Sininger. I mean, maybe I  
20 am being naive here, but isn't this as simple as turning it  
21 up? I mean, the device will have a range of amplification  
22 like any other conventional amplification, and it will be  
23 appropriate and can be adjusted for that range of hearing  
24 loss. And I would think if a patient is being fit right at  
25 the edge of what the capability of the device is, that they

1 can be counseled to that regard, but even the totally  
2 implantable should be able to be modified to accommodate

3 DR. KILENY: So would a statement such as that  
4 these devices should have the same range of flexibility in  
5 terms of gain and frequency response as the average acoustic  
6 hearing aid, would that be a reasonable statement to make?  
7 Okay.

8 DR. PATOW: Okay. That is the last of our  
9 questions. This is Carl Patow again. I would like to now  
10 go around the panel table and ask for each one of the  
11 panelists to comment on the very first question, which was:  
12 What are the significant issues of safety and effectiveness  
13 for purposes of development of a guidance document for  
14 implantable middle ear amplifications? And if I could get  
15 the comment of each panelist on what they feel are the  
16 important safety and effectiveness issues that should be  
17 included. Dr. Campbell?

18 DR. CAMPBELL: Yes. Dr. Campbell. We have  
19 covered some of these already, such as erosion of the incus  
20 over time; and placement of the device, on which ossicle;  
21 and removal of the incus; and use the stapes, especially if  
22 you have to remove the incus, to prevent feedback; the ease  
23 of placement for the surgeon; and surgeon's competency and  
24 training.

25 I still am pondering the question of saying that

1 training is necessary, but I have been teaching anatomy and  
2 surgery and temporal bone dissections over 30 years, and I  
3 am just frightened about some of the things that can happen  
4 without good training when you enter the facial recess. So  
5 it is hard to say which one should have which, but if you  
6 are going to do facial recess approaches, you should have  
7 special training. That should be a must if you are going to  
8 do the facial recess approach.

9           And the other question was microphone feedback,  
10 and the device should have the least revisions and it should  
11 be safe over time. Those are some of the questions, but a  
12 lot of these have been answered in the discussions already.

13           DR. PATOW: Thank you, Dr. Campbell.

14           Dr. Khan?

15           DR. KHAN: I will echo the statement made by Dr.  
16 Campbell regarding technique because I think that is very  
17 important, although we will be using it in future.

18           He talked about the ossicular placement and the  
19 ossicular joint, which seems to be a very important  
20 location. I would like to see some work done or some  
21 information that will tell us what this--what is the range  
22 of movement at this area and can it sustain for how much  
23 period of time this repetitive movement or area that is  
24 moving in the incudo-stapedial joint where things are going  
25 to be placed.

1           And the other one is the failure rate for this  
2 location, if there is any information that can be brought  
3 forth.

4           DR. PATOW: Thank you.

5           Dr. Woodson?

6           DR. WOODSON: I think that we definitely have come  
7 up with a range of kind of domains in which things have to  
8 be assessed. Certainly the document would need to cover  
9 biocompatibility issues, that they either use standard  
10 biocompatible materials, things that have already been  
11 proved, or that if they have something new, that that would  
12 need to be tested in animals.

13           In terms of the device performance, I think we  
14 decided that mechanical performance is best tested in the  
15 human temporal bone model. As to what measurements need to  
16 be made, I think that that is something that is going to  
17 have to be determined as the document is developed, because  
18 I don't think we have enough information right now to say  
19 you have to use a certain technique.

20           But I think that some consensus probably will be  
21 gleaned when the document is developed, probably with more  
22 input from the manufacturers, about what is the best way to  
23 ensure that they are going to be measuring roughly the same  
24 thing, and assuring that there is the same input-output--  
25 that they can document the input-output functions and that

1 it is going to be in the range of safety for trauma to the  
2 inner ear.

3 In terms of efficacy, I think we have all agreed  
4 that we want to compare it to the best aided speech, but  
5 that we have to look at how the unaided speech is affected,  
6 too.

7 In terms of the safety, I can't imagine that they  
8 would want to do a study and not train the surgeons to all  
9 do the operation the same way. So, I mean, later on we can  
10 get into, you know, whether or not people need to be trained  
11 to do it later, but I would think that in the study they  
12 would really want to have everyone trained to do the  
13 operation the same way.

14 And I think that pretty much covers the issues  
15 that we addressed.

16 DR. PATOW: Thank you.

17 Dr. Rosenthal, did you want to comment? Dr.  
18 Uthhoff?

19 DR. UTHHOFF: Peter Uthhoff, Health Canada. I  
20 think I look at the risks before I look at the benefits.  
21 You cannot look at them in isolation. You have to look at  
22 the risks first, I feel, see how many risks you have, how  
23 detailed the risks are, to what extent these risks are  
24 involved, before you can go further.

25 And I have outlined the five different areas of

1 risk I was thinking about: the type of contact, the effect  
2 of the contact, disarticulation or not, the surgical  
3 expertise approach and complications, and indications for  
4 use. And then only with that in mind can you start looking  
5 at the benefits.

6 MRI, I have made my points. I think I made my  
7 points. I just have an additional point: Maybe use a  
8 bracelet to notify the people in case of trauma or  
9 unconsciousness or emergencies.

10 Pre-clinical, I think the points made are  
11 excellent. The only thing I like to add is, certain devices  
12 may require specific animal testing for specific issues,  
13 mostly bone issues.

14 As far as battery replacement, I think the  
15 suggestion that it can be easily disconnected is excellent.  
16 Limitation of physical activity, I think cochlear implants  
17 are pretty similar.

18 On the second page, the last point, the (f) point  
19 was how should these devices accommodate for hearing  
20 changes? If they can--I am thinking about how to improve  
21 technology. If you can disconnect it easily then you can  
22 maybe connect up a new processor which has improved  
23 abilities. It would be a nice idea, but that is way down  
24 the road.

25 Also, electrocardery, too, you may wish to wear a

1 bracelet to notify the emergentologist about that. I am  
2 quite concerned about that.

3 DR. PATOW: Good point. Dr. Duffell? You had  
4 some comments earlier that you mentioned and we didn't quite  
5 get to them. Have we covered that concern, or do you want  
6 to mention it now?

7 DR. DUFFELL: No, but I will try to capture it in  
8 the wrap-up, so that will do. But maybe before doing that,  
9 I think this panel has probably benefitted, I know I have a  
10 great deal, from the people in the audience today which  
11 presented. I think the professionalism and the preparation  
12 that went into it showed, and I for one as an industry  
13 person, having participated in panels on both sides now, was  
14 astounded at the preparedness and the level of timekeeping  
15 that you all kept for the most part, so I applaud all of you  
16 for helping us in the discussions today.

17 But specific to the guidance document, some things  
18 that I think that are important for the industry, and I  
19 applaud, Dr. Rosenthal, your remarks about "least  
20 burdensome." I think "least burdensome" can oftentimes be  
21 captured in the start of one of these guidance documents,  
22 because these things take on a life of their own and of  
23 course they are going to live for some time to come, not  
24 just for the next year or two but for quite a long time. So  
25 I think that is important to keep in mind as you move

1 forward drafting the document.

2 I think specifically the contents of the document  
3 should look at the minimum number of patients that should be  
4 included in these trials, knowing full well that the claims  
5 and the statistical analysis will drive the final end, but  
6 certainly there is some minimum number that we would  
7 acknowledge you need to have evidence of safety and  
8 effectiveness on in order to seek an approval.

9 As well, I think, you know, the length of follow-  
10 up had a lot of discussion today, too. Whether it is a year  
11 or 18 months, you know, I think needs to be taken into  
12 account about the least burdensome approach. And I am not  
13 sure if there is really adequate justification for 18 months  
14 over one year.

15 So I guess my challenge to the agency in pulling  
16 together the guidance document, whatever the date is, that  
17 it not be grabbed out of the air, that there be some sound  
18 justification for why 18 months versus 12 months versus six  
19 months. And I am sure in working with the industry maybe  
20 something can--you can come up with something on that.

21 I think as well the type of controls that we  
22 discussed here today should be outlined in that document, so  
23 everyone can refer to those in the future. I think as well  
24 the frequency of follow-up that we discussed earlier, you  
25 know, how often those intervals should be and the types of

1 measurements should be spelled out there.

2 I think there needs to be acknowledgement in the  
3 guidance document that the--that one of the things industry  
4 is often guilty of, I have been of myself in the past, is  
5 the guidance document really should call for people to  
6 outline and specify what their claims and proposed labeling  
7 is. What is it you want to say about your device?

8 I know FDA has guidance documents on that, but if  
9 you could repeat it in the course of this one, I think it  
10 helps direct people as to what it is they need to do to  
11 prove that, because every company is going to have a  
12 different level of risk associated with their procedure and  
13 their device. It is all driven off of what is it you want  
14 to say about your product, say it up front, and then to  
15 build your study to support it. So I think the guidance  
16 document should highlight that.

17 I think the use of standards, which was discussed  
18 a little bit this morning but not in a great deal of detail,  
19 should be referenced in there, that international standards  
20 should be considered applicable, and which ones those are  
21 that the FDA is willing to accept for purposes of  
22 biomaterials and performance testing. Those should be  
23 called out in there.

24 And I think there needs to be an open  
25 acknowledgement that the risk may differ across the

1 different types of device, and therefore any company can  
2 obviously come in and make their own proposal for what they  
3 think ought to be done for their particular device.

4 I think on the issue of quality of life, the  
5 mention of the Hopkins study, I know quality of life is  
6 important to FDA. It is important to industry as well. But  
7 I will repeat again that I think any instrument that is used  
8 needs to be a validated instrument in the population in  
9 which it is intended to be used. If such an instrument does  
10 not exist, which it didn't sound like from the brief  
11 discussion that took place here, then I would submit that  
12 you really need to question whether or not the burden of  
13 doing those types of testing gives you any additional return  
14 on investment over what you might get out of the global  
15 assessments that we talked about.

16 I appreciated Dr. Sininger's remarks about not  
17 limiting these devices to people only who have moderate or  
18 severe hearing loss. I think mild hearing loss is  
19 appropriate and should be allowed for in the course of the  
20 guidance document, to be studied initially, if that is what  
21 a manufacturer is interested in.

22 And I think the idea of limiting it only to one  
23 ear implant I will take objection to, in the sense that I  
24 think FDA needs to couch in the guidance document that it is  
25 very dependent on the length of the development cycle for

1 these products. Some of these products could be in the  
2 research and development cycle for eight years possibly  
3 before they get approved, and if you are going to say so  
4 long as it is in an IDE phase that you can never do the  
5 bilateral implant, I think that might be a bit unreasonable.  
6 So I think there may be other criteria FDA may want to look  
7 into, to apply, as to when you can try the second ear.

8           And my last item, on the topic of training, I  
9 think training is generally a good idea. I think it should  
10 be stipulated in labeling. But my note of caution for the  
11 industry, on behalf of the industry, is the difference  
12 between training and competency and certification testing.  
13 I do not think it is appropriate to ask the industry to do  
14 those types of things. You know, we are not medical  
15 schools. We are not, you know, wanting to be and incur that  
16 liability.

17           But I think it is incumbent upon us for liability  
18 reasons and others, to at least provide the tools of  
19 training to physicians and educated people to learn from.  
20 But then they should be the ones that bear the burdens of  
21 either certifying their fellow colleagues through certain  
22 testing requirements or competency testing. So I would  
23 leave training, again, just simply as a requirement that it  
24 should be obtained, and that possibly the sponsors provide  
25 some materials and wherewithals to get that but be left out

1 of the certification role.

2           And thanks a lot for the opportunity to  
3 participate today.

4           DR. PATOW: Dr. Middleton?

5           DR. MIDDLETON: I would agree with the request for  
6 special training, specifically with respect to consistency  
7 of the surgical technique, and also in the guidance document  
8 to indicate who the target--who the agency is targeting or  
9 marketing their product to. There was some discussion that  
10 they would not, by one agency, they would not fit mild or  
11 profound losses, and then some moderate to severe. So I  
12 think that the guidance document ought to request that the  
13 institution just indicate who they are targeting or  
14 marketing their product to.

15           Also, I think if we could have them specify what  
16 they believe would be the minimal criteria and baseline data  
17 that would be acceptable for making judgments regarding  
18 effectiveness, or FDA ought to certainly indicate what the  
19 minimal criteria and baseline data would be desired or  
20 required for making those effective judgments.

21           And then I would like to see some discussion on  
22 the risk or the long term effects of coupling the devices to  
23 the middle ear structures, and also how they would indicate  
24 how they are going to provide for the safety of the  
25 ossicular chain and other middle ear structures.

1           And then, finally, I do believe that it is  
2 important to obtain initial assessment regarding the  
3 patient's perception, self-reporting in their perception of  
4 how they are doing prior to the implant, especially if they  
5 have been wearing hearing aids, and then their assessment  
6 about how they are doing after the implant, for comparison.  
7 The patient's perception I think is important.

8           DR. PATOW: Thank you.

9           Dr. Kileny?

10          DR. KILENY: Thank you. I just want to mention  
11 briefly two issues, one that has been already mentioned. We  
12 need to have some documentation on the durability and  
13 integrity of the device over time, and that needs to be done  
14 on a preclinical basis.

15                 And then the other issue is, certainly for the  
16 devices which involve direct coupling to the ossicular  
17 chain, there should be some documentation of effects of  
18 surgical variability or surgical variation of the exact  
19 coupling. There could be slightly different angles of  
20 coupling of the driver, in the case of devices that require  
21 some kind of a depression to accommodate the driver with  
22 different depth, just to determine whether that will make  
23 any significant difference in the operating characteristics  
24 of the device. And, again, this is another preclinical  
25 issue.

1 DR. PATOW: Thank you.

2 Dr. Shelton?

3 DR. SHELTON: When you get at the end of the line,  
4 it is hard to come up with anything original.

5 The issues that I would be concerned about, as  
6 many other people have said, the first one is the stability  
7 of the ossicular attachment, to have follow-up adequate to  
8 make sure that attachment has long term stability.

9 I would want to make sure that there is human  
10 temporal bone studies to make sure that the output of the  
11 device is within safe limits for sensorineural loss, not to  
12 induce any more sensorineural loss.

13 I would want to compare this device to best aided  
14 air conduction hearing.

15 I think that the idea of training the surgeons to  
16 put in the device is a good idea.

17 And then, finally, I am not worried about MRI  
18 compatibility. I think it is desirable but not necessary.  
19 And I am not worried about battery changes, either, as long  
20 as they can be accomplished without displacing the active  
21 part of the device.

22 DR. PATOW: Thank you.

23 Dr. Sininger?

24 DR. SININGER: Yvonne Sininger. Again, I am not  
25 going to mention much about safety. I think that has been

1 covered very, very well. More about efficacy. First, I  
2 would like to make certain that we see some preclinical  
3 specification measurements in temporal bones of  
4 amplification characteristics, including distortion and the  
5 potential gain of the device.

6 And then in patients themselves I would like to  
7 see some characterization of the audibility of both speech  
8 stimuli and pure tone stimuli across a broad range of  
9 frequencies, and these measures I would like to see compared  
10 to unaided as well as optimized aided, not necessarily  
11 binaural optimized aided. One thing we didn't mention is,  
12 some patients don't do well with two hearing aids.

13 And so to whatever their optimal performance is,  
14 monaural or binaural, with conventional best fit hearing  
15 aids, so to compare the audibility of the stimuli, and also  
16 to compare in all those conditions some speech  
17 intelligibility functions for single words and speech  
18 intelligibility in noise, and finally to include, both pre  
19 and post, some subjective benefit measure, something like  
20 the APHAB measure.

21 DR. PATOW: Thank you. I would like to, as Chair,  
22 thank all of you who have had the patience to sit through  
23 what has been a rather long marathon session, but I think  
24 which has been very, very valuable to the panel members in  
25 learning about these new technologies, and to the FDA.

1 I would personally like to thank the FDA staff,  
2 Harry Sauberman and his staff, for the tremendous amount of  
3 work that they put in preparing and coordinating this  
4 meeting, and also thank each one of the panel members for  
5 coming here today to participate.

6 The information that was gathered today will be  
7 very helpful to us as panel members when we get PMAs, and I  
8 think this is excellent background material. I want to  
9 thank all the industry representatives who are here, and  
10 especially those who presented, and especially the fact that  
11 they stayed on time. It was extremely helpful.

12 Industry will have an opportunity to review the  
13 guidance document as it is developed, and so this is not the  
14 last chance that you will have for input.

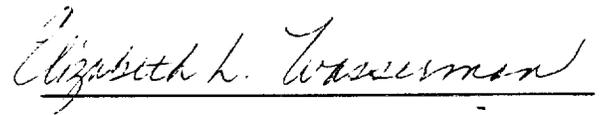
15 We do have a closed session that begins at 4:30.  
16 That is seven minutes ago. So if I could ask you to clear  
17 this room quickly, and we will begin our closed session, and  
18 thank you so much. Have a safe trip home.

19 [Whereupon, at 4:38 p.m., the panel recessed, to  
20 reconvene in closed session.]

21

**C E R T I F I C A T E**

I, **ELIZABETH L. WASSERMAN**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in cursive script, reading "Elizabeth L. Wasserman", is written over a horizontal line.

**ELIZABETH L. WASSERMAN**