actually develop a load that simulates the drive that these systems connect to, or the load that these systems connect to.

And in fact as a first approximation, I don't think one has to take into account the ossicles that the cochlear load will be the main factor there, which I think is fairly well known and described.

In the case of the totally implantable, there is another factor that has to be taken into account, and that is the input part. And it seems to me that the right way to go in this specific case, and I don't think it need be so difficult that one would expect it to take a year or two years, and amount to a tremendous development effort, to actually specify the input to the device, in terms of acoustic input, and be able to relate the output of the device to an equivalent acoustic input. And be able to directly therefore compare it to hearing aids, and use the specification standards that are already developed for hearing aids that have been tried and true over many years.

In addition, it provides comfort for the clinicians, in a sense that they know what that stuff means, and may have used it in their clinical lives for many years, and are adept at using that information to fit devices.

So my question is why now take advantage of what we have, and specify the device in a way to me at least make sense, and is a complete specification, and provides consistent units across devices.

And I didn't warn anyone that I was going to call on them first, and so I will take volunteers. If I don't see any, then I will exercise my prerogative as a discussion starter. I don't see any brave individuals.

DR. WALDEN: Well, I was sort of a half-volunteer.

DR. EDDINGTON: I thought it was a nervous twitch.

DR. WALDEN: Maybe it was, but really out of my area, but I just wonder how many audiologists -- I mean, the quality of the signal processors that are built into hearing aids now are so good that I wonder in terms of sort of the basic measures that we are talking about here do audiologists really take these into consideration in fitting devices, in terms of dynamic range, and distortion, and that sort of thing, which is what I think we are talking about here.

As opposed to the question earlier about prescriptive formula and so on. And my guess would be probably not a whole lot, and I am wondering if computer models or mathematical models would suffice, as opposed to actually looking at or requiring mechanical movement and measuring the mechanical movement.

And that is a question, and I don't know the answer to that, but I just wondered.

DR. EDDINGTON: I think that is a very important -- I think you have raised two very important issues, and I

should obviously let the audiologists respond. As I poll the audiologists at the infirmary, they are dying for that kind of step.

Granted, they don't use them all, but because systems have become so complicated, you really do need very tight specifications for how to make the measurements.

So when you have these highly compressive aids, for instance, with automatic gain controls, it is extremely difficult to characterize those devices. And those issues have been faced already, and at least the audiologists that I talked to at our institution have tremendous confidence, and know what that means, and when they start looking at how the IMEHDs or whatever we are calling them, they don't know where to begin.

Your other point about models was an excellent one, and that would be wonderful. I had the feeling that in terms of developing and validating those kinds of models that that is a longer process than simply having what is in a sense a model, a simulated load that is analogous to the coupler.

But I would be interested in what others have to say. I think those are two very good important issues, and you may want to respond before we open it up to others.

DR. WALDEN: Well, I think your point about specifying output, in terms of advanced processing algorithms, and noise suppression, directional hearing aids and so on, is a very good one. And I wonder how that fits into this discussion

given that we can't do it very well right now with the technology that we have available to us with air conduction hearing aids.

How would we expect to do that with something where what we are trying to measure is movement, as opposed to an acoustic signal?

DR. EDDINGTON: Well, what I am saying is that we could do it at least as well as we can with the acoustics. But that is my opinion, and others may have other opinions.

DR. SOLI: Sig Soli. Brian, I understand what you are saying about advanced signal processing in a hearing aid, but I don't think that is the point where we are at in this issue. The issue is what are the output levels and how do they correspond to hearing levels, and are they safe in terms of the amount of energy they are putting into the middle ear.

When you do advanced signal processing that brings up a whole range of other questions. But if you have a model or a calibrated reference receiver that you can put your device that would normally transmit to the middle ear, if you have an appropriate model that is calibrated, you can -- when you put your device and you come to these higher level questions, you might have a chance of answering them then is the way that I would view it.

DR. CUEVA: Bob Cueva. I would agree. I think

there needs to be some way I guess to calibrate the mechanical output of the devices, correlate it to a X-decibel level. So that when you come to program it, it is not okay, tell me when it hurts, and how loud does it get. And then we back off from there, and it has to be a little more refined than that certainly.

DR. EDDINGTON: Right, and unless you have that, how will you measure the amount of distortion that may vary its function without the level?

DR. KILENY: Thank you. Paul Kileny. I just wanted to get back to what I said before and I do agree that you do need to be able to characterize the output if you want to approximate some of the current hearing aid standards.

And I was actually a little bit amused listening to the discussion about functional gain measurements, because those had fallen into disfavor many years ago, and I don't think anybody around the table here uses them routinely to securing aids.

But those are actually pretty good measures, but in this case, if you want to make some kind of an analogy between current prescriptive methods for hearing aid fitting, I need to reiterate that some type of -- the ability to telemetrically measure the output when the device has been placed, I think that is really the only way to do that. Coupled with the knowledge of what the output is in some kind of a low simulator that has a

known load, I think that is the way to go. And then you can in fact mimic or copy those prescriptive measures if you have a telemetry measure of ossicular chain displacement.

DR. LONSBURY-MARTIN: Could you explain that a little bit more, Paul? This is Brenda Lonsbury-Martin. In the sense, do you mean like actually have a transmitter that is sitting in there with a device in the middle here?

DR. KILENY: Right. Yes. Basically what we call back telemetry, measuring -- if there is some kind of a component of the electronics that is within the device, which would allow you to measure either transcutaneously or in some other way, the actual output of the -- your input, you know, and you can measure that, especially in a totally implantable device, which does use the ear canal as the input.

The microphone is sitting there someplace, and then how do you measure the output? Well, you measure the output by this back telemetry, measuring the actual mechanical information coming back from the ossicular chain.

And how do you do that? The device is riding on your ossicular chain, or rather displacing the ossicular chain, and you get that measurement back from the device.

DR. EDDINGTON: Yes. Can you state your name?

MS. HOOD: This is Linda Hood, and I didn't know if you were going to respond to Paul, or if I should change the --

DR. EDDINGTON: No, I am going to try to stay out of it now since I put in my two cents.

MS. HOOD: Then I will change the topic.

DR. EDDINGTON: And reduce the likelihood that I will say something stupider.

MS. HOOD: I was just going to say from a clinical audiologist standpoint relative to labeling, and characteristics, the standard characteristics of hearing aids, I think that is something that we want to be assured that those exist, and that they are -- you know, what the variation is, and what the expectation is there. And to the degree that it can relate to what clinical audiologists use now with acoustic hearing aids, I think that would make a transition into this for many clinicians smoother.

DR. EDDINGTON: Are there comments? I have got to imagine that our industry representative must have several on the tip of his tongue.

MR. CROMPTON: Just a few. Mike Crompton again. Again, I don't think that there is widespread opposition to the concept of developing a model. Again, we do view it as the next sponsor to come down the pike to have to bear that burden would be an extreme challenge, believe me.

With the first approved IMEHD, attempts were made, and we know for a fact that other sponsors and developers are working on models, and Dr. Soli presented a model two years

ago. So, it could work, and I think we would like that to be maybe industry wide or academically-led exercise, where we could have a reference standard if you would.

I think it is an obligation of industry to try to convey the information for these devices and relate them to in a language that the audiologists can understand. But to have a one-to-one comparison to state-of-the-art hearing aid frankly is an impossible task. Both sponsors of the PMAs faced this challenge when they started their trials. The first sponsor faced a challenge of the advent of the digital hearing and the widespread use of that device was not even contemplated when the study was designed. We had to go back and review and enroll additional subjects, and whole new questions were raised.

So we kind of chasing a moving target there. So I have been very pleased with the discussion around this. A model would be a value, and also I think just to echo one comment that Dr. Blumenstein made; the non-inferiority design for the clinical trial. Certainly with a totally implantable system, where there could be some other advantages may not be exactly equivalent to the state-of-the-art hearing aid or whatever that is. But there are intangible and tangible benefits for patients, and so to encourage sponsors to take that risk I think some flexibility in experimental designs would be advantageous.

DR. EDDINGTON: I have got maybe a question for

the FDA officials here, and that is to what extent is it possible that in cases like this some joint effort between the --it is not the National Bureau of Standards now. What is it called now, NID, but the FDA, the manufacturers, might provide some impetus there.

MR. WHIPPLE: There is a good chance. A very good chance.

(Laughter.)

MR. WHIPPLE: Both Teri and I are members of the CDRH standards task groups. I chair the Ophthalmic one, and Teri chairs the ENT one, and we recently have been given the opportunity to propose projects that can be brought forward to new standard development organizations, where existing standard development organizations for new projects.

Several of the things that were discussed here today would make great projects for them, and we are very much in touch with these standards organizations, and we can propose them, and I have already mentioned to several panel members here already that I thought this has been a fruitful discussion for standards groups if they are listening anywhere, and we will definitely take it forward.

DR. EDDINGTON: Maybe the rock has been cut out of the mountain. Sig, did you have --

DR. SOLI: I would like to -- at the risk of going back to a previous issue, since you brought up this thing

about non-inferiority designs, I would like to comment on that for a moment.

I am certainly comfortable with the idea that there might be non-biological or audiometric variables that provide or characterize benefits for the device. But in my mind it is extremely important when you go to the self-report measures to be certain that you are not dealing with cognitive dissonance and Hawthorne effect, and things like that, because those are very, very real. I have seen them myself many times, and so I would like to go on record that if those types of self-report measures are to be used, there is a pretty substantial burden of proof on the user to show that they are objective, that they are valid, that they have acceptable reliability, and that we can feel comfortable in interpreting them.

DR. BLUMENSTEIN: Brent Blumenstein. When I spoke about non-inferiority design, I was talking more about the performance measurements of the device, and the difficulty that one has when one is designing a trial with two kinds of end-points, two disparate types of end-points, such as patient satisfaction types of end-points, and performance types of end-points, is putting a weight on those two, a utility function if you will. And that is nearly impossible to do, and so the way that we usually work in clinical trials is that we will focus on the performance end-points, measure them, and so forth.

So a non-inferiority type of design may be

appropriate to say, okay, the performance is roughly equivalent, or something like that, but the context in which everything is put together, and interpreted, that is where your comments directly apply. Because if you then have a whole bunch of these other touchy-feely type measurements that are subject to all of these kinds of things, this makes a very difficult interpretation of what those things mean, but nonetheless, it has to be done.

CHAIRPERSON GULYA: Don, I think we need to have your summary and wrap up, please.

DR. EDDINGTON: I guess the way that I would summarize it is that to the extent that it is possible, and I think there needs to be work done to determine whether it is possible in the short term, but maybe with some collaborative effort among the various agencies and the manufacturers, we could develop at least simulated loads and sources in one case that would allow common specification of inputs/outputs. Therefore, performance characteristics or specifications for these devices.

CHAIRPERSON GULYA: Well, I thank all of my host chairs here for taking on these questions. They relieve my burden considerably. FDA, how did we do? Any other questions that now pop into your head? Have we answered the questions to your satisfaction?

DR. MANN: Yes. I would like to thank all of the

panel members. We have had a very thoughtful, educated discussion of all of the questions that we had raised. There has been consensus on some of the questions, and on questions where there were varying viewpoints, that perspective has been very helpful to us as well, and we appreciate all the time and effort that you all have put into preparing for this meeting.

CHAIRPERSON GULYA: Okay. Great. So we will now go to our second open public hearing session. This again is our opportunity to hear from public and industry representatives. The same rules as before. Please state clearly for the record your name and affiliation, interest in the topic at hand, and any consulting arrangements or financial interests with medical device firms, and if travel expenses have been paid, by whom. We have allocated 30 minutes for this segment. I don't exactly see anybody running to the microphone though. Going once -- yes?

MS. ARTHUR: Debara Arthur. I was before this panel two years ago, and I am the vice president of regulatory and clinical affairs for Symponics Devices. What I wanted to do was mention two things, most of it in support of the trend of your conversation over the last hour.

In looking at performance measures of these patients, we found with almost 100 patients implanted worldwide that patient expectations will never be appropriately met if these patients for the most part don't have a good acoustic

hearing aid experience, or trial prior to implantation. There are certain exceptions and usually these are medical exceptions, but for the most part, if these patients aren't fit with an appropriately fit device, we find that expectations are very difficult to manage post-operatively. And we have had that experience here and in Europe.

The second point I would like to make speaks to the issue of having some sort of a common denominator or a common measurement tool so that we can describe the output of these devices across manufacturers. I think with the fact that we are dealing with electromagnetic, as well as piezoelectric, and whatever new ones will come up in the end transducers, the confusion that we are seeing in an audiologist already is resonating. They are having a very difficult time understanding when we come in with laser Doppler vibrometry measures and take millivolt, and talk about equivalent SPL, they are very confused. I think the motion to have this set before a standards committee is an excellent one, even if it takes 2 or 3 years. The fact is that these devices are continuing, and we are going to see more of them in the next 2 years or 3 years, 5 years, and to know that we have something like that in the future as manufacturer to work towards would be very, very helpful for us.

And I think for the audiologists and audiologists, that we are trying to understand how these

products fit into their practice, and the hearing health care management of their patients, it would really be a valuable asset. So I encourage you to go down that road. Thank you.

CHAIRPERSON GULYA: Thank you. Any other presenters? Thank you very much for your comments. I think I would like now to turn to Mr. Whipple. If he would give us a little bit of an overview as to what the next steps are for this guidance document for the FDA, and where we might take it from here.

MR. WHIPPLE: Sure. Thanks. I want to thank you, too, for the great discussion today. It is going to be very helpful. And it will also determine how quickly we can get this guidance out.

As Teri mentioned in her presentation, the docket will close on the 12th of September, and any comments that are in that docket, along with the discussion here at this panel, we will take all those comments back and we will sit and evaluate them.

We will bring in the appropriate people that we need to discuss and make the appropriate changes to that guidance document. The process and how it gets out of the agency is a longer one than some of the other documents that we usually deal with.

This is because this is a Class III PMA, level one, guidance document, is what we call this. It is the highest level of guidance that issues from the agency.

So it has to come out of not only the branch, and then the division, and then the office, but also the center. So it takes it up all the way to Dr. Feigal's level, and then through his office. Sometimes that can take a long time, depending on what policies, and what new things are being proposed, but this is a pretty specific guidance. This is one that is dealing with the specific device type. It is not changing the way the Food and Drug intends to regulate all medical devices in any way, shape, or form.

So I don't anticipate it being a difficult process to get through the center. It will be just more of a scientific issue of us coming to conclusions and making the right changes. Without being held to any specific due date or time frame, what I have heard here and in some of the discussion, and knowing the process, I would like to see this out before the end of the year, and anything earlier than that would be wonderful.

CHAIRPERSON GULYA: Well, taking the Chairman's prerogative here, I would like to thank all the panel members for all their thoughtful comments and hard work, in addition to the effort that they took to he here, and help us run on a timely schedule.

I would like to thank the FDA staff for their informative presentations, and all the hard work they have evidenced in putting together this meeting. It is much

appreciated. And unless there is any other pressing issue, I would call this meeting adjourned. And Sally has one thing.

MS. THORNTON: One thing. I just wanted to announce to the panel, and to the public, and the staff, that the October 17th-18th, 2002 tentatively scheduled ENT-THAL meeting has been canceled, and we will go forward toward the December 12th and 13th date, and I will let you all know by mid-October what the status of that meeting date is. I will be coming out with a new calendar for the panel probably sometime in September that I will be able to get that together. So I thank you very much for your time and for your attention, and it has been very nice meeting all of you for the first time, and I welcome you to the panel.

We have a lot of new talent and new expertise, and we are very grateful that you are willing to take time away from your busy schedule to work with us. Thank you.

CHAIRPERSON GULYA: Now we are adjourned.

(Whereupon, at 3:51 p.m., the open session was concluded.)