

FOOD AND DRUG ADMINISTRATION

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MEDICAL DEVICES ADVISORY COMMITTEE

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EAR, NOSE AND THROAT DEVICES PANEL

MEETING

+ + + + +

THURSDAY

JULY 20, 2000

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This transcript has not been edited and FDA makes no representation regarding its accuracy

The Panel met at 9:45 a.m., in the Goshen Room of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, Dr. Carl A. Patow, Chair, presiding.

PRESENT:

- CARL A. PATOW, M.D. Chair
- WILLIAM H. DUFFELL, JR. PhD Temporary Voting Member
- HOWARD W. FRANCIS, M.D. Temporary Voting Member
- A. JULIANNA GULYA, M.D. Temporary Voting Member
- LINDA J. HOOD, PhD Temporary Voting Member
- ANJUM KAHN, M.D. Voting Member
- PAUL R. KILENY, PhD Voting Member
- ROSS J. ROESER, PhD Temporary Voting Member
- GAYLE E. WOODSON, M.D. Voting Member
- SARA M. THORNTON Executive Secretary

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## I-N-D-E-X

	<u>Page</u>
Introductory Remarks, Conflict of Interest Statement, Temporary Voting Appointments Sara M. Thornton, Executive Secretary	5
Open Public Hearing Session	14
Open Committee Discussion Session Carl A. Patow, M.D., Chair	34
Division Update Nancy C. Brogdon, Acting Director Division of Ophthalmic and ENT Devices	34
Branch Update Morris Waxler, Ph.d. Acting Chief, ENT Devices Branch	38
Sponsor Presentation R. Michael Crompton, Deborah Arthur, Thomas J. Balkany, David M. Fabry	39
Panel Questions For the Sponsor	78
FDA Presentation Morris Waxler, I. Sidney Jaffee, Teri M. Cygnarowicz	106
Panel Questions for FDA	124
Additional Comments From the Sponsor	126
Committee Deliberations: Panel Reviewers A. Julianna Gulya, MD, Ross J. Roeser, PhD	136
Committee Discussion	141
Open Public Hearing Session	224
FDA: Closing Comments	226

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I-N-D-E-X (continued)

	<u>Page</u>
Sponsor: Closing Comments . . . . .	229
Panel Recommendation Taken by Vote . . . . .	231
Concluding Remarks . . . . .	258

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## P-R-O-C-E-E-D-I-N-G-S

(9:51 a.m.)

CHAIRMAN PATOW: Good morning, and welcome. My name is Carl Patow. I'd like to call to order this meeting of the Food and Drug Administration Ear, Nose and Throat Devices Panel on July 20, 2000.

I would like to particularly welcome all the members of the panel and from industry and also the FDA. I know that there has been a tremendous amount of work that has gone into preparation for this meeting, and I hope that we will find it an efficient process for looking at this data regarding the Vibrant Soundbridge.

If I could now introduce Sara Thornton, the Executive Secretary, for introductory remarks.

MS. THORNTON: Good morning, and welcome on the first day of the Ear, Nose and Throat Devices Panel Meeting. I am Sara Thornton, the Executive Secretary.

Before we proceed with today's agenda, I have a few short announcements to make. I would like to remind everyone here, panel, public, staff, to sign

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1 in on the attendance sheet in the registration area  
2 just outside the meeting room.

3 All handouts for today's meeting are  
4 available for you at the registration table. Messages  
5 for panel members, FDA participants, information or  
6 special needs should be directed to Ms. Anne Marie  
7 Williams who is in the back of the room over there,  
8 and Ms. Carol Coy who is outside the registration  
9 table. If you need an assistive listening device,  
10 please see Ms. Williams or Ms. Coy outside.

11 Phone number for calls to the meeting  
12 area: 301-948-8900. I would like the panel and FDA  
13 to know that there is a reserved area for lunch in the  
14 back of the restaurant immediately to your left as you  
15 go out the door.

16 In consideration of the panel, the sponsor  
17 and the agency, we ask that those of you with  
18 cellphones and pagers either turn them off or put them  
19 on vibration mode while in this room. This is very  
20 important. If there is any kind of distraction for  
21 the panel, you will be asked to take your phone and  
22 yourself out into the hall.

1                   Lastly, will all meeting participants  
2 speak into the microphone and give your name clearly  
3 so that the transcriber will have an accurate  
4 recording of your comments.

5                   Now at this time before I ask the panel to  
6 introduce themselves, I'd like to extend a special  
7 welcome and introduce to the public the panel and the  
8 FDA staff to panel consultants who are with us today  
9 for the first time.

10                  Dr. Howard Francis on my right is an  
11 Assistant Professor with the Division of Neurotology  
12 and Skull Base Surgery, Department of Otology, Head  
13 and Neck Surgery at the Johns Hopkins University  
14 School of Medicine in Baltimore.

15                  Dr. Linda Hood on my left is a Professor  
16 at the Kresge Hearing Research Laboratory of the  
17 South, Department or Otorhinolaryngology, Louisiana  
18 State University Health Science Center in New Orleans,  
19 Louisiana.

20                  Dr. Catalina Garcia, who is our consumer  
21 rep, who I would like to introduce to you today has  
22 not arrived at the meeting, unfortunately. But I will

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1 welcome her when she comes.

2 Welcome to you both. I would now like the  
3 others at the panel table to introduce themselves,  
4 starting with Dr. Patow.

5 CHAIRMAN PATOW: My name is Carl Patow.  
6 I am the Executive Director for the health Partners  
7 Institute for Medical Education. It's a large  
8 educational enterprise nonprofit in Minneapolis  
9 responsible for residency education for physicians,  
10 nursing education, allied health education. I am also  
11 a practicing otolaryngologist and am on the clinical  
12 faculty at the University of Minnesota.

13 DR. KHAN: I'm Anjum Khan. I am one of  
14 the local otolaryngologists practicing in Silver  
15 Spring, Maryland. I am involved in teaching of the  
16 residents of the George Washington University and hold  
17 an appointment at the Uniform Services Health Sciences  
18 as an Associate Professor.

19 DR. GULYA: I'm Julie Gulya. I am a  
20 clinical professor of otolaryngology specializing in  
21 otology, neurotology skull base surgery, and I am  
22 currently employed at the National Institute on

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1 Deafness and Other Communication Disorders as Director  
2 of the Clinical Trials Program.

3 DR. DUFFELL: I'm Bill Duffell. I'm the  
4 industry representative. I am also the Officer and  
5 Vice President in Charge of Regulatory Affairs and  
6 Clinical Research for Cyberonics in Houston, Texas,  
7 and will be holding a similar position starting August  
8 1 with Gambro Company in Denver, Colorado.

9 DR. KILENY: I'm Paul Kileny. I'm a  
10 professor of otolaryngology at the University of  
11 Michigan Medical School and the Director of the  
12 Division of Audiology at the University of Michigan  
13 Health System.

14 DR. WOODSON: I'm Gayle Woodson. I'm  
15 professor of Otolaryngology at the University of  
16 Tennessee Memphis School of Medicine. I'm currently  
17 a Volunteer, but as of September 1 I'll be a Gator at  
18 the University of Florida in Gainesville.

19 DR. ROESER: I'm Ross Roeser. I am a  
20 professor at the University of Texas, Dallas. I am  
21 also the Director of the Callier Center for  
22 Communication Disorders, which is a large center in

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1 Dallas, Texas, specializing in communication  
2 disorders; and I am on the clinical faculty at the  
3 University of Texas Southwestern Medical Center in the  
4 Department of Otorhinolaryngology, Head and Neck  
5 Surgery.

6 MS. THORNTON: Nancy.

7 MS. BROGDON: I am not a panel member. I  
8 am Nancy Brogdon. I'm the Acting Director of the  
9 Division of Ophthalmic and ENT Devices, and I'll be  
10 your liaison to the agency at this meeting.

11 MS. THORNTON: On behalf of the FDA, I  
12 wish to extend our sincere appreciation to the panel  
13 for the time they have taken from their busy schedules  
14 to prepare for and participate in the meeting today.

15 CHAIRMAN PATOW: I would like to just take  
16 a moment to read a charge to the panel which, I think,  
17 is quite important. This has to do with the  
18 importance of confidentiality during this process.  
19 I'd like to remind the panel that we are not to  
20 discuss any PMAs under consideration with anyone else,  
21 including the FDA staff and other panel members.

22 For our own protection, we must be very

1 cautious about the perception of bias and conflict of  
2 interest that can arise at a public meeting attended  
3 by members of industry who may be in market  
4 competition with each other. To that end, I would  
5 caution you against having extended conversations with  
6 individuals who are not on the panel, conversations  
7 that might be misinterpreted by others as  
8 demonstrating favoritism or bias.

9 Particularly in the hallways, elevators,  
10 restaurants, I would just urge the panel members to be  
11 very aware of who they are talking to and what the  
12 conversation is so that we can protect the  
13 confidentiality of these proceedings. It's very  
14 important to not only FDA but to industry and all of  
15 us.

16 MS. THORNTON: I would like to read the  
17 conflict of interest statement for today's meeting.

18 The following announcement addresses  
19 conflict of issue issues associated with this meeting  
20 and is made a part of the record to preclude even the  
21 appearance of an impropriety.

22 To determine if any conflict existed, the

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1 agency reviewed the submitted agenda and all financial  
2 interests reported by the committee participants. The  
3 conflict of interest statutes prohibit special  
4 government employees from participating in matters  
5 that could affect their or their employer's financial  
6 interests. However, the agency has determined that  
7 participation of certain members and consultants, the  
8 need for those services outweighs the potential  
9 conflict of interest involved, is in the best interest  
10 of the government.

11 A waiver has been granted for Dr. Paul R.  
12 Kileny for his interest in a firm at issue that could  
13 potentially be affected by the panel's deliberations.  
14 The waiver allows this individual to participate fully  
15 in today's deliberations. Copies of this waiver may  
16 be obtained from the agency's Freedom of Information  
17 Office, Room 12A-15 of the Parklawn Building.

18 We would like to note for the record that  
19 the agency took into consideration certain matters  
20 regarding Dr. Howard Francis. Dr. Francis reported a  
21 previous and a current related financial interest with  
22 firms at issue. However, in the absence of any

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1 personal or imputed financial interest, the agency has  
2 determined that he may participate fully in the  
3 panel's deliberations.

4 In the event that the discussions involve  
5 any other products or firms not already on the agenda  
6 for which an FDA participant has a financial interest,  
7 the participant should excuse him- or herself from  
8 such involvement, and the exclusion will be noted for  
9 the record.

10 With respect to all other participants, we  
11 ask, in the interest of fairness, that all persons  
12 making statements or presentations disclose any  
13 current or previous financial involvement with any  
14 firm whose product they may wish to comment upon.

15 I would like now to read into the record  
16 the appointment to the temporary voting status for  
17 today's meeting.

18 Pursuant to the authority granted under  
19 the Medical Devices Advisory Committee charter dated  
20 October 27, 1990, and as amended August 18, 1999, I  
21 appoint the following individuals as voting members of  
22 the Ear, Nose and Throat Devices Panel for this

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1 meeting on July 20, 2000: Howard W. Francis, M.D.; A.  
2 Julianna Gulya, M.D.; Linda J. Hood, PhD; Ross J.  
3 Roeser, PhD.

4 For the record, these individuals are  
5 special government employees and consultants to this  
6 panel or other panels under the Medical Devices  
7 Advisory Committee. They have undergone the customary  
8 conflict of interest review and have reviewed the  
9 materials to be considered at this meeting. Signed by  
10 Linda S. Kahn for Dr. David Feiger, Jr., M.D., MPH,  
11 Director for the Center for Devices and Radiological  
12 Health, dated 7/11/2000.

13 Thank you, Dr. Patow.

14 CHAIRMAN PATOW: I would like now to  
15 proceed to the open public hearing session portion of  
16 our meeting. We have had a request from three  
17 individuals to speak during this portion of the  
18 meeting.

19 Because we have so many speakers today,  
20 and it's very important that all of them be heard and  
21 that they have an opportunity to express their views,  
22 I would like to be very careful in allotting time to

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1 all our speakers today. So because we have a half-  
2 hour allotted for the open public hearing session, I  
3 would like to ask that each of the three speakers  
4 limit their time to ten minutes or less.

5 When you come to the microphone, could you  
6 please identify your affiliations and also who paid  
7 your way to the meeting today.

8 The first request we have today is from  
9 Lee Richardson, DBA, Professor of Marketing,  
10 University of Baltimore.

11 DR. RICHARDSON: My name is Lee  
12 Richardson. I'm a professor of marketing at the  
13 University of Baltimore. I appear as a consumer. My  
14 wife and I paid for the gasoline for me to drive over  
15 from Columbia to give this presentation. Not even my  
16 audiologist knows I'm here.

17 On its Website Symphonix indicated that  
18 this hearing would occur, and their Website in general  
19 is a very valuable source of information for  
20 consumers. I commend them for putting so much  
21 information out available for the public.

22 While I do have affiliations with consumer

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1 groups and other groups, I am indeed just speaking for  
2 myself. I've not even had any of those organizations  
3 look at my comments or give suggestions for it.

4 I've come to try to raise questions about  
5 the device that is before you from information  
6 available to the public; and as I say, much of that is  
7 from the Symphonix Devices, Inc. Website.

8 One issue I see as very important is how  
9 to look at the general risk and benefit of this new  
10 device. This device is a surgical implant and, just  
11 because it is surgery, it brings significant new kinds  
12 of risk into the picture of hearing devices that are  
13 not present with hearing aids as such.

14 Outpatient risks in this particular case  
15 I cannot address, but after hearing the titles of many  
16 of the people here, I'm glad to see that kind of  
17 talent is on this panel, and you can address the kinds  
18 of issues that are related to surgery that will take  
19 place, should this new device be approved by the panel  
20 and ultimately the FDA.

21 Now this surgery<sup>\*\*</sup> that will take place is  
22 in relationship to what Symphonix calls a device that

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1 can be used for people who have anywhere from mild to  
2 moderate to severe hearing loss. I think the degree  
3 of potential gain of a consumer or user from this  
4 device has to be balanced against the risk of all the  
5 procedures involved and the risks of what might happen  
6 after the procedure takes place and the implant is in  
7 place.

8 Then all of that has to be looked at in  
9 terms of what is available on the market in the form  
10 of other standard hearing aids, and there is a  
11 tremendous variety of hearing aids available that may  
12 be equal to, for many types of population groups, any  
13 of the benefits that are offered by this device.

14 I ask you to look particularly at the  
15 health benefits and the real gain in user hearing  
16 improvements. There are many convenience factors  
17 associated with hearing aids that will probably be  
18 talked about by the marketers of hearing aids as well  
19 as the marketers of this device.

20 I'm sure potentially the advertisements  
21 will be full of things that talk about the  
22 disadvantages of the wax in your ear, and I can't help

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1 but agree as a wearer of a CIC device that that is  
2 really an inconvenience, and it causes various kind of  
3 mild problems -- no infections for me, but I know that  
4 happens, too.

5           These many conveniences of not having to  
6 replace your batteries or deal with the wax world of  
7 the ear canal, I think, just have to be put aside and  
8 you take a strong look at the real health benefits and  
9 the real health risks associated with the product.

10           The company has said on its website that  
11 after implant that there are certain situations in  
12 which there may be problems for the users.  
13 Specifically, they point out that an MRI may not be  
14 performed when an implant is in place, and I think  
15 that's good of them to disclose that kind of problem,  
16 but what else is there to know? What other kinds of  
17 issues arise?

18           There are apparently some problems with  
19 the outer piece when it comes in contact with water.  
20 Of course, hearing aids aren't -- the kind I wear, can  
21 be affected by water as well, but that, too, would  
22 have to be looked into.

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1 I'm sure you have whatever evidence there  
2 is so far that has been gathered by the company and  
3 perhaps other research. In your expert opinions,  
4 there may be other questions that need to be asked,  
5 and I hope they will be satisfied. But then we have  
6 a third category of real risk for users, and that  
7 would be what might happen in the real world use of  
8 the device by thousands and potentially millions,  
9 since there are 20-some-million people with various  
10 stages of hearing problems just in the United States.

11 What kinds of head bumps will they be  
12 affected by? What other magnetic fields will they  
13 come in contact with? What kinds of sports activities  
14 should they be advised not to get into? What types of  
15 occupational hazards are there where you might bump  
16 your head or something else or be around certain kinds  
17 of equipment with a magnetic field and so forth?

18 I am not a medical person at all, and I'm  
19 only raising questions which, fortunately, you can't  
20 hold me to answer. But it seems to me, there are a  
21 lot of them, and that the clinical research that you  
22 have access to, while I think it involves several

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1 hundred people, may simply not be able to cover all  
2 the potential risks associated with the product, and  
3 particularly those risks associated with long term  
4 use.

5 There's other cautions, and give me a  
6 couple of minutes if I get close, that I think you  
7 should take into account. Because of the large number  
8 of people with hearing loss, the chances for very  
9 aggressive marketing efforts to arise to convince  
10 people that they ought to take the convenient way to  
11 dealing with their hearing loss might arise.

12 It could be perhaps something like the  
13 laser eye solutions that are so widely advertised.  
14 That would be fine if you find that the product is  
15 indeed all that good, but I think you should have in  
16 mind that the marketing stakes here are very high.

17 The market potentials are very high, and  
18 you should look down that road to see just what kind  
19 of promotion, marketing, advertising might develop,  
20 and perhaps suggest or recommend that certain measures  
21 to be taken, particularly in the early stages of the  
22 introduction or launch of the product to prevent

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1 excessive marketing, because all the data will not be  
2 in yet from long term use.

3 Perhaps the wise consumer should wait a  
4 year or two to see what the results are. I think I  
5 would also point out that you ought to look at the  
6 hearing aid dealers and the many different channels of  
7 hearing aid distribution and look at the advisability  
8 of which types of channels or marketing companies  
9 should handle advice like this.

10 There are many documented problems with  
11 certain kinds of marketing of hearing aids, and  
12 perhaps much to be learned to help you in advising the  
13 company or restricting the company in its choice of  
14 distribution and marketing methods. Thank you.

15 CHAIRMAN PATOW: Thank you for your  
16 comment. The next request has been from Jose Bedoya,  
17 President, Otologics.

18 MR. BEDOYA: Good morning, distinguished  
19 panel members, distinguished FDA staffers, colleagues  
20 in industry, and other participants.

21 My name again is Jose Bedoya, and I am the  
22 President of Otologics, and the company has sponsored

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1 this trip. I'll wait a few seconds here for Dr. Soli  
2 to connect our slides here. Maybe I could start.

3 Middle ear implants designed to stimulate  
4 directly are a brand new class of devices that offer  
5 many hopes for overcoming some of the disadvantages  
6 and limitations that conventional hearing aids have.  
7 It's a wonderful and exciting time for many of us.  
8 It's the birth of an industry. It's the creation of  
9 a new market which holds many promises. But with any  
10 new endeavor there are a lot of responsibilities and  
11 needs that must be satisfied.

12 In order to establish a new medical  
13 device, there are several things that we must do. We  
14 must establish a clear understanding of the benefits  
15 that this device can provide. We must measure and  
16 define the benefits, ensuring that they outweigh the  
17 risks and the costs that this device can provide.

18 In order to get it accepted, we must  
19 establish a level of trust and credibility with health  
20 care providers and patients. To do this is not a  
21 simple task.

22 To do this, we must compare our new device

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1 to the best alternative that patients can have. In  
2 this device we have the need for surgery and the  
3 enhanced risks in comparison to the conventional  
4 hearing aids. Consequently, a more serious,  
5 scientific methodology must be employed to make the  
6 assessment of this benefit than previously has been  
7 done with other devices for the same reason.

8 As a suggestion, we believe that we should  
9 look at the state of the art in the hearing aid  
10 industry and compare the device performance to the  
11 best available there. There are many factors that can  
12 confuse this comparison, and we need to eliminate as  
13 many variables as possible from this comparison.

14 Signal processing is one of those  
15 variables. The fitting strategy is another one, and  
16 we must take extra care that that comparison on an  
17 individual basis has been made properly. In other  
18 words, we must compare the fitting of these hearing  
19 aids.

20 When we say a state of the art hearing  
21 aid, there are tremendous variables there, because the  
22 hearing aid industry is well established. There are

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1 many advances over decades, and they will continue to  
2 have many advances. But there are some general, I  
3 think, accepted characteristics of a state of the art  
4 hearing aid, and that would be a multi-channel aid  
5 with compression, possibly a digital signal processing  
6 scheme, and maybe even multiple and directional  
7 microphones.

8 When we talk about similar signal  
9 processing, here again the hearing aid industry has  
10 strived to develop means to amplify sound for the full  
11 spectrum of the hearing impaired, from that of the  
12 mild to the severest. At first, analog peak-clipper  
13 devices became available, and they were the standard  
14 for many decades. Recently, multi-channel, digitally  
15 controlled devices with compression have become  
16 available and are helping those patients with the more  
17 severe levels of impairment.

18 We must be very careful that the patients  
19 that we are comparing to are fitted with the best  
20 devices for them, and that means selecting the proper  
21 signal processing, and for the levels of impairment  
22 that these implanted devices are treating, we believe

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1 that the proper comparison is the multi-channel,  
2 digitally controlled aid with compression.

3 The same fitting strategy: This is also  
4 very important. There are a number of theories on how  
5 to amplify sound for a particular level of impairment,  
6 and much discussion is ongoing in the field of  
7 audiology, and they keep refining these theories and  
8 strategies. So the level of gain, the prescription  
9 that is achieved must be the same when we compare both  
10 of these devices, that of the hearing aid -- that is  
11 achieved with a hearing aid and that which is achieved  
12 with the implant.

13 If we use different prescriptions,  
14 different formulas for overcoming this impairment, we  
15 are apt to create confusion in the patient. We are  
16 apt to create a situation in which the comparison is  
17 invalid.

18 So we believe that the patient should be  
19 fit to a target gain, and they should be achieving  
20 that with both the conventional hearing aid and the  
21 implant. The best measure of achieving this proper  
22 amplification is to look at the gain that has been

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1 achieved by both devices. If the gain is different,  
2 then it's a sign or documentation of the fact that the  
3 comparison was inadequate.

4 It is obvious that if a patient does not  
5 hear at the same level, their stimulus would be  
6 different. Their preference of a device will be  
7 different, and their ability to distinguish speech  
8 will be different. So much care has to be placed on  
9 looking at how this comparison was made.

10 In summary, it is critical that we make  
11 this proper assessment, and this proper assessment  
12 should include a state of the art aid, a new multi-  
13 channel aid with compression. It should use the same  
14 fitting strategy, and the fit of the device must be  
15 proper.

16 In conclusion, this is again the birth of  
17 an industry, and there's great responsibility on all  
18 participants, whether it's industry, whether it's FDA,  
19 whether it's the thought leaders in the field. Your  
20 colleagues' patients, and our fellow neighbors who are  
21 impaired are going to look toward us as a group to  
22 bring forth a device that is safe and effective, and

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1 you as panel members and FDA are going to sanction  
2 that safety and effectiveness.

3 If we are going to grow as an industry, it  
4 is essential that this be done very carefully. Thank  
5 you.

6 CHAIRMAN PATOW: Thank you for your  
7 comments. Our final request is from Sigfrid Soli,  
8 PhD, Vice President, Technology Transfer and head of  
9 Human Communication Science and Devices Department at  
10 the House Ear Institute. Dr. Soli.

11 DR. SOLI: Thank you very much. In the  
12 spirit of disclosure, I should inform you that our  
13 laboratory at House is conducting clinical trials and  
14 research under contract with Otologics, and the travel  
15 to this meeting was supported by that contract.

16 As Dr. Patow said, I am at the House Ear  
17 Institute. I am a researcher in hearing aids, and  
18 over the last almost 17 years I have worked on the  
19 development and evaluation and testing of technologies  
20 in cochlear implants, hearing aids, and most recently,  
21 implantable hearing aids.

22 I have also spent a lot of time thinking

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1 about and trying to address issues related to the  
2 design of appropriate outcome measures for evaluating  
3 these devices, and also the selection or  
4 identification of patients who might be candidates for  
5 these devices. I would like to share with you today  
6 some of my thoughts in regard to that.

7 I'd like to address really three separate  
8 issues. The first has to do with the issue of output  
9 power and gain. A middle ear implant is similar in  
10 some respects to an air conduction acoustic hearing  
11 aid. We know from many, many years of research from  
12 throughout the world that probably the most important  
13 factor that tells you about the potential benefit of  
14 a hearing aid device is whether it amplifies sounds  
15 appropriately to compensate for the individual's  
16 hearing loss.

17 So the issue I would like to try to focus  
18 on this morning is does the middle ear implant provide  
19 adequate output power and gain to meet amplification  
20 needs, and how we might think about and address that  
21 issue in selecting patients.

22 Second, I'd like to discuss briefly some

1 techniques and instrumentations that may be useful for  
2 verifying that the amplification needs are met.  
3 Again, from the hearing aid world we know that there  
4 are clinical tools and instruments that can be used to  
5 determine the output levels of the hearing aid and to  
6 verify through electro-acoustic or psychophysical  
7 measurements that those output levels are appropriate  
8 for the hearing needs of the individual.

9 I think it's appropriate to look for  
10 similar types of techniques and instrumentation in  
11 dealing with middle ear implants as well.

12 Finally, the third issue is can candidates  
13 be selected to ensure that amplification needs will be  
14 met with a middle ear implant? That really draws  
15 together the other two.

16 So let's begin briefly with looking at the  
17 output power. I don't know if this will project on  
18 the board, but this little cartoon drawing here is  
19 meant to show a human ear with a generic middle ear  
20 implant in place. The point I want to make here is  
21 that stimulation reaches the inner ear to produce  
22 hearing between threshold and UCL or upper comfort

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1 level, their uncomfortable level, either via sound  
2 path or via the middle ear implant path.

3 When an air conduction hearing aid is  
4 placed in the ear, of course, we amplify the sound,  
5 reaching the inner ear to produce hearing between  
6 threshold and UCL. The middle ear implant must do the  
7 same thing via different means. Via vibration of the  
8 ossicles it must produce sensations that are at the  
9 patient's threshold and above the noise floor of the  
10 device, and it must produce output levels that reach  
11 the patient's UCLs at or below the maximum output of  
12 the system, and it must do this over an acceptably  
13 wide frequency range.

14 These same criteria are applied to hearing  
15 aids in the selection and fitting of hearing aids, and  
16 I would encourage you to consider that such criteria  
17 can also be applied to the selection and fitting of  
18 middle ear implant devices.

19 Okay. Second point I want to talk about  
20 is techniques and instrumentation. In the fitting of  
21 hearing aids, as you may know, there are instruments  
22 that are called real air systems and hearing aid

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1 acoustic test boxes that can be used to measure the  
2 sound levels reaching the ear and the sound output of  
3 the hearing aid to ensure that the hearing aid  
4 produces levels that are appropriate to the hearing  
5 needs of the individual.

6 I would suggest that the same should be an  
7 objective in the fitting of middle ear implants to  
8 patients. I've drawn again a simple cartoon drawing  
9 of what such a system might look like with an  
10 audiometer. Rather than using headphones, as you  
11 would test for acoustic hearing, you use a transmitter  
12 system that provides an output signal that is  
13 delivered to the external coil of the middle ear  
14 implant. That signal is transmitted to the implant,  
15 and can be used to test the patient's hearing in the  
16 same way that an audiometer with a headphone might be  
17 used with air conducted sound.

18 These types of instruments and the  
19 metrology or measurement procedures are well  
20 established and used to verify the amplification needs  
21 for hearing aid patients, and I would argue that  
22 similar instrumentation should be used to achieve the

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1 same level of fitting and comfort for middle ear  
2 implant patients.

3 These systems have been around and in use  
4 for cochlear implants and auditory brain stem  
5 implants for some time as well.

6 Finally, how does this bear on patient  
7 selection? I've drawn on the top of this slide a sort  
8 of a number of blocks here that summarize the steps in  
9 processing between sound reaching the microphone of a  
10 middle ear implant and the occurrence of hearing  
11 that's caused by the stimulation of the middle ear  
12 implant.

13 The sound goes through the microphone,  
14 the external processor, the transmitter. The transmit  
15 signals through the skin. It covers a transmission  
16 path to an implanted receiver. Then there are implant  
17 electronics, the stimulator that makes contact with  
18 the middle ear via some means of coupling.

19 These two blocks in the process here are  
20 unique to each individual patient, the transmission  
21 path and the method of coupling. They affect the  
22 output power and the gain that the device can produce,

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1 and it is for that reason that one would expect that  
2 there would be variability in the extent to which a  
3 middle ear implant can achieve the amplification needs  
4 of a patient.

5 That's why I would encourage the use of  
6 metrology and instrumentation of the type I showed you  
7 on the previous slide. It's also possible to use  
8 measurements on middle ear implant patients from  
9 clinical trials to make predictions about the range of  
10 coupling and transmission path effects that are seen  
11 in the patient population, and you factor that into  
12 the patient selection criteria. I think that's very  
13 important.

14 So my last point is that it's appropriate  
15 to derive selection criteria based on empirical  
16 measurements that characterize this path during a  
17 clinical trial, and that can be used to select  
18 patients appropriately for future implantation.

19 So let me summarize by just reading three  
20 comments that are listed on this slide.

21 Patient selection for middle ear implant  
22 devices should be based on empirical information about

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1 the middle ear implant's output power and gain, using  
2 procedures similar to those for hearing aids and  
3 cochlear implants that are already well established.

4 Variability in the transmission and  
5 coupling between the external and implanted system  
6 must be taken into account as well. These steps, if  
7 they are followed, will assure that the maximum device  
8 benefit is obtained for patients who receive this  
9 implant. Thank you very much for your time.

10 CHAIRMAN PATOW: Thank you for your  
11 comments. I appreciate the fact that each of the  
12 speakers stayed on time. It's very helpful, and that  
13 they gave us their valuable opinions.

14 At this point we will begin the open  
15 committee discussion session. I would like to  
16 introduce Nancy Brogdon, Acting Director of the  
17 Division of Ophthalmic and Ear, Nose and Throat  
18 Devices, who will present a Division update.

19 MS. BROGDON: Good morning. I have  
20 several items that I want to mention to you this  
21 morning. First of all, I would like to let you know  
22 that our Division Director, Dr. Ralph Rosenthal, is

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1 working temporarily in our Center Director's office on  
2 issues related to the Health Care Financing  
3 Administration. He will be out for several months,  
4 and that's why I'm sitting here at the table today.

5 Secondly, I'd like to introduce our new  
6 office director, Dr. Bernard Statland. Dr. Statland  
7 just arrived this week, and he is getting baptism by  
8 fire. He attended a two-day industry meeting, and he  
9 is attending our panel meeting today and another panel  
10 meeting being held at the same time here.

11 Dr. Statland received his M.D. degree and  
12 his PhD in biochemistry from University of Minnesota.  
13 He did residencies at the University of Copenhagen and  
14 University of Minnesota hospitals. He also served in  
15 the Public Health Service, both in New Orleans and at  
16 the NIH Clinical Center.

17 Dr. Statland is a clinical pathologist.  
18 He has held a number of positions in his career, one  
19 of the most recent being the Medical Director and CEO  
20 of the laboratories at the North Shore Long Island  
21 Jewish Health System, and he has run his own  
22 consulting company. He has many publications in

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1 several fields of interest, and we are very happy to  
2 have him as our new office director.

3 The next item I'd like to mention is Mr.  
4 Harry Sauberman, who is the Chief of our ENT Branch,  
5 is working in the Office of Device Evaluation on  
6 special projects, among them partnering with Canada  
7 and other governments.

8 In the meantime, Dr. Morris Waxler is the  
9 Acting Chief of the ENT Branch. Dr. Waxler's  
10 experience as a branch chief in our division and as a  
11 neuropsychologist make him very well suited to be the  
12 Acting Branch Chief, and we are pleased that he agreed  
13 to step into this position.

14 Next I'd like to introduce a new reviewer  
15 in the ENT Branch, Dr. James Kane. Dr. Kane is an  
16 audiologist. He has his Bachelor's degree in speech  
17 and hearing science from California University of  
18 Pennsylvania. He has his Master's and PhD in  
19 audiology from the University of Pittsburgh, and he  
20 did a post doc at the University of Pittsburgh Medical  
21 School. \*\*

22 He has practiced for 22 years, both

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1 privately and in the Veterans Administration, and he  
2 has held a number of supervisory positions. Jim is a  
3 Fellow of the American Academy of Audiology. We are  
4 very pleased to have him in the Division.

5 The last item is the fact that we have  
6 three ENT panel members who will be finishing their  
7 four-year terms, mainly in October of this year, I  
8 believe. Those three are Dr. Woodson, Dr. Duffell and  
9 Dr. Shelton. We have for each of them a letter from  
10 our Commissioner of Food and Drugs, Dr. Jane Henney,  
11 and the letters read as follows:

12 "I would like to express my deepest  
13 appreciation for your efforts and guidance during your  
14 term as a member of the Ear, Nose and Throat Devices  
15 Panel of the Medial Devices Advisory Committee. The  
16 success of this committee's work reinforces our  
17 conviction that responsible regulation of consumer  
18 products depends greatly on the participation and  
19 advice of the nongovernmental health community.

20 "In recognition of your distinguished  
21 service to the Food and Drug Administration, I am  
22 pleased to present you with the enclosed certificate."

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1 We have these certificates and letters for  
2 both Dr. Woodson and Dr. Duffell. That's all the  
3 announcements I have. Thank you.

4 CHAIRMAN PATOW: Thank you. Harry  
5 Sauberman called me the other day and just wanted to  
6 wish the members of the panel with whom he had worked  
7 over the past years the very best, and wished them  
8 also a successful session over the next two days. So  
9 just to pass on his greetings.

10 I would like to now introduce Morris  
11 Waxler, PhD, for the Branch update. He is the Acting  
12 Chief of the Ear, Nose and Throat Devices Branch.

13 DR. WAXLER: Good morning. I'll be brief.  
14 Basically, what I would like to do is introduce the  
15 staff. Some have already been introduced.

16 I'd like to introduce Karen Baker, R.N.  
17 She is a scientific reviewer in our branch. Teri  
18 Cygnarowicz, who is M.A., CCC-A, F-AAA, a scientific  
19 reviewer, audiologist and great all-around person.

20 Sidney Jaffee who is our medical officer;  
21 James Kane who you have already met; Vasant Malshet,  
22 Dr. Malshet, who is a scientific reviewer and

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1 toxicologist; and Dr. Alfred Montgomery, our senior  
2 regulatory reviewer.

3 In addition, we have from time to time  
4 lead reviews from other components of CBRH, including  
5 Dr. Brian Beard and Dr. Bill Regnault and others, Dr.  
6 Victor Krauthamer. You will see a list later during  
7 the proceedings of some others who participate.

8 In addition, we have the pleasure today of  
9 having Dr. Fred Lapner and Dr. Delian Wang here as our  
10 partners from Canada and here as observers, and we're  
11 delighted to meet them and enjoying continuing our  
12 partnership with them.

13 That will be my comments. Thank you.

14 CHAIRMAN PATOW: Thank you very much. At  
15 this point we will begin the sponsor presentation for  
16 PMA P990052. I understand that there will be four  
17 speakers from Symphonix, and I would ask that they  
18 each introduce themselves as they speak.

19 The sponsor presentations will last an  
20 hour, and so at about twenty of, an hour from now, we  
21 hope to conclude the sponsor's presentation.

22 DR. CROMPTON: Good morning, Mr. Chairman,

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1 Madam Secretary, members of the Ear, Nose and Throat  
2 Devices Advisory Panel. My name is Mike Crompton. I  
3 am the Vice President of Regulatory Affairs and  
4 Quality Assurance at Symphonix.

5 First of all, I'd like to thank FDA for  
6 all its efforts in arranging today's meeting to review  
7 the data supporting the safety and effectiveness of  
8 the Vibrant Soundbridge. We look forward to  
9 presenting this information to the panel to assist it  
10 in its deliberations today.

11 We are fortunate to have an experienced  
12 and knowledgeable group of individuals to join us in  
13 our presentation. I've got them listed there on the  
14 agenda. First, Dr. Thomas Balkany will review the  
15 surgical procedure used to implant the Soundbridge and  
16 then will review the safety profile of the device.  
17 Dr. Balkany is professor and chair of the Department  
18 of Otolaryngology/Head and Neck Surgery at the  
19 University of Miami, and he served as one of the  
20 principal investigators for the IDE study.

21 Next Ms. Deborah Arthur will describe the  
22 study design and patient demographics, and then

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1 Deborah is going to summarize the proposed labeling  
2 claims for the device. Ms. Arthur is an audiologist.  
3 She is the Vice President of Clinical Affairs at  
4 Symphonix, and she is responsible for all the clinical  
5 studies for the Vibrant Soundbridge.

6 Our formal remarks will conclude with Dr.  
7 David Fabry who will offer an audiologic perspective  
8 on the Vibrant Soundbridge as an alternate treatment  
9 option for patients with moderate to severe  
10 sensorineural hearing loss. Dr. Fabry is Director of  
11 Audiology at the Mayo Clinic, and he serves as a  
12 member of Symphonix's Audiology Advisory Board.

13 Now all of our speakers will be pleased to  
14 entertain questions from the panel, but again, in the  
15 interest of time, we do request that you hold your  
16 questions until our formal presentation is done.

17 Symphonix was founded in 1994 as a hearing  
18 management company to develop a direct-drive,  
19 implantable middle ear hearing device. We have ISO-  
20 certified facilities in San Jose, California, and also  
21 in Basel, Switzerland. We were the first company to  
22 gain CE mark authorization for an implantable system

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1 to treat sensorineural hearing loss.

2 As part of our PMA process, the company's  
3 facilities and quality system were audited by FDA, and  
4 we did successfully pass the preapproval inspection.

5 Today Symphonix will be seeking the  
6 panel's recommendation for approval of two version of  
7 the Vibrant Soundbridge. The first is the Vibrant P  
8 Soundbridge. It consists of the components that are  
9 listed here. The Vibrant P Soundbridge contains an  
10 analog system for signal processing.

11 The second is the Vibrant D Soundbridge,  
12 and it consists of the components that are shown here.  
13 The Vibrant D Soundbridge contains a digital system  
14 for signal processing. Now both the Vibrant P and the  
15 Vibrant D Soundbridge use the same Model 502 implant.  
16 That is, the two systems are identical except for the  
17 type of signal processor and the programmers that are  
18 used by the audiologists to fit the devices.

19 The Vibrant Soundbridge has two main  
20 parts. The external portion is called the Audio  
21 Processor. It contains a microphone that picks up the  
22 acoustic signal, processes it, and then transfers it

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1 to the implant. The implanted prosthesis, which is  
2 called the VORP, receives the signal and mechanically  
3 vibrates the ossicles of the middle ear.

4 The VORP, shown here, has dimensions that  
5 are roughly equivalent to that of a cochlear implant.  
6 The Floating Mass Transducer, or FMT, is a small  
7 electromagnet that is attached to the long process of  
8 the incus, using that titanium attachment there. The  
9 FMT directly drives the ossicles in response to the  
10 acoustic information that is processed by the system.

11 The analog Audio Processor P is a two-  
12 channel device. It is programmed by the audiologist.  
13 The digital Audio Processor D is a three-channel  
14 device that affords the audiologist additional  
15 programming options.

16 Today Symphonix will be summarizing the  
17 data contained in PMA P990052. It supports the safety  
18 and effectiveness of the Vibrant Soundbridge Systems  
19 for the following Indications for Use Statement.  
20 Specifically, the Vibrant Soundbridge is intended for  
21 use in adults, 18 years of age or older, who have a  
22 moderate to severe sensorineural hearing loss and

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1 desire an alternative to an acoustic hearing aid.

2 Now I would like to introduce our first  
3 presenter, Dr. Thomas Balkany.

4 CHAIRMAN PATOW: If we could break just  
5 here for one minute to distribute the informational  
6 packets to the panel. Thank you very much.

7 DR. BALKANY: My name is Tom Balkany. I'm  
8 from the University of Miami, Florida. I'm an  
9 otolaryngologist and otologist, and I've been asked to  
10 talk about the surgery to implant this device.

11 I've had some experience with that as a  
12 co-investigator during this study. I have also been  
13 asked to talk about the safety profile, and I've had  
14 a chance to go over this data, and I'll make some  
15 comments about that as well.

16 The basic thing that I want to do in my  
17 talk is to compare this to two surgical procedures  
18 which otologists commonly perform. It's my feeling  
19 that the surgery is very similar to those procedures  
20 and that the safety profile of that operation is very  
21 similar to the safety profiles of those two procedures  
22 as well. Next slide, please.

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1           The two procedures that I'm referring to  
2           are cochlear implantation in which a device is  
3           implanted into the mastoid cavity in the bone behind  
4           the ear, and a stapedectomy in which a prosthetic  
5           device is attached to the long process of the incus.  
6           Next slide, please.

7           You've seen this slide before, but  
8           basically it's very similar to a cross-sectional  
9           artist's interpretation of cochlear implant. We have  
10          an external component and the implanted receiver  
11          component here. Next slide, please.

12          The difference is that at the end of the  
13          device, instead of an electrode going into the  
14          cochlea, we have a prosthesis -- next slide -- which  
15          is made to attach to the incus right here. Next  
16          slide, please.

17          Here we have an implant slide showing the  
18          opposite where an electrode goes into the cochlea.  
19          Next slide, please. The surgery begins with a skin  
20          incision and skin flap, and here we can see some  
21          pictures that were taken<sup>\*\*</sup> of a procedure that I had  
22          done several years ago. This is the incision made

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1 behind the penna. We can see the incision is very  
2 similar for the Soundbridge. Next slide, please.

3 The next step of the procedure is to drill  
4 a seat for the implanted portion and a short trough  
5 which leads the cable down into the mastoid cavity.  
6 We also have small holes in the skull for a tie-down  
7 suture, as you can see here, and schematically you can  
8 see how similar that is to the Soundbridge procedure.  
9 Next slide, please.

10 Here we can see one type of cochlear  
11 implant tie-down in that seat with its cable running  
12 into the mastoid cavity, and this is the Soundbridge  
13 schematically tied down into its seat with a cable  
14 running down into the mastoid cavity as well. Next  
15 slide, please.

16 At this point the procedures differ, and  
17 implanting the Soundbridge is more similar to a  
18 stapedectomy operation. In the stapedectomy operation  
19 a prosthesis is attached to the long process of the  
20 incus. This is something which is done far more  
21 commonly than cochlear implants, and is done for  
22 conductive hearing loss.

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1           The Soundbridge, similarly, is attached to  
2           the incus to deliver sound vibrations at that point.  
3           The difference between these two is very obvious in  
4           that in the stapes operation and the stapedectomy  
5           operation the stapes bone itself is partially removed;  
6           whereas, in the Soundbridge operation the entire  
7           ossicular chain, the three smallest bones in the body,  
8           the malleus, incus and stapes, are all left intact.  
9           So none of the bones are removed, and hearing is  
10          designed to remain the same after the operation  
11          without the Soundbridge turned on as it is before the  
12          operation. Next slide, please.

13                 This is a closer picture of the prosthesis  
14                 attached to the long process of the incus right here,  
15                 looking through the facial recess. Here we can see  
16                 the stapedius tendon and a portion of the stapes  
17                 remaining in its normal position. Next slide, please.

18                 This is what the device looks like, the  
19                 external portion of the device looks like when it's  
20                 turned on. Next.

21                 I'd like to <sup>\*\*</sup>switch gears for a second and  
22                 just talk about the safety profile of the device.

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1 Again, just to lead into that, the safety profile is  
2 very similar to those other two procedures. Next  
3 slide, please.

4 This is data collected by the company on  
5 all devices put in with n of 351. The adverse events  
6 are listed here, and this represents all of the  
7 adverse events which had been reported by people  
8 around the world.

9 The fullness sensation has been reported  
10 by 6.8 percent of people, and this is just a sense  
11 which is often hard for patients to describe, but  
12 fullness is the closest word they have to it. I have  
13 one patient with this that I can tell you about. He  
14 is an orthodontist, and he said he has a sensation  
15 which is not really bothersome, but he wanted to let  
16 me know that the ear almost feels like it's full.

17 Transient pain was reported by 4.8 percent  
18 of the patients, altered taste sensation in 2.3  
19 percent, clinically significant change in residual  
20 hearing at 1.7 percent, flap complications in 1.4  
21 percent, and the rest are quite small, skin  
22 irritation. Facial nerve problems is important. It

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1 occurred in 0.6 percent of the patients, and transient  
2 post-operative dizziness occurred in 0.6 percent.

3 Next slide, please.

4 Other adverse events of very low incidence  
5 are increased tinnitus, infection, disconnection of  
6 the prosthesis from the incus, wound hematoma or a  
7 collection of blood under the skin flap, transient  
8 intermittent signal, and a constant noise in the ear  
9 were each present in 0.3 percent of the patients.

10 Next slide, please.

11 Next we'll talk about the U.S. study  
12 separate from the European and South American  
13 components of the study, and this is a report on 81  
14 subjects. So n = 81 on each of these slides. We  
15 divided the adverse events into those which generally  
16 in the field are considered to be major versus those  
17 which generally in the field are considered to be  
18 minor.

19 Two patients had a clinically significant  
20 change in residual hearing. That change was 12  
21 decibels in one, 18 decibels in another, and those  
22 changes -- and that is for three-time pure tone

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1 average for bone conduction. So these were  
2 sensorineural hearing losses of 12 and 18 percent  
3 measured at three months post-op.

4 Seven patients required surgical  
5 revisions. Six of those were due to device failures.  
6 All of the failures were caused by the same problem.  
7 That problem was identified and subsequently fixed,  
8 and following the change in manufacturing process  
9 there have been no device failures.

10 The final failure was caused by a  
11 disconnection of the prosthesis from the incus. It  
12 came loose, something that any prosthesis can do, and  
13 sometimes occurs with stapedectomies as well. Next  
14 slide, please.

15 These are considered minor complications  
16 in the cochlear implant literature, primarily worked  
17 at New York University by Dr. Neil Cohen. Transient  
18 post-operative facial weakness occurred in two  
19 patients.

20 In one patient the onset, I believe, was  
21 at three weeks after surgery, and the surgeon who did  
22 that procedure also noted that, besides the facial

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1 nerve, another nerve had a change in it as well, which  
2 is very typical of Bell's palsy and the diagnosis of  
3 Bell's palsy was made by that doctor. The patient was  
4 treated, and the facial nerve came back to completely  
5 normal within a short period of time.

6 The second patient also had a delayed  
7 onset of facial weakness, did not happen at the time  
8 of surgery, and again within a matter of weeks that  
9 patient's hearing returned to normal -- excuse me.  
10 That patient's facial nerve function returned to  
11 normal as well. So both of these had delayed onset,  
12 and returned to normal within a short period of time.

13 The flap complication which is presented  
14 here was a stitch abscess. Sometimes when a suture is  
15 placed, a small infection occurs around the suture  
16 with any type of surgical procedure. It's certainly  
17 not surgical procedure specific. That resolved when  
18 the suture was removed and antibiotics were used,  
19 without readmission. Antibiotics were given orally.

20 The final two patients here had post-  
21 operative dizziness. One of those was dizzy when he  
22 stood up quickly and was considered to be postural

1 dizziness, and the second patient eventually developed  
2 TIAs, transient ischemic attacks, and those both were  
3 considered not directly related to this device. Next,  
4 please.

5 This is a comparison of adverse events  
6 that occurred with the Soundbridge device and with  
7 either stapedectomy literature or with, for the second  
8 group of three, the cochlear implant literature. We  
9 can see that the hearing got worse in 1.7 percent of  
10 patients with the Soundbridge, and with cochlear  
11 implants -- excuse me, with stapedectomies, the  
12 literature demonstrates a range of worsening hearing  
13 of .6 to 5.6 percent. However, generally, figures of  
14 1 to 2 percent are considered to be the norm in terms  
15 of negative effects of stapedectomies on hearing.

16 Post-operative facial paresis occurred in  
17 .6 percent, and although the early literature showed  
18 that two percent or so of patients had some weakness  
19 after cochlear implantation, that figure now is well  
20 below one percent, very similar to the Soundbridge  
21 literature.

22 Flap complications at 1.4 percent: Early

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1 with cochlear implantation there was a higher  
2 incidence of flap complications. That rate now is  
3 down around the one percent level as well. Finally,  
4 post-operative dizziness occurred in .6 percent of the  
5 patients, which is similar to the rate that is  
6 reported by most cochlear implant patients. Next  
7 slide, please.

8 So in summary, surgically this is very  
9 similar to operations that ear surgeons routinely do,  
10 and the incidence of adverse effects are also very  
11 similar to the outcomes of other operations which we  
12 routinely do. Thank you very much.

13 MS. ARTHUR: Good morning. The clinical  
14 trial of the Vibrant Soundbridge employed the  
15 traditional single-subject, repeated measures study  
16 design in which each patient served as his or her own  
17 control. The study sample size exceeded the number  
18 required to obtain the statistical power of 0.9 for  
19 detecting treatment effects.

20 Multiple measurements were made across  
21 experimental conditions over time for each patient at  
22 the study intervals shown here. More specifically,

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1 measurements were taken on the pre- and post-operative  
2 conditions, and then compared.

3 Postoperative evaluations occurred at  
4 eight weeks post-surgery, which was called activation,  
5 and then followed at one month and three months post-  
6 activation for the 53 patients participating in the  
7 clinical study of the Vibrant P Audio Processor.

8 For the 50 patients participating in the  
9 study of the Vibrant D Audio Processor, baseline  
10 measures were taken after completing the trial with  
11 the Vibrant P, and then again after six weeks of use  
12 with the Vibrant D. Patients were then followed on a  
13 semi-annual basis.

14 Preoperatively, patients were given a  
15 complete otologic and audiologic evaluation, of which  
16 the latter included measures of air and bone  
17 conduction, immittance, aided and unaided word  
18 recognition, hearing aid analysis and performance, and  
19 self-assessment of patient satisfaction, benefit, and  
20 device preference in a variety of listening  
21 environments. \*\*

22 Methods of assessment were consistent with

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1 standard audiometric practice, and all speech  
2 recognition material was delivered via recordings in  
3 a calibrated soundfield.

4 Patients were enrolled in the clinical  
5 study under the Phase I, Phase III or Phase IIIa  
6 protocols. This slide indicates the total number of  
7 patients enrolled by phase. It's important to note  
8 that this is not cumulative, since some patients  
9 participated in more than one of the studies. As an  
10 example, those patients participating and completing  
11 the Vibrant P clinical study were then invited to  
12 participate in the clinical evaluation of the Vibrant  
13 D Audio Processor.

14 The multi-center clinical investigation  
15 was conducted at ten sites throughout the United  
16 States. All surgeons were otologists experienced in  
17 cochlear implantation as well as middle ear  
18 reconstruction. Surgeons were trained on the surgical  
19 procedure of implanting the Soundbridge. Audiologists  
20 were trained in the clinical protocol and worked with  
21 the surgeons for patient selection and conducted the  
22 post-operative patient evaluations.

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1           With respect to patient selection,  
2 patients needed to exhibit a bilateral sensorineural  
3 hearing loss, moderate to severe in nature as  
4 indicated here. Normal middle ear anatomy and  
5 function was verified by immitance measures and bone  
6 conduction. Word recognition scores were required to  
7 be better than 50 percent at the implant ear.

8           With regard to hearing aid use, patients  
9 were full time hearing aid users with 96 percent of  
10 the population full time binaural users. In  
11 conformance with the protocol, patients were  
12 monaurally implanted at the poorer ear.

13           Demographics of the study population are  
14 summarized here and indicate the study population was  
15 an experienced group of hearing aid users with a mean  
16 duration of hearing loss ten years or greater for 76  
17 percent of the population.

18           Implantation was evenly divided between  
19 the left and right ears, and patient participation was  
20 non-biased based on gender. The etiology of the  
21 hearing loss in the vast majority of the subjects, as  
22 seen here at 82 percent, was unknown, consistent with

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1 what we find in the general hearing impaired  
2 population. Additionally, the mean age at  
3 implantation was 58 years, with a range between 28 and  
4 86 years.

5 Clinically, the study patients were  
6 appropriately fit using a variety of hearing aid  
7 styles and circuits, consistent with use in the  
8 general hearing impaired population. Of interest, the  
9 mean duration of reported hearing aid use with a  
10 patient's current hearing aid or hearing aids in  
11 general was 3.2 years at the time of enrollment in the  
12 clinical study.

13 Appropriateness of hearing aid fit was  
14 verified by several measures, as indicated. They  
15 included, first, electroacoustic analysis and real-ear  
16 measures. Then they were further verified by clinical  
17 assessment, which included listening check,  
18 soundfield-aided and unaided thresholds, measures of  
19 unaided and aided word recognition, as well as patient  
20 self-reports.

21 The clinical data supports the ten claims  
22 for the Vibrant soundbridge which can be grouped into

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1 four categories. These categories are represented  
2 here under the safety and effectiveness headings.

3 The safety claim is based on the fact that  
4 there was no clinically significant change in residual  
5 hearing. The effectiveness claims for the Soundbridge  
6 are demonstrated by improved sound quality and  
7 clarity, increased functional gain, and the patient's  
8 perceived benefit in various listening conditions.

9 The claims are based on pre- to post-  
10 operative comparisons at the implant ear only, with  
11 the non-test ear occluded for all soundfield testing.  
12 Data was gathered first with the Vibrant P Audio  
13 Processor and then with the Vibrant D.

14 The claim for safety with the device is  
15 based on changes to unaided hearing thresholds. Mean,  
16 pre-operative, air conduction thresholds are shown  
17 here at the implant ear for all 53 study subjects as  
18 well as their thresholds at three months post-  
19 activation are shown. Pre-operatively, the thresholds  
20 are indicated in the blue boxes, post-operatively at  
21 the three month post-activation interval, as indicated  
22 by the green circles.

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1 Post-operative, the mean change on a  
2 frequency by frequency basis was less than 5 dB, as  
3 indicated on this audiogram. For group data with  
4 respect to a three-frequency, pure tone average, the  
5 mean change was 2.8 dB between the pre-surgical  
6 condition and the post-surgical condition.

7 For the purposes of establishing a  
8 clinically significant change in hearing, 10 dB was  
9 determined to be the most appropriate based on  
10 discussions at last year's public meeting of the ENT  
11 panel on implantable middle ear hearing devices. This  
12 is further supported by information from the standards  
13 on hearing conservation, which has established 10 dB  
14 as a clinically significant change based on a three-  
15 frequency average.

16 Patients as a group in the clinical study  
17 of the Soundbridge did not exhibit a clinically  
18 significant shift in residual hearing and, for  
19 individual patients, 96 percent of them did not  
20 demonstrate a change in pure tone average equal to or  
21 greater than 10 dB. \*\*

22 The first claim for effectiveness

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1 references improvement in sound quality and clarity.  
2 This slide addresses possible explanations for patient  
3 reports of improvement in sound quality and clarity.  
4 With the absence of an earmold or hearing aid in the  
5 ear canal, there is a resulting lack of occlusion  
6 effect and insertion loss. The open ear canal also  
7 offers ear canal resonance benefits.

8 With this particular technology, patients  
9 report an absence of acoustic feedback, which further  
10 enhances the quality and clarity of speech as well as  
11 environmental sounds.

12 Data taken from the hearing Device  
13 Satisfaction Survey, also known as the HDSS, which is  
14 ranked on a five-point scale from "very dissatisfied"  
15 to "very satisfied," reveals that, compared to their  
16 acoustic hearing aids, 86 percent of the patients with  
17 the Soundbridge expressed satisfaction in clearness of  
18 sound and tone, compared to 31 percent with their  
19 hearing aid.

20 Similar improvements were seen with regard  
21 to overall sound quality as well as the sound quality  
22 of their own voice. Of particular note, it should be

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1 seen that for the category of "very satisfied," as  
2 marked by the diagonal boxes, there was no report of  
3 "very satisfied" with the hearing aid for either  
4 clearness of sound and tone or for overall sound  
5 quality, with minimal reports in sound quality of  
6 their own voices, as compared to that seen with the  
7 Soundbridge.

8 For claim 3, patient expressions of  
9 satisfaction in fit and comfort with their  
10 amplification device were also captured on the HDSS.  
11 As seen here, patients were overwhelmingly more  
12 satisfied with the Soundbridge than with their hearing  
13 aid in fit and comfort.

14 For claim 4, the significant reduction in  
15 acoustic feedback is based upon patient self-reports  
16 of acoustic feedback with their hearing aid and then  
17 with the Soundbridge. As seen, 97 percent of those  
18 patients reporting feedback with their hearing aid  
19 indicated that there was none with the Soundbridge.

20 Based on the comments from the agency and  
21 the primary panel reviewers, Symphonix has modified  
22 the proposed language of claim 5 as shown. Symphonix

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1 agrees that it is more accurate to state that the  
2 Vibrant Soundbridge provides equal or increased  
3 functional gain as compared to the hearing aid.

4 For measures of audibility, comparison of  
5 soundfield functional gain measures showed increased  
6 functional gain across the displayed frequencies of  
7 500 through 6000 hertz. For the Vibrant P as well as  
8 the Vibrant D Audio Processors, there was a  
9 statistically significant increase between mean  
10 hearing aid and Soundbridge thresholds across the  
11 identified frequencies.

12 These measures indicated that, with the  
13 Soundbridge technology, patients are able to  
14 experience increased audibility, especially, it should  
15 be noted, in the higher frequencies. In addition,  
16 they noted improvements in sound quality and clarity,  
17 which could be captured with this increased audibility  
18 gain in the higher frequencies.

19 The fourth and final group of claims  
20 centers on patients' perceived benefit with the  
21 Soundbridge in a variety of listening conditions. The  
22 first, claim 6, is for everyday listening situations

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1 and is based on patient results on the Profile of  
2 Hearing Aid Performance, also known as the PHAP.

3 This standardized and normalized self-  
4 assessment tool is widely used in hearing aid research  
5 and was selected, because it is a more comprehensive  
6 questionnaire than its well known clinical version,  
7 the APHAB.

8 The 66 situations posed on the PHAP  
9 questionnaire are grouped into the seven subscales  
10 representing real life communication situations, as  
11 shown. Reading from left to right, we have familiar  
12 talkers, ease of communication, reverberation, reduced  
13 cues, background noise, aversiveness of sounds, and  
14 distortion of sounds.

15 Those of you familiar with the scoring for  
16 the PHAP will notice that the data is presented as  
17 situations without problems, as compared to situations  
18 with problems, the more traditional scoring method.  
19 This was done to more clearly illustrate patient  
20 perceived performance with the device.

21 The Vibrant<sup>\*\*</sup> P Soundbridge results  
22 displayed here reveal patients as a group felt that

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1 the listening situations they experienced without  
2 problems significantly increased with the Soundbridge,  
3 as compared to the hearing aid. This held true for  
4 the Vibrant D Audio Processor as well.

5 As an example, we have the subscale for  
6 background noise which shows that with the hearing  
7 aid, patients reported in 37 percent of those  
8 listening situations they did not have problems, as  
9 compared to 61 percent with the Soundbridge. A two-  
10 sided, paired t-test, as well as the nonparametric  
11 Wilcoxon sign-rank at each of the seven subscales  
12 showed significance at a "p" value of .0001.

13 Again, based on input from the agency and  
14 primary panel reviewers, Symphonix has amended the  
15 proposed language of claim 7 by specifying that the  
16 perceived benefit with the Soundbridge in challenging  
17 listening environments was reported by many patients.  
18 The use of this term, "many," is defined by the FDA in  
19 its guidance to hearing aid manufacturers and  
20 represents 51 to 75 percent. This claim is supported  
21 by data from the PHAP and the HDSS self-assessments.

22 Specific subsets of these self-assessments

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1 ask questions related to patient performance and  
2 device effectiveness in challenging listening  
3 environments represented by the background noise  
4 subscales. Group analysis of the PHAP for the  
5 background noise subscale indicated a significant  
6 increase in situations without problems with the  
7 Soundbridge as compared to their acoustic hearing  
8 aids.

9           Also of interest is the patients'  
10 perceived benefit with a direct-drive system, meaning  
11 with a Vibrant P and with a Vibrant D, as compared to  
12 their hearing aid. It didn't matter whether the  
13 circuit was analog, in the case of the Vibrant P, or  
14 digital, as in the case of the Vibrant D. The  
15 patients perceived an increased benefit with the  
16 Soundbridge in the presence of background noise.

17           Supportive data from the HDSS revealed  
18 that significantly more patients were satisfied or  
19 very satisfied, as seen here, with the effectiveness  
20 of the Soundbridge in the presence of background noise  
21 than they were with their traditional hearing aid.

22           For claim 8, the obvious absence of any

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1 part of the device in the ear canal results in a  
2 reduction of maintenance and reliability issues due to  
3 cerumen and moisture accumulation. This was  
4 supported, once again, with the high level of patient  
5 satisfaction with cleaning and maintenance of the  
6 Soundbridge.

7 A third self-assessment tool used was an  
8 outcomes measure called the Soundbridge Hearing Aid  
9 Comparison Questionnaire, also known as the SHACQ.  
10 This simple test for device preference is administered  
11 only once at the three-month post-activation interval  
12 and lists a variety of listening situations. This  
13 questionnaire was used to support claim 9 which is  
14 based on patient reports of device preference while  
15 listening to speech in various environments.

16 Word recognition tests done in controlled  
17 laboratory soundfield environments indicated  
18 equivalent performance between individuals using their  
19 hearing aid or the Soundbridge. Yet patients  
20 overwhelmingly preferred the Soundbridge in a variety  
21 of real world conditions, such as outdoors, in quiet  
22 environments, in a restaurant, while listening to

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1 television or to the radio.

2 It should be noted here there was  
3 significant difference between their preference for  
4 devices. This is further supported by other patient  
5 satisfaction and benefit measures, once again  
6 demonstrating a strong preference for the Soundbridge.

7 Finally, claim 10 is a comparison of  
8 unaided to Soundbridge-aided performance on the low  
9 predictability portion of the revised SPIN test.  
10 Ninety-two percent of the patients fit with the  
11 Soundbridge demonstrated a mean improvement of 33  
12 percent or greater in word recognition in the presence  
13 of background noise when compared to their unaided  
14 condition.

15 This may be particularly important for  
16 those patients with serious external ear conditions  
17 such as contact dermatitis or psoriasis which may  
18 interfere with or even preclude the use of traditional  
19 hearing aids.

20 In summary, Symphonix would like to thank  
21 the clinical investigators and the site audiologists  
22 whose diligence and commitment to the IDE study of the

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1 Vibrant Soundbridge resulted in all patients  
2 completing each test interval per the protocol  
3 requirements, with no patients lost to follow-up.

4           Symphonix believes that its claims for the  
5 safety and effectiveness of the Vibrant Soundbridge  
6 System are strongly supported by the data gathered  
7 during the course of the clinical trial. We believe  
8 that, for those patients who are seeking an  
9 alternative to acoustic amplification, the Vibrant  
10 Soundbridge offers them a solution to many of the  
11 problems associated with acoustic devices.

12           Concluding our formal presentation will be  
13 Dr. David Fabry.

14           DR. FABRY: Good morning. My name is  
15 David Fabry, and my employer is Mayo Clinic at  
16 Rochester, Minnesota. My participation on Symphonix  
17 Audiologic Scientific Advisory Board has been approved  
18 by my employer's Medical-Industry Relations Committee.

19           I have no further -- or no financial  
20 interest in Symphonix or in the outcome of today's  
21 proceedings. The company is reimbursing me, however,  
22 for the expenses incurred by my participation in this

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1 meeting.

2 My vantage point is that of a clinical  
3 audiologist working primarily with the assessment of  
4 hearing loss, hearing aid fitting, and oral  
5 rehabilitation with pediatric and adult patients. In  
6 addition, I have been engaged in a variety of hearing  
7 aid research, speech perception research, and signal  
8 processing studies during the past 17 years.

9 In our setting, I have worked primarily  
10 with digital and analog hearing aids on a clinical  
11 basis exclusively for about the last ten years. To  
12 that end, I will return to the indication slide shown  
13 earlier with emphasis added regarding those patients  
14 who desire an alternative to acoustic hearing aids.

15 The discussion then, I think, should focus  
16 on the key issue -- next slide -- the key issue of  
17 under what circumstances would clinicians recommend an  
18 implantable middle ear device, given all the  
19 improvements that have taken place recently in hearing  
20 aid technology? Next slide.

21 This issue, I believe, may be discussed in  
22 terms of changing demographics and in changing

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1 technology. First, world population has been  
2 increasing dramatically due to increased life  
3 expectancy and decreased infant mortality rates.  
4 Those 65 years of age and older will double over the  
5 next 30 years, and expected retirement by these  
6 individuals is anticipated to be different than their  
7 predecessors, much more active lifestyle.

8 Currently, there are 28 million persons in  
9 the United States with measurable hearing loss. Next  
10 slide, please. Looking over the last 15 years --  
11 Unfortunately, I can't see where the pointer is -- but  
12 from 1984 to 1997 the market penetration of those with  
13 measurable hearing loss who use hearing instrument  
14 devices from approximately one in four persons to  
15 current day figures of approximately one out of five  
16 people who have measurable hearing loss that are  
17 regular users of hearing aid technology.

18 Despite the fact -- next slide -- that  
19 hearing loss is seen as an older person's issue, this  
20 graph which shows age groups, different age groups and  
21 decades, along the ordinant as a function of the  
22 millions of people with measurable loss along the

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1 abscissa -- What it shows is with the green bar  
2 showing non-owners of hearing aids and the orange bars  
3 showing users or owners of hearing aids, is that the  
4 older you are, the more likely you are to wear a  
5 hearing aid if you have measurable hearing loss.

6 The important and sometimes overlooked  
7 issue is that there is a very large population of baby  
8 boomers right now, aged from mid-thirties to mid-  
9 fifties, that have measurable hearing loss but do not  
10 use conventional hearing aid technology, indicating a  
11 large number of hard of hearing persons have needs  
12 that are not met by conventional amplification. Next  
13 slide.

14 The issue then is what is it about  
15 conventional amplification strategies that do not meet  
16 expectations for hard of hearing users? If we look  
17 historically, if you will, in 1990 at this survey  
18 which was published in Hearing Journal evaluated and  
19 expressed here in decreasing order complaints of those  
20 who use -- or stopped using hearing aids for a variety  
21 of reasons, including performance in background noise,  
22 the physical fit of the device, battery life, sound

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1 quality, feedback, etcetera.

2 If we move forward five years now and look  
3 at a survey published by Sergei Kochkin in The Hearing  
4 Review in 1996, now expressing patient satisfaction by  
5 hearing aid technology, what we see now again is the  
6 shorter the bar, the less satisfied in the environment  
7 listed here, and use in noisy situations still is the  
8 most commonly cited problem with hearing aids,  
9 followed again by whistling and feedback, natural  
10 sound and sound quality.

11 The issue and the difference between the  
12 two surveys was that in 1996 Kochkin included state of  
13 the art, wide dynamic range compression devices and  
14 digitally programmable analog devices which were  
15 available at the time. Despite the time period that  
16 had passed and an evolution from largely peak-clipping  
17 hearing aids to compression and digitally programmable  
18 analog devices, the same complaints continued with  
19 conventional devices.

20 If we move forward to the next slide to  
21 today where we have digital <sup>\*\*</sup> hearing aids making an  
22 increasing component of audiologists' practice, we

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1 find that digital and digitally programmable devices  
2 have the highest return for credit rate. As most know  
3 here, hearing aids are available on a trial purchase  
4 basis where, after 30 or 60 days, the patient may  
5 return the devices to the audiologist if they are not  
6 providing them with adequate benefit.

7 So with an overall return rate of  
8 approximately 15 to 17 percent for hearing  
9 instruments, digital and digitally programmable  
10 devices are returned roughly one in four.  
11 Furthermore, even those who successfully wear hearing  
12 aids, it is estimated that up to 40 percent will wear  
13 their hearing aids in the dresser drawer at least some  
14 of the time. So we are not dealing with a population  
15 that is delighted with the technology overall.

16 In fact, I would argue that it's not so  
17 much an issue of digital or analog as to whether the  
18 device is properly fit to the patient, compensating  
19 appropriately for hearing loss and also compensating  
20 appropriately for some of the problems that are listed  
21 in the past three surveys<sup>\*\*</sup> regarding use of hearing  
22 aids, namely feedback and occlusion.

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1 that was published by Goode a number of years ago, he  
2 cited certain issues related to sound quality, reduced  
3 feedback, comfort and occlusion that are listed as  
4 significant and primary complaints with conventional  
5 technology.

6 As has been indicated, though, first and  
7 foremost and from a clinical environment, my concern  
8 is for my patients. In order to recommend a device,  
9 I need to ensure that their safety is not compromised,  
10 and a safe surgery, a reversible surgery that provides  
11 as few risks as possible is critically important to my  
12 recommendation for this technology. Next slide.

13 If we look at the results and briefly  
14 review those from the claim and from the issues that  
15 address significant concerns with conventional  
16 technology, we see improved sound quality in the  
17 present study was listed by 94 percent as improved  
18 with the Soundbridge versus their current state of the  
19 art device.

20 For feedback reduction, 97 percent of the  
21 32 patients who had complained of feedback as a  
22 notable problem when they began the study reported

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1 that the feedback was no problem and, in fact, out of  
2 the study then it is one out of 54 that complained of  
3 feedback, because the remaining subjects who didn't  
4 have feedback before did not have feedback with the  
5 Soundbridge. Next slide.

6 If we look at comfort and occlusion, again  
7 98 percent of patients reported satisfaction with the  
8 overall fit and comfort of the Vibrant Soundbridge,  
9 and 88 percent reported an improvement in their  
10 satisfaction with sound quality of their own voice,  
11 again listed as a frequent complaint.

12 From the cosmetics angle, there are 25  
13 percent more patients who are satisfied with the  
14 cosmesis of the Vibrant Soundbridge than with their  
15 pre-surgery device. Keep in mind that these were  
16 users of amplification. So they had already addressed  
17 the issue of cosmesis in hearing aids to a degree, in  
18 that most of the devices were somewhat visible with  
19 their conventional devices before the study.

20 So in conclusion, the Vibrant Soundbridge  
21 satisfies an unmet medical need. It addresses certain  
22 limitations inherent with acoustic devices. The

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1 Soundbridge increases perceived patient benefit for  
2 real world environments with equivalent performance on  
3 "objective" speech understanding and noise measures.

4 If it is assumed that successful hearing  
5 aid performance compromises both objective and  
6 subjective data using standardized, clinically  
7 accepted measures and they provide complementary  
8 information, then the patient's use or dis-use of  
9 hearing aids really represent the finally arbiter of  
10 hearing aid satisfaction.

11 In the present study of the 44 patients  
12 for which one year follow-up data exists when the PMA  
13 was submitted in May, all 44 are still wearing the  
14 device today, even though all 44 could have gone back  
15 to their conventional digital or analog technology.  
16 None of the other studies that I've been involved  
17 with, with advanced technology in hearing aids, have  
18 had such a high take-up rate after one-year time when  
19 any effects related to study participation would long  
20 since seem to have diminished.

21 Therefore, the Vibrant Soundbridge  
22 provides an alternative solution and viable solution

1 in the treatment of individuals with hearing loss.

2 CHAIRMAN PATOW: Does that end the  
3 presentation then? Thank you very much.

4 We now have an opportunity for the panel  
5 to ask questions of clarification from the sponsor.  
6 If I could have each of the members of the -- or each  
7 of the speakers for the sponsor come to the panel  
8 table in front of us, I think that will be helpful,  
9 since the microphones are available there.

10 This is an opportunity for panel members  
11 then to ask questions of clarification. Maybe you  
12 want to see a slide again or get some further  
13 information about any of the information that was  
14 provided. Are there questions from the panel?

15 MR. CROMPTON: One point. We have  
16 invited Dr. Martin Hyde -- he is our consultant  
17 biostatistician -- also to the table.

18 I do want to clarify that both Dr. Balkany  
19 and Dr. Hyde have no financial interest in the  
20 company, but they were compensated in terms of their  
21 expenses being reimbursed.

22 CHAIRMAN PATOW: Thank you. Dr. Roeser?

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1 DR. ROESER: Just a question about the  
2 device. At least one slide showed the floating mass  
3 transducer, and there was an antenna-like structure,  
4 and it wasn't shown complete. It was always chopped  
5 off. What is that, and what determines the length,  
6 and what factors -- I guess it's just an open-ended  
7 question. Is that an antenna?

8 DR. BALKANY: No. If you are referring to  
9 kind of an open loop-shape -- Maybe we could show a  
10 picture.

11 DR. ROESER: In your presentation, I think  
12 it was -- Well, it shows the floating mass transducer,  
13 and then --

14 DR. BALKANY: The one right after that,  
15 the next slide? Could you show the next one?

16 DR. ROESER: It's not a cable, is it?

17 DR. BALKANY: Could you please put up the  
18 transparency that follows this one? Is it that one,  
19 Dr. Roeser?

20 DR. ROESER: Yes.

21 DR. BALKANY: Which part of it?

22 DR. ROESER: Well, the conductor link. I

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1 guess that's what it is.

2 DR. BALKANY: Yes.

3 DR. ROESER: That's physically connected  
4 to the --

5 DR. BALKANY: Yes. Have a look at the  
6 conductor link, and then let's go to the previous one.  
7 The conductor link is that.

8 DR. ROESER: Okay. You answered my  
9 question. It's physically connected.

10 DR. BALKANY: Physically connected. There  
11 is no antenna.

12 DR. ROESER: Thank you.

13 CHAIRMAN PATOW: Dr. Woodson.

14 DR. WOODSON: Yes. Looking at this issue  
15 of the transducer being connected to the processor and  
16 so forth, I notice that there is not any mention of  
17 any problems with the stability of the device, but I  
18 do note that the implant is held in place by some  
19 stitches that are put through the bone, and there is  
20 always a chance for stitches to come loose and so  
21 forth.

22 I would think that, if one part of the

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1 device moves, it could potentially dislodge the other.  
2 Those are some of the questions that come to mind,  
3 thinking of how cochlear implants -- there has been  
4 some problems with trauma to, I think, specifically  
5 those that have fracturable cases. I don't see any  
6 mention of that being a problem. So I guess it wasn't  
7 encountered.

8 I also can't tell from the -- I'm having  
9 a hard time extracting the age range of the subjects  
10 and, therefore, probably their activity level. There  
11 are probably not many gymnasts or scuba divers or  
12 other very active people in there. I'm wondering if  
13 there is -- if you would suppose that people in that  
14 population might have a higher incidence of some kind  
15 of local complications related to the device or not.

16 DR. BALKANY: Well, I'll answer the first  
17 part of the question first, I guess. Maybe somebody  
18 else can address that second one.

19 CHAIRMAN PATOW: Excuse me just for a  
20 moment. Prior to speaking, if you could tell your  
21 name into the microphone with each time you speak, and  
22 the panel will also have to do that if I forget to

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1 introduce you by name, because otherwise the  
2 transcriptionist will have no idea who is actually  
3 talking. It's a little cumbersome, but it's what we  
4 have to do.

5 DR. BALKANY: Okay. Thank you, Dr. Patow.

6 This is Tom Balkany speaking. The device  
7 is seated in a bony recess similar to a cochlear  
8 implant. The sutures that tie it down are  
9 nonabsorbable nylon or similar material, usually a  
10 monofilament. Occasionally, when cochlear implants  
11 have been revised, those stitches are no longer  
12 holding it in place, but a very dense band of scar  
13 tissue forms. So the device -- That part of the  
14 device, moving no longer is a problem with cochlear  
15 implantation, although it was in the early stages when  
16 the devices were not seated properly.

17 The second part of the question?

18 DR. WOODSON: About risk of trauma to the  
19 device and activity range of subjects and so forth.

20 DR. BALKANY: As you said, no one in this  
21 group, which consists of people 18 years old and  
22 older, reported a problem with that device. I

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1 generally counsel my patients with cochlear implants  
2 that SCUBA diving is a dangerous sport. There are 80  
3 to 90 people a year without hearing aids or cochlear  
4 implants who die from SCUBA diving.

5 It becomes a little more dangerous if  
6 you've had any kind of ear operation done, from a  
7 mastoidectomy to a stapedectomy, and I recommend that  
8 they don't do it. However, these kind of devices may  
9 or may not withstand that, and that study hasn't been  
10 done, to the best of my knowledge.

11 MS. ARTHUR: Clinically, to add to that,  
12 on a worldwide basis -- Excuse me. Deborah Arthur.

13 To add to that, clinically on a worldwide  
14 basis we have had patients from 18 years of age and  
15 older, as Dr. Balkany indicated, and they do represent  
16 a wide range of physical activity and sports. We have  
17 had no trauma report to the device which resulted in  
18 any effects in performance or safety.

19 DR. WOODSON: Dr. Woodson. What's the  
20 mean age of patients implanted, and was there any kind  
21 of bimodal distribution in age?

22 MS. ARTHUR: The mean age we have up here.

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1 The range was actually 28 to 86 years of age with the  
2 mean being 58. This is just for the U.S. study  
3 population alone. We did a distribution here that you  
4 can see.

5 CHAIRMAN PATOW: Other questions from the  
6 panel?

7 DR. GULYA: Julia Gulya. I have a couple  
8 of them. The SHACQ -- I'm not familiar with that  
9 test, and I'm wondering, typical with questionnaires  
10 type surveys, I was wondering what type of validation  
11 measures you performed with that test. I mean, it  
12 looks like it has face validity from some of the  
13 questions you included that it addresses, but I'm  
14 wondering about its -- how does it bear up to a gold  
15 standard or what kind of criterion or other validity  
16 tests have you performed with that tool?

17 CHAIRMAN PATOW: Dr. Gulya, a few of us  
18 missed the name of the test that you're referring to.

19 DR. GULYA: It's the SHACQ, and I don't  
20 think it has anything to do with Shacquille O'Neil.  
21 It's a Soundbridge hearing aid comparison  
22 questionnaire.

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1 CHAIRMAN PATOW: Thank you very much.

2 DR. HYDE: This is Martin Hyde. There are  
3 no large scale validity studies done on the SHACQ, but  
4 it is psychometrically a very simple questionnaire  
5 with a five-point scale about which preference about  
6 which there is a lot of additional data for the  
7 validity of that kind of approach.

8 DR. GULYA: This is Julia Gulya again. I  
9 have a second question to Dr. Fabry. You mentioned  
10 that the recipients of the Symphonix device are  
11 wearing their device one year afterwards. My question  
12 relates to the fact that many of these were bilateral  
13 hearing aid users, and what is the recommendation for  
14 what they do with the unimplanted ear?

15 DR. FABRY: I can address the issue that--

16 CHAIRMAN PATOW: If you could state your  
17 name, please.

18 DR. FABRY: David Fabry. Sorry. Thank  
19 you. It's easier when someone else is speaking than  
20 when you're speaking.

21 The issue is that indeed all of the  
22 participants in the study were wearing binaural

1 amplification when they began the study, and some  
2 continue to wear binaural now.

3 MS. ARTHUR: Seventy percent of the  
4 patients -- This is Deborah Arthur.

5 DR. FABRY: Seventy percent of the  
6 patients continue to wear both the Soundbridge and  
7 their device after implanted.

8 CHAIRMAN PATOW: Dr. Kileny?

9 DR. KILENY: Thank you. I have a few  
10 questions, a couple of questions.

11 First, I have a couple of statistical  
12 questions. The study was a single subject design.  
13 Yet all of the data is presented in terms of mean  
14 standard deviations, and the comparisons are made  
15 using single one-tail t-test. Just wondering if that  
16 is, in fact, appropriate.

17 The other question is: Given that the  
18 same patient participated in the P and D trials, as  
19 you mentioned, what sort of adjustments were made in  
20 terms of the statistical analysis to account for the  
21 same subject being counted twice essentially and  
22 compared twice within the study?

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1 DR. HYDE: This is Martin Hyde. It was  
2 characterized as a single subject design, but there  
3 was, obviously, a large cohort of subjects. What  
4 makes it -- It, in fact, is a hybrid design which has  
5 both features of single subject and group designs.

6 What makes it single subject design is  
7 that for some of the outcome measures it was possible  
8 to do statistical significance tests on individual  
9 subjects and then to count up the portion of subjects  
10 of statistical significance. That is something you  
11 absolutely cannot do with a group design.

12 The other feature, of course, is that the  
13 measurements were taken within subjects. So within  
14 subject comparison, that's another feature within the  
15 subject design.

16 The group features? Yes, of course, there  
17 are some and, where appropriate, group statistics were  
18 used. As far as I know, the group statistics that we  
19 used were completely conventional. I consider them  
20 entirely appropriate.

21 I'll have to ask Deborah Arthur to address  
22 the second question.

1 MS. ARTHUR: This is Deborah Arthur. The  
2 same baseline was used in the comparison of the  
3 Vibrant P to the unaided condition in the Vibrant D.  
4 We used the pre-operative, pre-surgical hearing aid  
5 performance measures. The patient had a period -- a  
6 trial period of six weeks with the Vibrant D after  
7 completing the Vibrant P clinical trial.

8 DR. KILENY: But the same patients -- This  
9 is Dr. Kileny again. The same patients were counted,  
10 certainly for some of the group statistical measures,  
11 in fact, appeared twice in the end; because the same  
12 patient was investigated with two different  
13 processors. Is that correct?

14 MS. ARTHUR: No. These are separate  
15 studies and, as I indicated earlier -- Deborah Arthur.  
16 As I indicated earlier, it's not cumulative count. So  
17 the 53 patients who participated in the Vibrant P were  
18 invited then to participated in the D, of which 50 of  
19 those 53 participated.

20 DR. KILENY: And I have one more question.  
21 This is more of an audiological question.

22 The patient's performance with the

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1 implanted hearing aid was compared to their own  
2 hearing aid, and obviously, when the evaluation was  
3 done with their own hearing aid, at times adjustments  
4 had to be made to reach the target -- in this case, it  
5 was the NAL -- for their own hearing aid.

6           Maybe the information is in the packet.  
7 Maybe I missed it. In what percent, in how many  
8 patients was it necessary to make some changes in the  
9 way the hearing aid was adjusted or programmed,  
10 depending on what type of pre-operative hearing aid  
11 they were using, in order to reach that target when  
12 they were tested pre-operatively?

13           MS. ARTHUR: Deborah Arthur. Dr. Kileny,  
14 that information was not gathered during the course of  
15 the clinical trial in terms of which individual  
16 patients had to have those adjustments. The  
17 information resides in the clinical forms, but we did  
18 not cumulatively gather that afterward.

19           DR. KILENY: Thank you.

20           CHAIRMAN PATOW: Dr. Hood?

21           DR. HOOD: Linda Hood. I have a couple of  
22 questions just regarding the subjects. First of all,

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1 were there hearing loses such that they covered the  
2 full range that's recommended for this or were they  
3 more toward the mean?

4 MS. ARTHUR: The range of hearing loss by  
5 pure-tone average -- Deborah Arthur; I have a terrible  
6 time with that, don't I? Deborah Arthur.

7 The range of hearing loss as represented  
8 by pure-tone average ranged from 41 dB to 66 or  
9 actually 67 dB, which encompasses moderate to severe.

10 DR. HOOD: Okay. And the second question.  
11 Do you have information about the type of  
12 amplification that was used for the subjects as they  
13 entered the study? Particularly, how many were using  
14 either multi-channel or digital technology  
15 instruments?

16 MS. ARTHUR: Actually, we did gather that  
17 information and went back retrospectively. We have --  
18 Of the 53 patients who participated in the Vibrant P  
19 trial -- Deborah Arthur; I'm very sorry.

20 CHAIRMAN PATOW: Actually, I think once  
21 they get the idea of a voice, it will be fine. You  
22 don't have to do it absolutely every time.

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1 MS. ARTHUR: I'm just going to lift up my  
2 name card.

3 CHAIRMAN PATOW: At least for the first  
4 few times that we have a speaker, we should do it.  
5 They will catch on.

6 MS. ARTHUR: Of the 53 patients that were  
7 fit with the Vibrant P Audio Processor, 18 of those  
8 patients actually had digitally programmable devices,  
9 and the remaining 35 had conventional devices.  
10 Whether they were digitally programmable or  
11 conventional, both groups had compression or some sort  
12 of other output limiting circuit within the devices.

13 CHAIRMAN PATOW: Dr. Roeser?

14 DR. ROESER: Ross Roeser. An extension of  
15 that question: We heard that hearing aid satisfaction  
16 is based on whether the device is appropriately fit.  
17 What measures were taken to make sure that in the 53  
18 patients that were fit with the device, the middle ear  
19 implant, that the devices were appropriately fit?

20 MS. ARTHUR: Deborah Arthur. As we  
21 discussed earlier, the appropriateness of the fit of  
22 the hearing aid was first measured by electroacoustic

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1 analysis as well as by real ear. Then clinically, it  
2 was judged based on the listening check, soundfield  
3 aided thresholds, word recognition, as well as  
4 specifically some questions off the self-assessment.

5 DR. ROESER: Another unrelated question:  
6 Related to variability in the data and this term  
7 "clinically significant change," in the presentation  
8 there was a measure of variability shown. It was a  
9 bar. I assume that's the standard deviation. It's  
10 not a range. It's a standard deviation.

11 MS. ARTHUR: Yes, sir.

12 DR. ROESER: So if we looked at ranges, we  
13 would be looking at larger variability in that  
14 respect. Okay. I wanted to clarify that.

15 The thing about the pure-tone average, the  
16 10 dB criteria for pure-tone average, you said that at  
17 a previous panel meeting that had been discussed, and  
18 I'm at a real disadvantage; because I wasn't at the  
19 meeting, and I'd like to hear the rationale for using  
20 10 dB as a criteria. Maybe it should come from the  
21 panel.

22 MS. ARTHUR: I don't want to infer that --

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1 It was the June 18, 1999 ENT panel meeting on  
2 implantable middle ear hearing devices. At that time  
3 there was discussion among panel members as well as  
4 the participants in the panel public meeting about  
5 what would be considered a reasonable amount of  
6 expected shift in hearing per se as a result of  
7 implantation with a middle ear hearing device.

8 The value of 10 dB was mentioned by  
9 several of the panel members to be what they  
10 considered acceptable as a measure of judging a shift  
11 in hearing.

12 DR. ROESER: So that was a discussion at  
13 which time people rendered an opinion.

14 MS. ARTHUR: It was not a recommendation.  
15 Right.

16 DR. ROESER: And it wasn't something that  
17 the panel might have adopted.

18 MS. ARTHUR: I don't want to speak for the  
19 panel but, no, that was not the recommendation of the  
20 panel.

21 DR. ROESER: As you read, one of my  
22 concerns is 10 dB as being a criterion. Typically, we

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1 look at a 5 dB shift. I mean, test, retest, is 5 dB.  
2 The question I have and the question I posed in the  
3 review that I prepared and one that apparently will  
4 come up, is can you give us information about the  
5 variability or the threshold shift that would have  
6 occurred beyond -- if you used the 5 dB criteria? Do  
7 you have any data? I assume you would have that.

8 MS. ARTHUR: We do. Yes. As you can see  
9 here, 76 percent of the patients -- Deborah Arthur.  
10 Seventy-six percent of the patients would have had a  
11 shift equal to or less than 5 dB.

12 DR. ROESER: That shift is -- I'm assuming  
13 the change, because it talked about change.

14 MS. ARTHUR: It is.

15 DR. ROESER: In the direction of poorer  
16 sensitivity?

17 MS. ARTHUR: Yes.

18 DR. ROESER: Thank you.

19 DR. FABRY: Dr. Roeser, just one  
20 additional point. Dave Fabry. One additional point  
21 regarding the clinical significance of 10 dB.

22 In our facility we have a hearing

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1 conservation program for employees at Mayo and outside  
2 of Mayo for monitoring a standard threshold shift that  
3 may occur as a result of noise exposure. Currently,  
4 the standard for standard threshold shift is 10 dB or  
5 more for the average of 2000, 3000 and 4000 Hertz from  
6 baseline signifies a standard threshold shift, where  
7 then intervention needs to take place.

8 So it is somewhat consistent with values  
9 that exist in the workplace.

10 DR. ROESER: But it's not the pure-tone  
11 average. It's a different criteria for a different  
12 reason.

13 CHAIRMAN PATOW: Other questions from the  
14 panel? Dr. Khan?

15 DR. KHAN: The question is for Dr.  
16 Balkany. Since you described the surgery, I'm  
17 interested in finding out, once you had finished the  
18 surgery and accomplished the surgery, are they up and  
19 ready to go or is there a time period involved in  
20 their learning and ability to use, like for  
21 conventional hearing aids; and what is that time  
22 frame?

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1           The second part of the question is: If  
2 the guy with the fullness in the ear comes back and  
3 said I really want this out of my ear, how did you  
4 resolve your patient's problem?

5           DR. BALKANY: Tom Balkany. Thank you for  
6 your question. The guy with the fullness in the ear -  
7 - We talked about it, and I said to him, I don't know  
8 what causes this; I know that other doctors have  
9 experienced similar kinds of problems. There are some  
10 theories about what caused it. One thing we can do is  
11 to take it out, if you like. He didn't talk to me  
12 about fullness in his ear ever again after I said that  
13 to him. So I didn't take it out, and he seems to be  
14 doing okay with it right now.

15           CHAIRMAN PATOW: If I could just follow up  
16 before you go into the next point. One of the  
17 speakers mentioned that this is reversible. Is there  
18 anything special about removing the prosthesis or the  
19 device from the ossicle? Is there any technical  
20 recommendation or technical difficulty in actually  
21 removing the device?

22           DR. BALKANY: The device is held in place

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1 by a very malleable titanium clip which is formed  
2 around the stapes, as you would do with a stapedectomy  
3 -- around the incus, as you would do with a  
4 stapedectomy operation. The removal of it is the same  
5 way that a stapes prosthesis is removed. A right  
6 angle hook is placed between the bone and the titanium  
7 and just rotated about 30 degrees, which spreads the  
8 arms, and then it comes out quite easily.

9 CHAIRMAN PATOW: Thank you.

10 DR. BALKANY: The second part of the  
11 question was?

12 DR. KHAN: Was the preparation following  
13 your procedure -- do they require time to -- Are they  
14 up and ready to go and use it?

15 DR. BALKANY: We give them six weeks  
16 following surgery before we tune up the device. Our  
17 audiologists tell me that, unlike cochlear implants,  
18 these people experience benefit the same day that they  
19 are tuned up. That benefit may increase over the next  
20 month or two, but they experience some benefit from it  
21 immediately.

22 CHAIRMAN PATOW: Other questions? Yes?

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1 DR. ROESER: Just in my mind, I'm looking  
2 at numbers. Dr. Fabry said that all 44 are wearing  
3 the technology today. I keep thinking we had 52  
4 subjects. So I missed something.

5 MS. ARTHUR: There were 44 patients whose  
6 one-year test data was available at the time.

7 DR. ROESER: Thank you. I just wanted to  
8 clarify that.

9 DR. FRANCIS: I have a question for Dr.  
10 Balkany. Howard Francis.

11 It's regarding the dimensions of the  
12 facial recess. It relates to the dimensions that we  
13 normally achieve for cochlear implantation. Is there  
14 any significant difference there, number one? Number  
15 two, the second part of that question, has the  
16 consideration -- Has the decision ever had to be made  
17 to preserve versus cut the corti tympani based on  
18 difficulty getting that dimension?

19 DR. BALKANY: The dimension generally is  
20 four to five millimeters at the maximum, and that's at  
21 the most open end, closest to the incus bridge. It  
22 narrows down to the junction where it's less than a

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1 millimeter.

2 That has been enough for me to get the  
3 device in, in all the cases that I've done, without  
4 difficulty. I have experienced some cochlear implant  
5 patients, which is done through the same space, where  
6 that space was not large enough to put in a cochlear  
7 implant, and the corti tympani had to be sacrificed.

8 So I imagine a similar occurrence may  
9 occur in some people. Fortunately, using the CT scan,  
10 we are able to now tell the patients in advance  
11 whether it's likely that their corti may need to be  
12 sacrificed, and we warn them about that with implants.  
13 The same would be true with this device.

14 I don't know if in this clinical trial  
15 worldwide or in the United States the corti was  
16 sacrificed purposely in any case. Maybe someone else  
17 could answer that.

18 MS. ARTHUR: Yes. Deborah Arthur. That  
19 corti was sacrificed in fewer than ten cases in the  
20 United States clinical trial.

21 CHAIRMAN PATOW: Yes, Dr. Kileny.

22 DR. KILENY: Thank you. This is a

1 question to Dr. Balkany. Do you foresee that this  
2 operative procedure would be carried out in the future  
3 by non-otologically trained otolaryngologists? Was  
4 this appropriate? Could general otolaryngologists be  
5 trained to do this operation?

6 DR. BALKANY: That's a difficult question  
7 to answer, and I never like to tell somebody they  
8 can't do something, because many people without  
9 formalized training are quite good, say, at  
10 stapedectomy surgery. In general, though, I feel that  
11 a surgeon should have a large experience with facial  
12 recess surgery.

13 Now some people such as myself did not  
14 have a formal otology fellowship training. So,  
15 personally, I would not want to exclude all people who  
16 didn't have an otology fellowship. On the other hand,  
17 I do a lot of facial recess surgery and have found  
18 that that experience made this -- and stapes surgery -  
19 - Those experiences made this entirely possible.

20 I do feel that specific training is  
21 necessary for surgeons using this device or any  
22 implantable device specific to the type of device

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