I think the answer to that would be not necessarily, no. I mean these just could be something that make people look better, and you can speak to that in a minute, Rebecca, but if someone does claim an improved health outcome, I think that has to be substantiated because we do hear a lot of this, as you know, batted around about improvement in diabetes or whatever, as a result of decrease, and that information, if people are going to make any kind of a claim or if those claims are going to be out there, then those really have to be substantiated. So when you ask specifically what specific measures of clinical improvement, well it will depend on what the patient is claiming? Does it lessen back pain or is it improving their blood glucose level, whatever that clinical outcome that seems to be improved might be, and there are some and then I think it has to be substantiated rigorously.

DR. ANDERSON: Well, I would agree with that with regard to making a claim for improved health for just a little bit of body fat. However, I do know that a lot of times when people have liposuction or they have some body contouring procedure and they feel like they look a little better, that jump starts their dietary changes and

some exercise changes. So I would agree that it is a possibility that that might happen but I also agree with you. If somebody's going to make those claims, they need to be substantiated. They need to be measured and substantiated. And then we come up with the problem of how we're going to do that. The SF-12 and the SF-36, they're possible. They're outcome measures that are widely used by NIH and I think also from FDA but then again that becomes a very cumbersome process for both FDA to review and for the sponsor to deal with and for the patient to take. So I would take that claim off the table I think. I think it makes it easier if you just take that claim away. But perhaps that's not my decision.

But with respect to satisfaction as an outcome point only, I think that there needs to be some measure of effectiveness from an actual change in contour, and I don't think we can use satisfaction alone. However, if we decide to use satisfaction alone, I think that we have to validate an instrument to do it.

DR. LoCICERO: Other comments? Dr. Burke.

DR. BURKE: I just think that every instrument that makes a claim should substantiate the claim with quantitative, scientific data and not

totally subjective, and should obviously state the safety limits but I think within that, so I think that it is important to substantiate the claim just to prevent consumer fraud.

DR. LoCICERO: So just to be clear, when you say instrument, you mean a device --

DR. BURKE: A device, yes.

DR. LoCICERO: -- not the instrument as an instrument of measurement.

DR. BURKE: Exactly, a device that is used clinically. And I think I agree with Dr. McGrath that we don't have to -- I mean I don't think that they should make claims as to clinical improvement unless it's absolutely certain and proven, and then this device is a kind of different category of device. It may then become a medical device rather than something just used for aestheticians and non-medical professionals.

DR. LoCICERO: So let me just be clear. It's the consensus of the Panel or the thought that these should not be forced to prove that it improves health, but that if they make that claim, they better prove it. Is that the sense?

DR. BURKE: Yes.

DR. LoCICERO: Okay. So I think we can

answer this question now. We have really talked a lot, Mr. Melkerson, about the idea of validated evaluation scales and that this may be something that needs to something that needs to be developed with the sponsor and the FDA using what tools are currently available but being specific for the area and that if there is going to be a clinical benefit, improved health outcome, that that would be a claim that the sponsor would bring forward and that they would have to prove that claim in order to achieve that as an indication. Does this satisfy the FDA?

MR. MELKERSON: Yes, with a little clarification, to make sure when we're saying health benefit, it could also be a functional benefit. Potentially that would also fall under that category of meeting evidence.

DR. LoCICERO: Yes. And Dr. McGrath mentioned that specifically, like improvement in back pain as an example, and that would have to be something proven.

MR. FELTEN: The third question, again for device that are intended for aesthetic, temporary change in appearance, should the treatment be so well understood that the user can preset the amount of change that will occur? For example, if the device

is intended for eyebrow lift, should the amount of lift to be achieved be controlled and predictable before initiation of the treatment?

DR. LoCICERO: We're going to start with Dr. Li because he's been going around this issue for a while now.

DR. LI: The way this is worded is a little tricky for me. It seems like there should be some control over what it is that you're trying to do, and if it's something quantifiable, like the amount of an eyebrow lift, there should be some. I guess the patient satisfaction -- I guess why I'm going around in a circle is if the patient is unsatisfied after the treatment, for effectiveness, that really is kind of an endpoint to me. So it certainly seems that if it's going to be a viable, commercial procedure, that there should be some verifiable, noticeable change to the patient. So I'm struggling really with how this question is worded.

DR. LoCICERO: Let's be ridiculous. If Deforest Kelley, a/k/a Bones in Star Trek, were able to show a picture of the after and press a button and get the result, maybe that would be the most ludicrous at this point.

DR. LI: And your question is would that be

required of a device?

DR. LoCICERO: Right.

DR. LI: Well, I think that would be an excellent device. I think that would be a great model for a device. Now, whether or not it would be required I guess would be a secondary question.

DR. LoCICERO: Why don't you think about that.

DR. LI: Yeah, let me think about that. I'm not quite exactly sure how Bones would answer that question.

DR. LoCICERO: Mr. Melkerson.

MR. MELKERSON: Maybe to help with this question, I think the intent was, should there be some quantifiable and I think we've heard the Panel mention that there should not only be patient satisfaction but something that's quantifiable. The ability to predict I think is the fantasy, yes, if you could do that, that would probably put everybody else out of business but the issue that we were after is should there be some kind of quantifiable measurement associated with these types of devices, not just a patient satisfaction or whatever.

DR. LoCICERO: So these devices are going to be -- they're incremental in terms of how they're

applied. So are you also asking about if you just press the button, you're get a predictable effect for each time it's fired or used?

MR. MELKERSON: That is also one of the embedded questions. I'll defer to Richard on that one.

MR. FELTEN: Yeah, I think what we're trying to get through here is, an example I was thinking about is more the lasers that are approved for LASIK where you preset the amount of cornea removal and you get what is there, whereas with these devices in many cases, you know you can predict pretty much histologically how much of the tissue you'll get a lesion in but that doesn't necessarily always come out to the same amount of tightening let's say if you're doing let's say wrinkles or something. And the question we're having for these devices which are now into this body contouring or eyebrow lift, you know, are we saying the physician should be able to tell the patient before they even begin the treatment, how much change they're going to get from this particular amount of treatment or again should this be, you know, this biology, and it's going to vary between patients but there is a minimum amount that we would require to allow the device to

go to market, let's say, but should they also be able to tell the patient how much they're going to see which is sort of a different question I think.

DR. LoCICERO: So LASIK is really sort of set it and forget it, and they sort of said that this may not be possible here. Mr. Halpin.

MR. HALPIN: Yeah, I think this is a very different situation on LASIK where you actually couldn't do it from a technique point of view. You have to have a computer help you do it. This is the opposite where you're using the expertise of the user to actually achieve some sort of cosmetic change which is individualized for a particular patient and can't be standardized across the board. So I would actually say you don't want to do this because you would almost defeat the purpose of having a tool that physicians can use to help patients get whatever it is their cosmetic appearance would want to be.

DR. LoCICERO: Dr. Newburger.

DR. NEWBURGER: There are an awful lot of variables in the patient's health that are going to impact what the outcome of the treatment is, what their tissue response is, whether there are underlying diseases and what their medications are. With that said, I think that there should be a

guideline where the physician could say 50 percent of individuals who have this treatment can achieve a 2 millimeter brow lift. There should be something quantifiable that is clinically significant and relevant. A 1 millimeter change is not going to be clinically significant, and the exposure to risk certainly, you know, wouldn't be warranted in that situation. So there should be some guideline that shows that in a definite proportion of individuals, you will achieve an outcome which will be at least equal to the following.

DR. LoCICERO: Dr. Anderson, did you want to make a comment?

DR. ANDERSON: Well, I think this instrument is going to be in the hands of non-physicians, and what they're going to depend on is the programming of the device. I think that perhaps what you said about meeting minimal FDA standards for change is about all we can really hope to get without some extensive measurement that may not be worth it for these devices.

DR. LoCICERO: Dr. Burke.

DR. BURKE: I was going to echo what Dr. Newburger said, that I think that if every patient could be told the percentage of chance that

it works, in other words, is it a 50 percent chance or a 90 percent chance of some quantifiable data, but I think also part of the predictability and control is that it not overreact so that you don't have some patients per chance come out with a startled look for days or weeks. So I think that within this control and predictability is the safety issue of not over exaggeration or whatever the device does.

DR. LoCICERO: Additional comments?

(No response.)

MR. FELTEN: Can I just ask Dr. Newburger, for clarification, would you then be saying that we should be considering the idea that the operators manual information sheet should maybe contain something like a summary of the data from the clinical studies, that the user would actually have an idea of what was actually generated in the clinical study as a way of giving them that option of saying we know this many people got this amount of effect. Would that be --

DR. NEWBURGER: I think that's fine at least for those operators who read the instruction manuals.

DR. BURKE: May I just make one other comment, that I think that the operators may or may

not -- they certainly will read the manual but they may not assimilate everything but also I think that maybe with these devices, there should be a kind of mandatory handout to every patient so that at least the patient has the opportunity to read the qualifications that we're discussing now.

DR. LoCICERO: So we're dancing around one issue here that I think we need to get out, and that is -- well, two issues, and that is training and qualifications. And we need to kind of have a broad discussion about the operators of these devices and what we feel would be appropriate in terms of guidance for the FDA when they are talking with sponsors, and training again as a general issue in terms of these devices. Comments? Mr. Halpin.

MR. HALPIN: I think from an industry perspective, it's in the best interest of manufacturers to have operators who are actually appropriately trained and qualified to use the product to get correct results. So I think that's probably a very good idea and probably would help manufacturers meet their design control requirements.

DR. LoCICERO: Other comments? Yes, Dr. Anderson.

DR. ANDERSON: Yes, I feel very strongly

about training, and I agree with you. I think it's in the sponsor's best interest to avoid problems down the road by having these procedures done by people who are inadequately trained. And I think, you know, someone who knows how to operate a machine may not know how the skin works or how anatomy works, and I think it's very important that they have the necessary training.

DR. LoCICERO: Mr. Rue, what would a consumer feel comfortable with in terms of a woman walks in for a procedure and asks, are you qualified to do this? What information would be appropriate to provide to that consumer?

MS. RUE: Well, first of all, I think initially consumers need to have available to know what questions to ask, and then when they go to the facility, they should be able to ask for appropriate documentation as provided by the device manufacturers as well as their training people, to show that they have completed and recently, not something that they have done 10 years ago and may not have any update on. But the first part of it is getting them educated in what they need to ask.

DR. LoCICERO: Okay. Dr. McGrath.

DR. McGRATH: I think one thing that's

becoming clearer certainly to the professional organizations is that the question of training, not for people in training, but for people who are in practice, is a complex issue because there's the piece of imparting information about the device but then there's also training that involves hands-on experience with it but then probably equally important is if there's some process of verification, that the person has as you said, assimilated some of this information. So I guess this question is for Mr. Halpin. What's going on with industry now because we know that many devices have the attachment that there has to be training of an individual, and what's happening in industry in terms of their recognition that there are these pieces to education or training and where is that moving and what's going to happen when this goes way from training and education the physician to someone who is not a health professional?

MR. HALPIN: I think that the requirements are going to vary dramatically depending on what the product is. So it's hard for me to, you know, be very specific because if you have something which simply removes hair from your arm versus something which is lifting eyebrows, those are very different

things I would imagine in terms of your training and qualifications.

So I would think that this has to be done on a product-by-product basis or product category by product category basis and should be part of the approval process for the product and essentially part of the labeling if you will that, you know, a certain qualification is required to use this product and some of these may be over-the-counter products, some of them may require healthcare professional use and those are probably going to be very different products I think if you're talking about an over-the-counter product, that the requirements are going to be very different for that in terms of their investments in the product and the ability for people to use it on themselves or use it in a setting where they're not a healthcare professional.

But I think it's going to be very product specific, and I'm not sure if I answered your question or not.

DR. McGRATH: I think you addressed the part about the qualifications but not so much about the training.

MR. HALPIN: So I think if you -- each manufacturer may have a different opinion about this,

and it may be that we might have some manufacturers who would volunteer to talk about some of their training programs that they currently have in place, but I know that different manufacturers will have training programs for new customers, particularly if there's a piece of capital equipment where they're actually bringing equipment in, installing it and then training people on how to use it. So I don't know if that answers your question or not.

DR. McGRATH: Well, I guess for the FDA then the question is are you starting to draw, what's the word, kind of limits or levels on training for different devices or is the word training just remaining kind of generic term left up to the manufacturers. I mean where are we with this understanding of verifying if people have actually acquired the ostensible skill to use these things?

MR. MELKERSON: In general, the issue of training is not something that -- we can ask that they be properly trained or properly credentialed, but in terms of requiring a particular training, we usually ask the manufacturers to commit to a training and then identify what that training should be. So it's not currently a regulatory enforcement tool especially under the 510(k) process.

DR. LoCICERO: So another way to look at this question is that we know that there's going to be some predictable amount of change but it's sort of like getting into your car and stepping on the accelerator. The car moves but you don't have to know anything about the engine under the hood.

So in this case, though, should the operator of the device know what's under the hood and know the predictable change when they press the pedal?

DR. BURKE: They should certainly know the change when they press the pedal.

DR. LoCICERO: Okay.

DR. OLDING: I think it depends upon the variability and predictability of the result and also the possibility for complication rate as to how you answer that. So the more predictable, then the less they have to know.

DR. LoCICERO: Dr. Anderson.

DR. ANDERSON: I would agree with that because I've come out already as a proponent of training but I think it's a device by device. I would agree with Mr. Halpin. It's a device-by-device issue probably.

DR. LoCICERO: Okay. I'm getting the sense

that we feel that there should be some predictable amount. It should be something that the sponsor should be able to impart to the user and that the user needs to understand the device before stepping on the pedal. Does that answer your questions, Mr. Melkerson?

MR. MELKERSON: I believe you have addressed it, thank you.

MR. FELTEN: What recommendations would you make regarding the Agency's review of those aesthetic devices that present minimal risk and appear to have little or minimal tissue effect for indications such as body contouring or reduction in thank thickness or improvement in skin appearance? And I think we've already been talking about this.

DR. LoCICERO: We've been talking about it but before we go any further, do you mean something -- would snake oil fit in this?

MR. FELTEN: I guess maybe what we're talking about, snake oil or it's not a device. Well, if you make a claim, it might be.

DR. LoCICERO: You could.

MR. FELTEN: I think what we're trying, maybe try to distinguish between our things that we know definitely are causing tissue effects. Back to

the discussion of what it means by low -- I guess, to some of the LED type devices that are at least being sold in Nordstrom and places like that right now that are apparently not doing any direct tissue effect that we see that is obvious, like, you know, creating lesions from the ultrasound damage to cells and so on. But those devices also are making medical claims and if we have to review them, how do we go about doing that I guess is what we're asking for. So we are trying to make that distinction between those devices that very clearly we can see a tissue effect, we can see histological change versus the LED type, light sources, that are being promoted for improving the appearance of the face or clearer skin or changing pore size and things like that.

DR. LoCICERO: So our dermatologist on the Panel, I'm sure, have a lot of experience with phototherapy, and so I'd like to ask them each to make some comments. Dr. Newburger, why don't we start with you.

DR. NEWBURGER: Oh, no, don't start with me.

DR. LoCICERO: All right. We'll save you for last. Dr. Walker.

DR. WALKER: Actually the use of the low

level light sources even when they were first introduced were in my opinion, it wasn't clear what the histology was, what the endpoint was in terms of really reproducible effects, and I think that's probably still true for these over-the-counter. It's kind of the truth is in the eye of the beholder, and I am not certain that there was enough science at least initially, or available now, to actually support the claim of more youthful appearance. However, in the person's own view of their, you know, global, aesthetic improvement, it they feel that is true, it's somewhat of a snake oil effect but it's hard to disprove --

DR. LoCICERO: Dr. Burke.

DR. WALKER: -- or approve.

DR. BURKE: Well, I mean if we think of you UV salons, they're absolutely dangerous, and there are deaths because people don't ask what medications the patient's on that might make them photosensitive, and they can get total body burns that are lethal. The settings may not be as carefully regulated. Sometimes these are the things that we as dermatologist see and eye protection and again medications can very much affect this.

So let alone the fact that the UV itself is

dangerous and hurts the immune system of the skin and the appearance of the skin in the long run. So in that sense, these devices are incredibly dangerous. So we just have to have precautions so other future devices don't reproduce those dangers. So I think that every device should have some quantifiable proof that it works and definite safety limitations, and the device should have built into it, we should be assured that it cannot be used unsafely. I mean the woman that dried her cat in the microwave clearly. So the precautions that must be very clearly stated and I would think that the FDA should recommend that everything should define temporary with real time and define some percentage of possible efficacy that 20 percent of people this works on or 80 percent, whatever. And I think they should be kind of recommending those requirements.

DR. LoCICERO: Okay. So in this case, we're talking about the 20 percent and below group. Dr. Newburger.

DR. NEWBURGER: My experience is I've never seen anyone achieve benefit from these low level light sources whatsoever except psychologically, and I think them with one major exception basically as fulfilling one of the claims that are used in

cosmetics. In other words, the mind claim which is it makes me feel better, and that certainly is acceptable by CFSAN, but I don't think that that fulfills our criteria here. The so-called data that I've seen on several of these devices is -- it's certainly challenging for me to see any difference. If I can't see the difference between the before and answer, I don't think there is a difference.

My concern is I've not seen any evidence truly how these devices work on the cellular level, and it took us many years to see the impact of ultraviolet light treatments on the skin, and that's when they were controlled, that is to say administered by a physician. It certainly was the standard of care when I was a blemished teenager. So I'm concerned that many years later, we're going to find that there is some type of long-term impact, and that concerns me greatly. And as far as I'm concerned, unless some meaningful benefit is shown, I don't think they should be on the market.

DR. LoCICERO: Dr. Li.

DR. LI: One thing that kind of strikes me here, I think it really does a disservice to the public to call, I mean we kind of make fun of these things where you pass blinking lights over the people

hoping that it will cause some change, and those are probably, you know, costly but don't harm the patient. But there's a whole host of these things that cause cellular damage to some level, and I think, you know, either like a tanning bed for instance, I mean there's cellular effects going on there, and under a certain set of conditions, you know, you could really do the patient some harm.

So I think the mindset that these are essentially harmless devices that, you know, that really don't require a lot of attention or care I think is a serious mistake because I think really the dividing line should be is there a cellular effect by the device or not, you know, and if the answer is no, there's absolutely no cellular effect, then it falls into the category of perhaps that Dr. Newburger mentioned of a more psychological advantage because there's nothing going on cellularly. So I don't actually know what else could possibly go on there, but then in the other category where there are cellular effects, I actually don't think you could ever really drop your guard on this and, you know, I think to do so, I mean we've got example after example where we end up in trouble on that.

DR. LoCICERO: I think we're pretty uniform

at this point, Mr. Melkerson, that if it's a device that makes a change, that it needs to be proven, it needs to be shown and there needs to be some science in evaluating it and that regardless of how minimal we think it is, there may be issues and safety remains a concern. Does this answer the FDA's question?

MR. MELKERSON: Thank you for your input.

MR. FELTEN: And the last question is do you have any recommendations regarding the Agency's review of durability of effect for these devices intended for aesthetic indications?

DR. LoCICERO: Can we begin again with Dr. Li? You actually made some interesting statements in our discussion yesterday concerning timing and evaluation of effect.

DR. LI: Well, especially in this particular context I think where we start off the session with kind of a long laundry list of different devices with different mechanisms of action, and then we also heard by the presenting physicians that there were different time periods at which a maximum effect was observed. So clearly there's a time constant that's in these treatments that as far as I would guess is completely different for each treatment,

both in terms of the initial efficacy and then the way of remodeling that goes on and the type of remodeling that goes on.

So it's a little tough to figure out what the durability recommendations would be for me anyway given the lack of information in all these categories. So I don't really know how to come up with a global suggestion here given all the different mechanisms and devices and the amount of tissue that you're going to use it on. I'm kind of at a loss of how you could come up with a universal guideline on this.

DR. LoCICERO: Dr. Burke.

DR. BURKE: Well, again I just think every individual device should define the time they expect the treatment to be efficacious. So if it's a device that gives a temporary improvement, define the term temporary very specifically.

DR. LoCICERO: Dr. Olding.

DR. OLDING: I agree with that for those products that are indicating that they have a temporary. Absolutely, it has to be precisely defined. For those permanent ones like the ones that were presented today, where there's a histologic change, then I think that the duration of action at

the histological level has to be defined.

Now, I can't determine how long those changes will occur, but I think they have to be documented until they return to a stable -- whatever that is. If it's scar tissue, then that scar tissue was stable and not changing. For clinicians, we often say we will not reoperate on someone for nine months or a year because there's obviously collagen reformation occurring during that year.

So I would strongly encourage following again those changes either out to two a year or until there's demonstrable stability in the change that has occurred.

DR. LoCICERO: Part of this embedded in here is the evaluation. So histology is certainly one solid way to do that. We've talked about cellular issues, and one that has come up before and I'd like some additional discussion about is MR. Magnetic resonance can spin the molecules and we can choose the molecules to spin. And that gives us a deeper look and, in fact, we can focus this with appropriate coils to look at a variety of structures, maybe even small parts. In some interesting detail, in my own field, MR now can spin oxygen. They can spin helium. Now, they can spin xenon, and we can

actually now look at lung structure. We can talk about transfer of oxygen across membranes. We can see a lot of detail that was unavailable to us before. We can look at regional perfusion issues that we've not been able to see. So the technology is advancing pretty rapidly to do some of this. So is this the kind of thing, non-invasive approach to evaluation of cellular and molecular biology that might be useful particularly in terms of durability.

DR. LoCICERO: Dr. McGrath.

DR. McGRATH: Well, I would certainly, you know, respond in the affirmative that I think this is, it may be more expensive, but one thing I wanted to go back to is we kind of dismissed biopsies as problematic in, you know, for aesthetic applications but, you know, I think we're forgetting that the technology of biopsy like all, you know, transcutaneous things has come a long way and you don't need to excise a piece of tissue. There are all kinds of instruments for fine needle aspiration, for core biopsies from a distance and so forth, that if people can go in and take a core biopsy of the lungs safely, we certainly should be able to get under the skin without leaving a scar and take out some fat or whatever to look at that tissue.

So I think it's become in this day and age kind of spurious to say that you can't do biopsies in the aesthetic setting. I think we're past that.

DR. LoCICERO: Additional comments? Maybe Mr. Halpin.

MR. HALPIN: I think that there may be many ways for manufacturers to demonstrate the mechanism of action from a histological point of view. Biopsy certainly is one option. MRI is another option. I think some of these products maybe used in other areas and may have no mechanisms of action. So I think rather than unilaterally deciding one method is the preferred method. I think allowing manufacturers the opportunity to demonstrate that to the FDA from whatever scientific information they have may be a good approach.

DR. LoCICERO: Dr. Walker, you had mentioned in an earlier discussion about the real world and evaluating some of these patients. In the real world, do you feel that biopsy or MR would be other technologies that require return of patient either for some period of time or pain. Is it something that the real world will allow?

DR. WALKER: Actually, I was only focusing that as an idea towards any kind of clinical study of

the device prior to its FDA approval. Not after the fact. I mean there is a possibility in a postmarket study perhaps. I too agree that doing biopsies is not completely unwarranted. However, it seems in the situation where you're looking at fat reduction, that would be difficult where a MRI might be more feasible at least in a clinical study setting.

In the real world, that's difficulty I think. I really think the additional cost, at least for the MRI or the concern about end result scarring in an aesthetic patient would be somewhat of a distraction. Not to say that it's impossible. Yesterday we were discussing fillers and I think there are places that some of these products could be placed that at least in a clinical study they could be biopsied at a reasonable timeframe after the fact, in a setting that can be randomized to look at the tissue or histology at 3 months, 6 months, 12 months, but perhaps off the face if that was the case.

With these devices that we're discussing today, I do think the practical matter is that it's far more difficult. I'm not exactly sure I would resolve that in the real world. So that's why I mentioned it.

DR. LoCICERO: Good. Ms. Rue, in terms of

the consumer, if the consumer was told you can get this new treatment but you're going to have to come back in six months and have a biopsy or some other thing, the only way you're going to get the treatment is to commit to this additional evaluation.

MS. RUE: Well, I think if you're talking about in clinical studies and premarket evaluation, that's one thing, but not once it's approved, out on the market and is given by a variety of providers, no, they're not going to come back because they're done with it, they're on with their life. The clinical studies is a different thing.

DR. LoCICERO: Dr. Anderson.

DR. ANDERSON: I would just like to say one thing about the temporary products. As a satisfaction outcome, if we're going to ask them how satisfied they are and we expect the product to last for six months, in the clinical studies we need to take that into consideration because we're going to see a bell-shaped curve in their response. So I would suggest adding a question such as would you have this procedure done again because that's more of a constant question.

DR. LoCICERO: Other comments? Dr. Newburger.

DR. NEWBURGER: And with the temporary treatment, if there is the opportunity to have the treatment again, the pre-clearance data should show the effect of multiple treatments, and I think that there may be a need to separate the duration of observation for durability and effect versus the safety issues. It may be that the safety has to be looked at for a long period than efficacy.

DR. LoCICERO: Mr. Halpin.

MR. HALPIN: The only thing I wanted to add was that from a mechanism of action point of view, it may be possible in a preclinical or feasibility setting actually demonstrate robustly what the mechanism of the action is rather than trying to put that off to a pivotal clinical trial scenario where you're exposing larger numbers of patients to that activity.

DR. LoCICERO: Mr. Melkerson, I think we've provided a fair amount of discussion concerning this issue particularly for the temporary effect devices, and that there should be some evaluation for the FDA to see from the sponsor.

We struggle with the issue of the permanent devices and when the evaluation should take place. It's going to be least burdensome to sponsor and the

consumer and really can't come to a great conclusion about that. There may be some endpoint that's close in surveillance beyond that point.

Does this satisfy the FDA on this question?

MR. MELKERSON: Yes, thank you very much.

DR. LoCICERO: At this time, I'd like to thank all the members of the Panel, including Dr. Bigby who was here yesterday, for their time and effort and their participation. It's always encouraging to me and a lot of fun and satisfaction to come here for, you know.

MR. MELKERSON: I would also like to thank the Panel for their efforts, also the staffs for putting the presentations together, but as you've gone through your deliberations yesterday and today, you now have exercised the issues that we wrestle with every day. So thanks for sharing your expertise.

DR. LoCICERO: Thank you, Mr. Melkerson. We also want to thank the public speakers and those who provided written commentary to us. It was very helpful in focusing our discussion today.

Again, thank all of you for being here. This concludes the General and Plastic Surgical Devices meeting, and as we adjourn, there is going to

be another session in this room shortly. So please gather your stuff and clear the room and have your discussions outside. Thank you very much.

(Whereupon, at 11:28 a.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

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November 19, 2008

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were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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DOMINICO QUATTROCIOCCHI

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