be disabled. It was actually a functional defibrillator, but we did recall the device. The customer was contacted the next day, and the device was retrieved.

So our recall history is very solid, partly because of the comprehensiveness of the self-test. We call it our recall prohibitor. Because of the fact that we do a full functional test every day, we're able to identify random component failures and products before they occur in an emergency use and we're able to address that.

Now, to answer the rest of your question regarding our actual recall strategy, I'd like to introduce our regulatory Affairs Manager Theresa Scarr (phonetic).

MS. SCARR: Thank you.

I would like to start with our commitment to performing post market surveillance on this product, both now and in the future if we obtain OTC clearance. We have a number of ways -- slide up, please -- number of ways that we currently and will in the future contact customers in the event of a

recall.

Our current procedures require us to examine the shipments and the locations that we have shipped products to and there are three types of customers that we ship products to now, and these will not be changing. We ship products directly to customers ourselves. We drop ship products. That means we send them to customers of some of our distributors, and we also send to stocking distributors, such as retail stores, and so those are already currently on our list of customers.

And I want to point out that our current databases extend further than just the product registration database that Dr. Tovar mentioned this morning. We also maintain a shipping database of all of these locations where we have shipped to, and we have multiple ways of keeping track of where our customers are, including with our post market study and pads reorders.

And so in the event of a recall, our procedure requires consideration of the locations -- next slide, please -- and we work with our customers,

stocking distributors, as needed to contact their customers, and if that doesn't appear to be effective in the procedure, we require effectiveness checks of all recalls. If that doesn't appear to be effective, then we will move to consideration of public communications through press releases, news media, Web sites, Consumer Safety Product Commission, and we continue to work with our distributors as needed to insure the effectiveness of recalls.

DR. MAISEL: Okay. That sounds great. I think the product registration card with the device is going to be an extremely important thing for buyers to understand that they should be sending that in. I hope they don't get the idea that they'll be contacted or tried to be sold other products, and obviously I don't think it should be used for that purpose.

DR. SNYDER: I think it is worth noting that we do provide an incentive for registering your product, and in fact, if you contact Philips to purchase a defibrillator, the customer service actually fills out the registration card on line to

make sure we have that information.

DR. MAISEL: Great, and finally could you just talk a little bit about the expected lifetime of the device? I saw shelf life mentioned. I saw battery duration mentioned, but what is your feeling about the total lifetime of the device with multiple batteries, et cetera?

DR. SNYDER: If I may, I'd like to call our Chief Engineer, Mr. Dan Powers, to address that question.

MR. POWERS: Dan Powers, Chief Engineer, Philips AEDs.

Our specified design life for the defibrillator is seven years, and we base our use estimates and our qualification test planning on that lifetime in addition to what we estimate the use per year to be for defibrillators such as this.

Obviously this product will be a very low use device, and we expect that the lifetime will be well in excess of what we specify internally for the lifetime.

As far as batteries go, there's a four

year standby life for the batteries and a ten year shelf life, and pads are 28 months or 30 months of shelf life with a two year installed life.

Does that answer your question?

DR. MAISEL: It does. I guess I have a little bit of -- now, my recollection is the labeling has an expiration date on the device. Is that true or am I making that up?

MR. POWERS: No.

DR. MAISEL: So there's no way for a buyer to know when their device, quote, expires?

MR. POWERS: There's nothing in the device to expire. The whole purpose of self-test is to -- well, the major purpose of self-test is to detect those types of issues. So the device itself expires when self-test says it expires.

DR. MAISEL: Okay. So you said two different things then. You said the device is expected to last seven years or that it will last at least seven years. So if I'm a buyer and I have a device and it's ten years old and the self-test still says it's okay, can I be comfortable that that device

is going to work?

MR. POWERS: Yes.

DR. MAISEL: And so are the instructions keep your device until your self-test says it's not working? That could be 20 years, 25. I mean, is that your position?

MR. POWERS: Yes.

DR. MAISEL: Okay, great. I don't have any other questions. I guess my general position is that I think the sponsor has done a superb job in demonstrating both the effectiveness and the safety of the device. I don't know that we have all of the information we'd like to see in the population for which it's intended, which is the home use population. Nevertheless I think the benefits of having the device available over the counter strongly outweigh the small perceived or potential risks, which really are hypothetical at this point and not really well demonstrated.

We have heard multiple presentations that there are very few issues of actually harming patients, although devices certainly can malfunction.

I still feel strongly that having them is better than not having them.

I will turn it back to you, Warren.

ACTING CHAIR LASKEY: Thanks, Bill.

Okay. Time for the panel. Norm, did you want to start today or should I start on the other?

DR. KATO: Start on this side.

ACTING CHAIR LASKEY: Okay.

PARTICIPANT: I don't get a vote?

(Laughter.)

DR. KRUCOFF: Okay. Well, let me just follow. A lot of Bill's comments were things that I was interested in. So I'll try and be brief.

And, again, I think we all start on the same platform that this is not a discussion or an argument certainly about the utility or the value of AEDs. I think the real question is what role does the physician prescription requirement play in sort of the whole picture.

And some of the things that have been discussed -- and I will also say that I appreciate very much the array of expertise and information

that's been brought forth both from the sponsors and their experts and from FDA. There are some things that I think probably don't bridge in my mind. The drug prescription model, for instance, really doesn't translate to me where a drug gets purchased for an individual, whereas this is a device that can be in public access in a lot of different configurations, even in a home with a visitor or trained or untrained people.

And the real question in my mind is, again, not the utility that the prescription process or the physician role implies, but with the rapidly changing landscape, where does the physician's discretion or awareness of other issues that either currently or in the very near future may eventuate that makes this more complex or that actually creates safety related issues through a kind of back door that's not anticipated today?

And how much does it matter if we pull that discretion out of the picture?

And I guess what I've been listening for, on the one hand, is how much of an obstruction is the

physician's role today with the prescription to getting the product out there, but the back door side that I guess I'd like to come back to a little bit is with a growing population who have more and more complex AICDs implanted, AICDs that go through phases of defibrillation, rhythm reevaluation, packing, rhythm reevaluation; what are the growing possibilities that the device that's so safe at discriminating defib. and not defib. rhythms -- I'm convinced of that. You guys have done a great job making a convincing show there, but that actually with rhythms that you would want to defibrillate but you're now completing with an implanted device that's actually also doing multiple things over time, where we have an ongoing growing population with these devices, is that a back door to safety issues that we don't see so much today, but that with more access and more implants might eventuate tomorrow that if a physician's prescription was required, there would be a level of awareness of what's changing over time in the patient populations who fly on airplanes or walk through shopping malls and those kinds of decisions.

And that's honestly where I'm stuck because that's not a failure of the device. The device is going to be seeing defib., but the device is not tooled to understand that it may be seeing defib. while something else is also getting ready to defib. or trying to pace or do other things at a point along the way, and I'm sort of stuck on that.

And what goes with that is a concern, and again I'm not sure that the physician prescription is the right answer, but if we recognize that a lot of the data that we've seen about the value of AEDs are in patients who currently -- actually the highest occupations would be identified as candidates for ICDs.

So as we think about a growing access, if we make this OTC and we get into more public access where the highest risk patients have ICDs, we're getting out into a population where, in fact, they're are lower risk population.

I recognized you showed data. Some of these are not predictable. Some of these are not going to be identified ahead of time, but if we look

at what is the shifting terrain over the net five years, more and more high risk patients who are really vulnerable to VT/VF, sudden death events are going to have ICDs. That means fewer and fewer of them occupy the random, undetected population that would benefit from AEDs on a wider basis.

And I haven't seen the numbers, and I'm not sure how we get the numbers, but it really concerns me that we have a changing terrain with more and more complex devices that would actually be involved when this device is correctly charging itself and getting ready to defibrillate, where the expected results or concerns if a physician prescription is in the loop might have more wisdom over time than if we pulled that plug completely.

And then the flip side is how much of an obstructionist is the physician prescription piece as it is, which I get the flavor from everybody who's more involved. I'm a plumber. So you know, this is not my front line, but we do work a lot with ECG devices in a lot of venues, including pre-hospital.

So I guess can any of the sponsors help

me with understanding a little bit better just how obstructive the physician is?

You know, the numbers that you shared, which were very helpful, still don't say to me it looks like the vast majority of people are the 5,000 hits you got on your Web site or whatever. Most of those are people who just weren't interested. It wasn't that the physician turned them away.

And then of the actual physician comments you show, how many really were telling their patients, you know, something that's accurate. You don't need one of these things.

And, again, I know you don't know. None of us can know. So is there some way you can help me understand how obstructionist is the physician's prescription requirement today relative to how different would the access to these devices really be if that was OTC?

DR. RUSKIN: I can't give you a databased answer to that. I think that the best data is what you heard from David Snyder, but I think from that data it's clear that with the limited experience

Phillips has at least with this, even patients who knew what they wanted and understood how the defibrillator worked, a large majority were advised by the physician that they saw not to get a device and were not given a prescription.

I don't think the physician can actually make that decision in the context of what we're talking about here, which is a piece of time critical safety equipment that an individual or a family may choose to have in their home or in any environment. Because it's precisely that group in whom the event is unpredictable, and therefore, I don't think a physician or anybody else provided the individuals who wished to purchase it understand what they're getting can really make an accurate prediction.

And I think that probably gets to the heart of the matter, and what I'm going to say now is pure speculation and opinion, and that is I think most of us as physicians are used to prescribing for diseases, for individuals who have diseases that we can evaluate, quantify, and then make some sort of a risk benefit assessment and prescribe therapy for

that perceived risk or that illness.

We're not used to prescribing for an environment, which is really what we're talking about here, and I think it gets back to the issue that you raised with implantable devices. Yes, it's true that the numbers of people with devices is growing very rapidly, but that is not the target population here, and we follow more than 1,000 patients with ICDs at my institution, and there may be one or two who had AEDs, but none of us know about it because clearly these are people who are on the radar screen. They're followed. We talk to them four times a year.

The issue has occasionally been raised by a family and someone with an ICD, but that's a clear-cut situation in which the individuals are in the medical system and they're being followed, and that's not the target population.

Is there a potential for some interaction? I think one can't possibly exclude that with certainty, but that's what post marketing surveillance is about. That's what experiential observation is about, and I don't see a way to

actually make a dent in the problem without expanding access because this group is not identifiable by you or me or anybody in this room, and it is not within the realm of what we do on a daily basis to be thinking about prescribing devices for these patients.

Most of them will never call a doctor I don't think, certainly not in my experience. I have never had a call, a cold call from an asymptomatic 55 year old saying, "You don't know me, but I wonder if you'd be willing to write a prescription for a defibrillator. I want to have one in my home."

The real question to me is what value does that add, and I can't see any. I can't see any from a safety perspective, and I can't see any from an effectiveness perspective, provided they know what they're actually getting, and I don't think it's the physician's role there. I think that's the role of the manufacturer and the rest of society to educate ourselves about, you know, what is a defibrillator. What does it do?

I don't think that a physician writing

prescriptions is going to fill that need.

DR. KRUCOFF: Okay. I guess to me the question is is the physician writing prescriptions obstructing that, but I understand your comments.

All right. Let me shift gears a little bit. Has any thought been given as more and more of these get out and we have another population that actually doesn't want these used on them in end of life settings as to how or when or why increased access to these devices, assuming that if this goes OTC that the one unequivocal reality will be that more of these devices will be more available, more widely, under a wider range of untestable circumstances.

Have you all considered at all the ethical aspects of defibrillators applies to people who don't want them?, but can't speak for themselves in these kinds of public settings?

DR. BECKER: Well, again, it's not an easy question to really answer. If you think jus the design, this is in the phone. You would think that most people in the home would not put a device there

that they don't want used on themselves, but it is possible that that situation could change and a device could be there. The real issue is not about the AED though. It's about the resuscitation, and so what you're really raising is is it appropriate to resuscitate someone who doesn't wish to be resuscitated?

And, again, that has been reviewed extensively with chapters written about it, and what most, i think, thoughtful people suggest is that until such time as you have sort of a verifiable DNR order, do not resuscitate order, until such time as someone can express the wishes of that individual, most of us feel that the right thing to do is to attempt a resuscitation.

And of course, there are a very few times when that may be inappropriate, and at that point the therapy can be withheld. Additional therapy can be withdrawn at that point, and that has not, though it has been discussed a great deal, that has not turned out to be one of the major controversies or real problems that has emerged in our large scale studies.

DR. KRUCOFF: Okay. I take your point, but I guess what I'm anticipating is we're going to talk about a real life experience that starts to go potentially in a population exposure by a power of ten, and at that level -- and this is an issue, again, that to me is less than the individual home than in a business place, than in an IBM tower that has 4,000 employees in it that currently would have to at least consult a physician to write a prescription before they could put an AED on every floor in the tower, and a physician might actually be smart enough to say, you know, if we're employing people who have a terminal disease, we can have a way of identifying them or if we're employing people who have AICDs, we might have a way of identifying them as opposed to an MBA making the decision because they can now do that as an OTC product that we're less likely to get sued for being an inadequate work place if we have these things on every floor.

It's the shift of that kind of decision making and the real population who we're talking about being treated now not by hundreds of thousands,

but by millions that to me is the least visible reality and least testable certainly in a simulation environment in this kind of potential shift.

DR. BECKER: Again, I don't think we have a very precise answer for you, but I think what we know is that in broad strokes this has not been a problem even though we already have many devices in public settings.

DR. KRUCOFF: But those have all been placed with a prescription, right.

DR. BECKER: Indeed, they have, and as it goes up, I guess my thought would be we should be so lucky as to have that problem because it would really indicate that we have saved many, many other lives in the process.

I'm just saying if you just compare the cost benefit, we know we're saving lives. It may be that we occasionally resuscitate an individual for whom resuscitation is not indicated. That is not anything unique to the AED. I do that in the emergency department all the time, and we know how to take care of that.

So I would only say that we should be so lucky that that is our problem.

DR. KRUCOFF: Well, I wish I could go there. Okay. I just have two other quick, just technical questions thinking back about the individual at home.

Understanding that you guys now are checking your speaker, that you building in a check for loss of speaker function, if Mom collapses out on the sidewalk and I grab my AED as a teenager and in running out the door bang it into the door and break the speaker, is there a back-up function? Is there any LCD output? Is there anything instruction or am I just out of luck?

DR. SNYDER: Excuse me. The back-up is actually the quick reference card which has a detailed depiction of the graphics in the process, and we have performed a validation study, a very small one to evaluate individuals' ability to use this product in the absence of the voice prompts.

Speaker up, please.

This slide shows our results of our

testing under condition of speaker failure with the HeartStart Home device. We recruited 990 volunteers. Again, these are people never exposed to this device. We disabled the HeartStart speaker and all other functionality on the device remain the same.

The quick reference card was present in the AED case, and we presented the same scenario, entry to the room with a manikin, the naive untrained user was asked to attempt to save this person, and AED was available if they chose to use it.

The results were that we were successful in delivering shocks in eight out of nine of those volunteers. The average time to shock was just over 90 seconds. There was one failure due to individual placing pads over the clothing. As I mentioned earlier, this is an issue.

Now, the pictures and the quick reference card do show baring the chest, but we're certainly handicapped when we don't have the voice prompts, but nonetheless, we did have an eight out of nine success rate at delivering shocks in the absence of the voice prompts.

DR. KRUCOFF: Okay, and presumably that would be the same thing if you're just in such a noisy area. There's traffic or whatever that you can't hear the volume.

DR. SNYDER: That's correct. That's actually one of the purposes of the quick reference card, is exactly for that eventuality.

DR. KRUCOFF: Or if you're just excited and it says something, but you missed it. So you go to the card, and it's the same back-up.

DR. SNYDER: You could,b ut now missing a prompt is covered because you remember the device can detect the stage you're at, and if you haven't completed a task, it will repeat the prompt again and again.

DR. KRUCOFF: Okay.

DR. SNYDER: And if you're still failing, it will actually change the way it describes the activity you need to make in case there's a miscommunication or misunderstanding the prompt. We say it a different way.

DR. KRUCOFF: Thank you.

DR. SOMBERG: Well, I've been very impressed by the sponsor's presentations and the concept of this device and the benefit it could do, but with that said, I have a concern that 50 percent of the people who did come and request the -- when through the requesting of the prescription were told that it's probably not appropriate by the physician.

That is a bit troubling, and I empathize in what your statement is, that it's not really knowable what the reasons were, but is it knowable what type of physician turned this down? Was it a cardiologist versus a generalist? Is there any other data that was queried during that interaction with the patient?

You don't look like you're smiling.

DR. SNYDER: No, the answer is easy. No, we don't have that information.

DR. SOMBERG: Okay. Because that would have addressed some of the speculation that we heard that it may have been a lack of physician education, et cetera.

But with that said, and I was going to

ask this, which is what one of the recommendations is later, and I think it's important to say that both the sponsor and the FDA could not come up with an indication or a subpopulation that a physician would clearly identify that would be harmed by this device, and I think that's very important since half of the people may have been told by a physician out there that it was not appropriate, but we really don't really know what that group would be.

And, therefore, I'm suspect on that decision.

Now, this doesn't relate to taking away the physician approach or prescription because it could be said for the device in general, but I'm just going to say it very quickly, that I think there needs to be -- and it was said by the FDA in their review. So I think our doing it is still appropriate -- that repackaging storage and essentially getting it ready for the next use is a potential weakness here, and I think the sponsor could do just a little bit more on certain guides for that, how to get it ready, put it back together, get the equipment.

I know when batteries go dead on things, I said I'm going to reorder them, et cetera, and all sort of things. Clearly it's an emotional experience that will shock people, if you will, into thinking about this, but I think there could be some sort of card that's provided that gives you a checklist on what you have to do that's usually good in that regard.

Also, I think the sponsor should consider that there may be subgroups that are especially likely to buy this who could benefit from some recommendations, and there might be a device patient circulars, if you will, or something like that, and I'm thinking specifically a pediatric one and even a subpediatric in terms of the SIDS population because, I mean, that is a group of potentially at risk individuals. They're parents of people who might be worried about this, might buy that. There may be special training to be used for that, and there may be special information out there.

I always need to be reinforced that respiratory is more important than rhythm in

children, and I'm not even sure. When they get to be this small I get very concerned myself in what knowledge do I have, and I have a lot more than I think people who use it.

So these are some things that could be. Another thing is congestive heart failure, and we talk about pump failure versus rhythm, and You know, I can see we just discussed this extensively yesterday, but there is certainly almost half of people seccumb electrically, and we've pumped this. This is going to be a target population. It may be appropriate for everybody who has a loved one who's at risk because of low ejection fraction may want to be trained in CPR, the use of an AED, et cetera, but there are certainly different situations.

And since there may be a higher frequency of use in this population, but there may be also pump dysfunction, asystole and all of that, there could be a little description of this that a layman could deal with as well.

So I've just been thinking about this for a bit, and it seemed the sponsor really has a very

thorough approach to this. So they may think of the subpopulations in developing a little series of cards like we give out for different diets, you know, for different, you know, gout population with CAD and some other groups.

You might have a different series of cards that could be given out that could be very helpful.

Also, there was one thing that did disturb me, and that was the patient or probably the person who used the device was invited to contact the company after its use. Invited? I mean, I think it should say very clearly and maybe when you -- it could probably be put in as a prompt, as well -- when you rehook up the device and all of that, have you contacted the company and reported the use of a device?

I think that would be very helpful. It's a contribution to humanity in general, to the company, to the validation of the product, and it helps in that regard.

You know, people need to be sometimes

very strongly guided, and when you use something, I mean, clearly when my air bag discharges, you know, I know it's laying around there. When this thing discharges, it's the same sort of thing. It really should be noted and action done.

With that said, I do think that this will make a contribution to the public health, and I congratulated the sponsor for pursuing this.

DR. NORMAND: Hi. I only have a few questions, given that there really wasn't much data presented. I'm going to begin with some practical questions because you could think of me as the naive lay person on the panel.

And I was sort of excited seeing the manikin and all of the action going on, and one of the things that I noticed was the color codes. You have yellow and orange, and I was wondering were there any problems differentiating yellow and orange because I don't know. My husband would say that was yellow, and I might say that's orange.

So did you have any problems in your various tests about the color of the buttons? I

realize sometimes they flash, but I'm wondering if you're alone and looking back and forth.

DR. SNYDER: With respect to the buttons, actually there's only one, and it's the flashing shock button. The yellow was the color of the pad's liner.

We have not noticed any difficulties in the color sequencing.

DR. NORMAND: In the colors.

DR. SNYDER: Because of the fact that the items are marched through sequentially and they're illuminated. Plus the voice prompting reinforces the proper activity at that time. So, no, we haven't seen any difficulty with recognition of those.

DR. NORMAND: And then the other sort of practical thing, I think, there's an obvious answer to this, but we heard it in English. There's Spanish versions and other language versions for this device?

DR. SNYDER: That's an excellent question. At this point we're only asking for consideration of the English version of this product. The on-site product under prescription is available

in multiple languages, and should the marketplace express a desire for other languages, that's certainly possible.

But the device under consideration today is English only. It's labeled as English only, and for any household considering a purchase, that's obviously something they need to consider.

DR. NORMAND: Yeah, given the audit, that's a nice feature of the whole product, is to be automated in terms of telling you what to do, and clearly if you got something and couldn't understand it, that would be a problem.

DR. SNYDER: But I would like to remind of the results of the testing with the speaker disabled, which would be similar to the situation a person speaking a different language would have, and we did have a success rate of eight out of nine naive volunteers never having seen the device being able to deliver shock with effective vector.

DR. NORMAND: Okay. That brings me to another set of questions regarding your simulation test. I noticed in Tab 5.2 there are there are data

here. So I will comment on the data.

DR. SNYDER: Yes.

DR. NORMAND: In Tab 5.2, one of the tables, I was noticing that the education level of the participants, which seemed pretty high -- I think it was 47 percent -- have a college graduate. Now, I don't know. I'm pretty sure that's not really representative of the general population, but again, I'm not sure of the target population here, but that seems like a well educated testing population. Could you comment on the numbers and the successes in a less educated population?

DR. SNYDER: Yes. I need to ask you for reference on Tab 5 because I don't know the study by them. Was it the labeling evaluation?

DR. NORMAND: It's 5.2, Table 1.2, and I have so much information in front of me. It's the safety and usability characteristics, blah, blah, blah. I can give you the page number.

DR. SNYDER: I think the best way to answer the question is we have collected that data in the case of the labeling evaluation study, and we

have analyzed it by both education and age effects, although again, this was data that was not submitted to the FDA because it was not the primary hypothesis, but I'd be happy to share those results again with the Secretary's permission.

MS. WOOD: That's fine.

DR. SNYDER: Okay. Let me bring up the slide, please.

This shows the distribution of ages that we were successful in recruiting in the labeling evaluation study. Now, recall that this was a study where the volunteers first reviewed a piece of the supplementary labeling material that came with the project, performed a written exam, and then proceeded to a simulated use.

You can see the age distribution from 21 years of age up to 740. It's not perfectly uniformly distributed, but it's reasonably good, and what you see is the success in the blue, the failures in the gray, and the failures are certainly fairly uniformly distributed.

This study was not powered to detect

these kinds of effects, but we don't see any reason to suspect that success by age is affected.

Next slide, please.

Owner's manual. This is by education -- oh, excuse me. Never mind.

Quick reference again by age. We weren't quite as successful in getting a uniformed distribution, but we had failures at both the high end and the low end of the age range.

Next slide, please.

And your primary question was regarding education. These are the results by education. For the owner's manual where we had the most failures, we had about equivalent percentages, slightly better in the advanced education, but again, we had in both groups failures.

And with the quick reference guide -- next slide -- the only failures were actually in the advanced education group. Slide down, please.

(Laughter.)

DR. NORMAND: Didn't I tell you? We overinterpret, I think.

The next question I have relates to your survey of households. You had some statistics regarding 145 households that you attempted to contact.

DR. SNYDER: Yes.

DR. NORMAND: And I noticed that you only had a response -- only 78 of the 145 responded to your telephone survey, and I was hoping you could characterize those that did not respond to this household, like where they were. Were they rural households, et cetera, et cetera?

DR. SNYDER: I don't think we have that data. Let me confer and I can find out if we do.

MS. SCARR: I'm Theresa Scarr, the Regulatory Affairs Manager again.

This survey was a survey. We contracted with the Telephone Center to attempt at least seven, if not more, times to contact individuals in homes and businesses,m and through that process there were some that just never responded and never picked up the phone.

DR. NORMAND: That's pretty standard

though, but typically such an agency would then provide you with information about the people who didn't respond.

MS. SCARR: We had the list, yeah.

DR. NORMAND: I'm sorry. I just didn't hear you.

MS. SCARR: We were the ones that provided them with our list.

DR. NORMAND: Okay.

MS. SCARR: From our database, the ones that I've mentioned before. We have provided the contract telephone agency with a list of our home and business consumers of the ForeRunner and FR-2 devices for that survey, and they proceeded to contact them.

DR. NORMAND: Okay. So you had no information that you can provide us regarding who didn't respond.

MS. SCARR: Just their names.

DR. NORMAND: Certainly don't want that. Okay.

I guess my next question is one that is probably, I think, a practical question, and I was

wondering with the manikins, why don't you have little child manikins. Why is it always an adult? Was that always the case? It's an adult-like manikin that's used?

DR. SNYDER: No. That's not always the case. In the pediatric validations, we performed or were done with a toddler manikin. So there are different manikins available, but we've used the manikin that's been appropriate for the primary use, and in this case, the product is really intended primarily, and in fact, the way it ships is for adult applications. So we evaluate it on adult manikins.

DR. NORMAND: Okay. So you don't have any information about the success rate with the pediatric?

DR. SNYDER: Actually we do have data. That was in some of the slides I showed earlier about the ability to both exchange the cartridges and deliver therapy, as well as the pad placement accuracy, and that was performed on pediatric manikins.

DR. NORMAND: Okay. That leads me to the

next question, and I may have misunderstood a response that was stated earlier, but there was a question raised about 911, the order of when you dial 911 and when you proceed with the shock, and I think the answer started out with an adult, that you could go to the shock.

Should I infer by that that if it was a child, you should dial 911 first? I may have overinterpreted the answer that was given.

DR. SNYDER: Were you asking specifically about what's implemented in the product or the comments of Dr. Becker about what's --

DR. NORMAND: The comments by Dr. Becker.

DR. SNYDER: Okay. Dr. Becker?

DR. NORMAND: Were you meaning to say that there's a different rule or algorithm for children versus adults in terms of the order of dialing 911 or administering the shock?

DR. BECKER: Again, a topic that has received great attention by experts, and a difficulty one.

The AHA in their guidelines would suggest

that for a child, unlike an adult, one should first being CPR prior to calling 911 if you are the lone rescuer, and it's for exactly the comment that was raised. The concern over respiratory distress is hypoxia being a leading cause of death in children.

Does that answer your question?

DR. NORMAND: Yes, it answered the questions, but I just then want to make sure. Are those instructions clear that there's a different protocol, so to speak, when you have a child versus an adult?

DR. SNYDER: The answer is, no, we do not have different instructions for this particular aspect of pediatric resuscitation.

DR. NORMAND: So I'll leave it to the clinicians on the panel to comment more for the pediatric sides of things.

I just have one final question. This has got to do with the post market information. You indicated a product registration card that should be filled out. Can you tell me what percent of products actually have a card filled out and sent in?

DR. SNYDER: We do have that information, and let me check.

DR. NORMAND: I don't think that's violating anything, is it?

DR. SNYDER: I need to check with my support team to get the exact number.

We have approximately a 44 percent completion rate with owner's registration cards at the current time.

DR. NORMAND: I'm sorry. Forty-four percent?

DR. SNYDER: Forty-four percent, yes.

DR. NORMAND: Okay, and so that's saying that -- is that across -- that's, of course, stratified, and clearly that must differ depending obviously if they register with you directly. You're more likely probably to get the card than if it's bought -- I don't know -- somewhere else.

DR. SNYDER: I don't have specific information on that.

DR. NORMAND: Okay. You don't have the stratified. Okay. No problem.

That's all I actually have to ask.

ACTING CHAIR LASKEY: Well, in the interest of keeping us on time, I'll defer to the remainder of the panel, but I do have one area that's still bothering me. I'm not clear about your system for getting back to the individual should Philips need to contact the individual for any reason whatsoever, be it upgrades, modifications, newly discovered hazards.

I don't understand your system for this life saving device whereby this doesn't seem air tight. There's no one-to-one connection between your company and the individual that purchased this. The information that you're getting is relating to the wholesale buyer, to the distributors, occasionally to the individual that purchased this.

Can you describe a mechanism whereby you can tighten this up?

MS. SCARR: Theresa Scarr, again, Regulatory Affairs Manager for Philips.

I did go very quickly over the steps involved. So I apologize for that earlier.

For the different types of customers that we ship to, there are different methods utilized. We will always try to directly contact either by phone or by letter whenever we discover an issue that requires a recall.

And for direct sales, we go directly to the customer, with a combination of our databases that I mentioned before. For our non-stocking distributors, we also ship directly to the customers, and so we have shipment records where we can contact those customers directly ourselves.

And for stocking distributors, such as stores and other types of distributors that hold their own inventory, we work directly with them to coordinate recalls as needed.

So the same methods before. We use our shipment records by serial number. Every shipment record is tied to a unique serial number so that we can identify which customers we ship to with those serial numbers, and we contact them directly, and if the product is no longer with the stocking distributor, for instance, we will work with them,

with their own methods for customer communications, including their own databases for direct communications, opt-in E-mail, Web sites, in-store signage, et cetera.

And if that doesn't appear to be effective, then our current process that will remain the same after OTC availability would be to evaluate the need for public communication. In the case that we are not able to contact some customers with an important safety issue that we need to notify them about through these different methods I mentioned before, Web sites, press releases, et cetera.

ACTING CHAIR LASKEY: And did I understand you correctly? I had heard that there were no ID numbers on these units.

MS. SCARR: Oh, oh, there are serial numbers on every --

ACTING CHAIR LASKEY: There are.

MS. SCARR: -- device shipped, and the device itself does not have an expiration date.

ACTING CHAIR LASKEY: I see. Thank you.

George.

DR. VETROVEC: Well, I would just begin by seconding what some of the other panel members have said regarding congratulating the sponsor for really trying to, I think, do a very good job of presenting the material and being responsive.

For my own perspective, the issue of a doctor prescription seems to be probably more of a barrier than a help. One can always think of how a physician could make a good decision or learn something else about the patient that might change it, but there's probably more disinterested physicians who see this as a question that they're not really familiar with and may not give the best answer.

The thing that worries me the most about this is the issue of once the patient is down and someone is trying to manage this, the thing that will make the biggest difference, it seems to me, is their obtaining expert help, which is EMS, and this issue about do you call first or shock first in the setting of being scared, confused, I think this is somewhat of an issue, and I don't know how well to define this

for the individuals using it. But I think that seems to me to be a crucial issue.

And not to design your equipment for you, but in this era of technology, I kind of am surprised that it doesn't automatically call 911 with a GPS system. That's a no charge phone call, and I find that amazing.

That would seem to me to solve the problem, but this is an issue in my mind as to how you get the help that you need to make sure and the pediatricians -- I'm not a pediatrician -- have brought up these issues about, well, if it's breathlessness in a child, it's really why they're down, and this may not be the right device and calling may be the important first thing.

That's the piece that I think needs to be well defined.

DR. RINGEL: First, I'd like to say that I've been persuaded by the information that was provided both here and in our packets as to the importance of making AEDs widely available, the lives that can be saved.

I also agree with the other members that have said this. I've been very impressed by product development by the company and the information provided by the company, the care taken to assure safety and efficacy.

I'm well aware that you can't make an entirely idiot-proof device. There are people that are going to mess it up, but it seems as if the company has tried very hard to address some of these issues.

Having said that, I remain concerned over some of the pediatric issues, and this is a difficult position for me because, on the one hand, we in the pediatric word don't want to be seen as being so difficult that corporations will try to avoid us like the plague.

I was happy to see that you've taken this step to include pediatrics in your product so that if I come along and make all of these protestations, I am afraid that the next time you'll say, "Ah, forget about it. They just cause us too much trouble."

But now that I've said that, I'm going to

launch into some of my concerns. The two paddle design troubles me only because I have trouble understanding how this would work in practice.

Say there's an elementary school that wants the device. So they buy the device, and they say to themselves, "Well, we should have the pediatric paddles in the device."

And then of course, it's much more likely that one of the parents or one of the teachers goes down than one of the kids because it's just way more likely even though there are fewer adults in the school.

So then you have a situation where you have the pediatric paddles in. It's recognized as pediatrics. People come to the device. They either then have to go find the adult paddles and put them in and be, you know, unemotional enough to realize that they have to switch the paddles. So then they go and maybe they even put the pediatric paddles on the adult patient.

Or another scenario where you're in an elementary school and the kid is over 55 pounds.

It's a big kid. We have elementary schools that go from kindergarten up through fifth grade, and some of those fifth graders are very large. So they put the pediatric paddles on thinking that it's a kid. It's a child, and your algorithm, unless I've missed it, gives 50 Joules. It doesn't step up to 150 afterwards.

It would seem like it would be very simple to protect people from making that mistake of trying to use pediatric paddles on a large child or an adult; that you could have easily built an algorithm that the first shock is 50 and the next shock is 150, especially since we agree that, and you've said it in your own, that the American Heart Association says that if somebody is down and they need to be shocked, just shock them. It doesn't matter how much juice you give them. It's an important thing to do.

So that would mitigate against many of my concerns if you had that algorithm built in, that first is low voltage; second is high voltage. So that was one issue about the pads.

I have concerns also then about the issue that you say it can be used for kids. It is a pediatric approved device, let's say, or you market it as such, and then you don't include the pediatric pads. Well, then why bother making pediatric pads? Why not just make a diagram on your adult pads that say if you're going to use this for a kid, put it on the front and the back? And then just have one set of pads, and you have your pediatric front-back and you just shock them with 150 because, again -- and I'm referring to your response to one of the FDA questions saying that the American Heart Association says then it's fine. Just use adult pads and just shock them that way.

It would seem to simplify things. Include the children and not run the risk of complicating the issue, having people fumble around.

That brings me to the next issue, is the fumbling. Most pediatric arrests -- and, again, it's problems when we talk about pediatrics because it encompasses the ages up to 18, and really it's only the toddlers and the infants that we're talking about

primarily respiratory arrest. Once we get to the school age child, if they go down on the soccer field, they have long QT, they have hypotrophic cardiomyopathy, they have, you know, anomalous coronary arteries or something like that.

So we're really talking about the lower end of our pediatric range, the toddlers and the infants. But the issue there is respiratory, and we could get to the point somewhere these were so widely available that people forget the order of things. So that comment about the order of things, I think, should be carefully written in the brochure, in the manual again, that for infants and toddlers, respiration, you know, ABC, airway breathing circulation.

I think you know, that's the mantra in the pediatric world, and I think that that has to be included at least in the documentation, that infants and toddlers, it's ABC. It's not SABC, shock, airway, breathe and circulation.

So I just thought I'd mention those issues. I think those pretty much cover the

pediatric concerns.

I must admit in your answer to one of the FDA questions, Question 12, your last paragraph I didn't understand at all, but I think I have just answered it. Because there are currently no established criteria for assessing the usability of defibrillators, Philips believes this is an important question for the panel to consider and that different usability for criteria for the intended pediatric versus adult use may be appropriate.

I think that's what I just did. I don't know, but I think that's what I was addressing.

That's it.

ACTING CHAIR LASKEY: Are we responding?

DR. RINGEL: I think they're going to try.

DR. BECKER: We are going to try. It's like I couldn't keep the list quite. So I'll try to answer some of those questions.

The first thing is that for the school situation that you raise, which is a really good one, most people would say have the adult pads as the

default position because, in fact, the most likely person in a school to go down is not going to be a child, and so we just know epidemiologically again that the most likely person to have cardiac arrest is going to be an adult, and that's why the adult pads are sort of the default position.

So what is actually required is if it's a child, you have to do the switch, and that part is exactly right.

The critical thing is that I think if you just look at a worst case scenario, the pads are not there. You know, AHA -- and there's good data to back it up -- would suggest just use the adult pads, and we all acknowledge that.

DR. RINGEL: So why have pediatric pads? Why confuse the situation?

DR. BECKER: Well, one answer would be because the pediatric community really asked for it, and there is good reason that at certain weights, particularly in the small children, you begin to deliver more current than is really required to the heart. So there's a good reason to have the

pediatric pad, and the optimal thing would be to use it in a very small person, but at the same time, most of us also recognize, as do the pediatric EP folks, that if you have nothing better, you use what you have.

DR. RINGEL: But will it step up from 50 to 150 on a subsequent shock?

DR. SNYDER: No, it will not. It's a fixed 50 Joule.

And I do want to add you actually put your finger on precisely why we have pediatric pads. Lance, correct me if I'm wrong, but I believe the AHA recommendation is in the absence of a pediatric treatment option for patients one year and older use the adult dose.

But as you mention, the two groups that we're really concerned about is the top of the pediatric age range and the infant, and for the infant, I really don't believe that 150 Joules is necessarily appropriate.

DR. RINGEL: Right.

DR. SNYDER: The other benefit you get by

snapping the cartridge in, that's how it's identified to the device. What is the appropriate device? It also switches the CPR protocol so that the voice coaching you get when you're performing CPR switches to pediatric CPR, and we have to have some mechanism in the device to recognize the pediatric treatment is desired.

Now, we did consider putting a switch on the device, adult versus pediatric, but what we found was that confused and compromised the primary use of this product, which is treatment of adults.

DR. RINGEL: I appreciate all of that, and believe me, I probably haven't spent as much time as you guys thinking about it because you, I'm sure have talked about this a lot, but I have thought about it a lot. The chance that you need to shock an infant, like I say, you said under a year is small, but the chance that you might need to shock a child playing soccer or whatever goes up a bit, and my concern is that someone well meaning will think that that's a small child, put the small pads on, and get 50 Joules and that's it.

So it seems to me that you're more likely, even though this is rare -- all of this is vanishingly unlikely -- but you're more likely to be erring on the side of under treating an older pediatric patient than over treating an infant or small toddler.

If the panel, EP people here -- tell me what you think about that, but my concern is that you've got that big elementary school kid, and they put the pediatric pads on. They miss the 55 pound or whatever, think it's a small child, and they're not delivering enough.

DR. SNYDER: I actually do have some data that I can share. Again, I keep apologizing for going to unpublished data.

DR. RINGEL: Okay.

DR. SNYDER: But we do have a post market study of pediatric attenuating pads that the 50 Joule defibrillation capability that's ongoing, and we did present to the last scientific session's interim results. I do have updated results. Again, the FDA has not reviewed this data, but I would be happy to

share it with the Commission.

MS. WOOD: That's fine.

DR. SNYDER: Okay. Slide up, please.

To date we have -- excuse me -- as of July 4, we have 22 reported uses of the 50 Joule attenuating pads for treatment of patients. The age range was from five minutes of age to 23 years of age, which I hope is going to address your question. This was a very small adult, and in the case of the 23 year old, it was actually a medical professional that made the judgment that a reduced therapy was appropriate for this particular patient.

Five of these patients received shocks, four VF. The ages were 18 months, three, seven, eight, and ten years. Average number of shocks required delivered to each patient was two, and four of those patients survived to hospital discharge. So that's four or five patients treated with this therapy did survive to discharge.

It was judged the AED performed appropriately in all uses, and again, no safety problems were recorded with use of the product.

Slide down, plesae.

DR. RINGEL: Well, that obviously is very interesting, and again, as I stated before, it's very nice to see how much work you have done on this.

So a ten year old, a normal size ten year old responded fine to the 50 Joule shock.

DR. SNYDER: That's correct.

DR. RINGEL: So I should feel better about the risk of under treating by misplacement of pads on large children.

DR. SNYDER: It's certainly an issue that can't be dismissed. I think it's a fairly minimal issue, however.

DR. RINGEL: Okay, and an algorithm of ramping up is not practical or was rejected because?

DR. SNYDER: Well, interestingly the energies that we're using compared to previous protocols were considered rather high.

DR. RINGEL: Okay.

DR. SNYDER: Compared to weigh based protocols used with MDS defibrillators, we're actually delivering a fair amount more energy to the

smaller patients. So we did go ahead and advance the energy to give us a large degree of margin for these in-betweeners where accurate age and weight determination could not be performed.

DR. RINGEL: Okay, and then the final questions, again. If this is felt then to be the appropriate way of going, why are you not giving the pads in the kits?

And then the other question is: if it's likely that the -- which is a corollary to this -- it's likely that the pediatric pads are not going to be used, they're likely and I would agree that the thing that makes most sense even in an elementary school situation, which as I said before it's going to be an adult so that the adult pads should be in the machine.

The pad that's in the machine will be checked regularly. The pad that sits in the foil pack will not be checked regularly. So if someone goes and buys the pediatric pads, there's no way to know that that pad is still functional as opposed to the one that's in the machine.

So, again, that would be another concern over the two-pad system, and then, again, the question: why are you not including the pad if you think it's important for kids to have the small pads?

DR. SNYDER: I do want to acknowledge that you have some valid concerns regarding two pads and confusion. I don't want to dismiss those, but I do want to try and address as best I can the concerns with respect to this product.

A pad that has not been or cartridge that has not been installed into the device actually has another layer of packaging around it that performs another vapor seal, which greatly extends the life of the pad. So the day-to-day pad testing which is really performed to insure that the packaging has not been accidentally compromised, for example, by poking a hole in it, is really mitigated by the fact that there is an additional layer of packaging on top of the pediatric pads when they're stored not in the device.

I think you had another concern I wanted to address, but I have forgotten what it was.

DR. RINGEL: Why aren't you giving the pads?

DR. SNYDER: Why aren't we giving them away.

DR. RINGEL: Right.

DR. SNYDER: One of our interests certainly in doing this is achieving broad dissemination, and I think our real purpose was not to burden the cost of the basic product for its most common application, which is the application for adults, and there are certainly going to be households where no children are present.

It is available as an accessory item for anyone that's interested in purchasing it.

DR. RINGEL: Thank you.

DR. ORNATO: I have just one question to begin and a number of comments. And my question is perhaps going to seem a bit odd, but perhaps you can help me better understand your intent. The device is entitled HeartStart Home Defibrillator, and yet I don't see in the indications for use or contraindications, unless I've missed it, anything

either restricting its use to the home or not restricting its use to the home.

We're to pay attention to the labeling and where it's leading the user. What am I to understand about the intent of this product and will there be any, in your minds at least, any issues with respect to restriction because of the label you've chosen?

DR. SNYDER: You are correct in observing that there are no particular restrictions in the labeling materials, and in fact, as I mentioned, this product is identical in the case and the defibrillator itself is the product we saw for corporate markets.

Where it has been specialized for the home is actually in the additional materials that are provided with it, the training video. The owner's manual is different from the corporate owner's manual, and so forth.

So the labeling components have been optimized for understandability by a home purchaser in order to enhance their ability to use the device.

DR. ORNATO: If this device were to be granted over-the-counter status, and a corporate user was to purchase it -- and I don't know if this is a question for you or perhaps my colleagues from the FDA, but it would certainly be enlightening to me if it's a fair question in terms of process to understand what that would mean in terms of its ability to be sold.

DR. SNYDER: I think it's more a question actually for the agency.

DR. ZUCKERMAN: I don't think that's the primary concern we would have. I think the primary concern is what we've dealt with all day, which is the risk-benefit of removing a prescription label, make available to the consumer the device, and do we still end up with a positive risk-benefit profile.

DR. ORNATO: Okay, wonderful. Thank you for that clarification.

Okay. That said, I just have a couple of very brief comments that I'm hoping may help my colleagues on the panel and the FDA maybe understand a couple of additional things regarding some of the

questions that have been posed that haven't, I think, been fully resolved.

As you heard earlier, I've had some personal involvement in the PAD trial, and I think there are some lessons that we've learned that have relevance to this device question that we're being asked, and there are also some notable differences.

And so briefly, the similarities are that we're really talking about lay persons. The differences fundamentally are that the lay persons in the PAD trial were trained and in advance were identified, and so as I'm trying to process the question regarding this device, there are from the get-go some issues with respect to getting into an area that is really to some extent a bit of an extrapolation beyond the information we have from the PAD trial in that these are not rigorously trained rescuers.

On the other hand, I think it very clear even in the PAD trial that were was remarkable safety to this family of devices, and in the PAD trial the specific devices that were used were an earlier

generation without the kind of, if you will, protective features that this device appears to possess in terms of coaching and guiding the lay person, and actually keeping up with them in real time whether they require prompts very quickly or not so quickly at all.

In the PAD trial, we really had virtually no issues of safety with respect to the devices harming patients. We deployed thousands of defibrillators 20,000 lay persons over a couple of year period. No one was shocked who didn't need a shock, and not a single person who required a shock failed to be shocked by this family of devices.

So I guess my personal confidence is that even the predecessors to this device in the family have already achieved a fairly high degree of safety, and certainly from what I've learned today, it appears as though this device is, if anything, setting the bar higher.

As far as ICDs, Dr. Krucoff's concern, I think you're right, Mitch that clearly more and more folks are going to have ICDs, and interactions are

going to be, I think, an increasing concern as time goes on, but the number is still relatively small.

I am aware of one case, not published, but I've seen the case, seen the strips of approximately ten years ago where there was an interaction between an AED, a much earlier generation, and an implantable device where both committed to fire roughly at the same time, and one fired first. I think it was the ICD. Then the AED fired. The ICD got the patient out of defib. The external put him back in, and the ICD immediately cycled and got them back out and the patient did okay.

So the only instance that I'm aware of proved to be not a particularly important one, but I think, as Dr. Krucoff has pointed out, these isolated exceptional cases, I think, over time will have to be watched, and I like the fact that there's a surveillance that's being proposed to look at such things.

As far as the issues of efficacy of this device, I think the PAD trial would give me a lot of

confidence that lay persons likely can use this device safely, but I think the efficacy is likely, but yet to be proven, and that's just a personal opinion.

But I wanted the panel to be aware if you're not aware already that there is an NIH sponsored trial called the HAT trial. Dr. Gus Brady is the principal investigator from Seattle, and it is unrelated to the PAD trial in that it's a different group of investigators.

However, it is somewhat related in that it is putting AEDs in the hands of lay persons, but that trial will be, I believe several years. So I don't think there will be a lot of data that will help the FDA or the panel anything materially beyond what we likely know already.

And finally, the issue of what is the value of the prescription is one that I may be able to help shed some light on from a maybe personal point of view. As a medical director for a city EMS agency, I'm the EMS director for Richmond, and I wind up writing most of the prescriptions for AEDs that

are used in public places in the city, and typically I'll get called because -- and this is not for home use so much as for public use businesses, hotels and the like. The typical call will be that an entity, a corporation, an office, a gum, a YMCA, et cetera will make contact with a physician and try to get a prescription, and the sense that I've gotten is that there's a discomfort on the part of many physicians with writing the prescription.

I think some have expressed to me a concern about liability. I know a number of our physicians in the committee have called me personally asking about what their personal liability would be if they wrote such a prescription. I don't think this is a trivial issue, and I think the medical directors in communities, perhaps the colleagues that I have that shared their experiences are somewhat similar, and I think that may be in part why we're seeing some of the experience that until today I was unaware of in terms of what you've stumbled into.

So finally, in my mind this question is really boiling down to, I think, a point that a

number of our colleagues from the company and their advisors and their consultants have made repeatedly, and that is I'm becoming persuaded strongly that the fundamental paradigm, to use your term, that we physicians operate under, which is we write a prescription for a medication or a device for a specific patient or for a specific user of a device for a specific patient. It's really not applicable here, and I think I'm beginning to see that more and more clearly.

Even when we medical directors write prescriptions for public access defibrillators and we have a cadre of trained people in a public building, just as in Chicago O'Hare's experience, we have no idea who the victim is going to be, who the patient is going to be, and to a great extent we have absolutely no idea who's actually going to use that device.

And so I think that internally is perhaps driving maybe more than almost any other of the important issues that we've all struggled with today to have to conclude that the real intent of the

prescription really is not being met here, and therefore it falls back, in my mind to the regulatory two issues that our colleague started the day with.

You know, is the labeling sufficient for the layperson without a physician? Is it sufficient for that layperson to be able to safely and successfully have reasonable probability using the device?

And I think this specific device appears to have set a fairly high bar, at least in my mind, in meeting that requirement, and so I think I will stop there. That's kind of how I feel about it at this point.

DR. KATO: I have a couple of comments and a couple of questions. I look upon the issue of AEDs as we've been struggling today, and I have to agree with many of my panel members who stated that we don't really have the data to extrapolate from, you know, corporate or public access programs.

It's important to understand that there is federal and state legislation that requires standardized and proper training, annual review

processes, coordination with local EMS facilities, medical director coordinators and a public access defibrillator director. Overall emergency response has to be working, as well as scheduled maintenance and quality assurance of the device, and ancillary medical equipment provided by an EMS team.

And I think that many of these facets of what makes the AED work and the amazing results that we've heard today not only in testimony from members of the public, but also in our panel packets and certainly from the sponsor, attest to the fact that in many cases there's a very good system out there that supports people who have been shocked by and resuscitated by an AED.

To some degree I think the AED is a little bit ahead of its time in that if it goes out in an OTC fashion to the general public without the public understanding that these are the inherent assumptions behind the support system of making this AED work, I think that there may be a lot of problems, you know, with the public in terms of accepting these things for the long run.

I'm also a little concerned that we did not have data regarding the storage and maintenance of this device. As the sponsor clearly stated, most of the time in the general public this device will be sitting on a shelf gathering dust, and how does it respond just sitting there for four or five years before it's ever used?

And that to me are some of the still critical questions that I have to ask about the device per se. I think that as far as the physician prescription issue, that is becoming one of a regulatory nature. I think that to some degree we are dealing with laws that have been written years ago and we have technology that's changing, and maybe we need to change the laws that govern this.

But in general, I guess I'm a little bit concerned that we are raising the expectations of the public in this matter by claiming the -- and rightly so -- pointing to many of the great successes of this device without the underlying assumptions of why this works.

On the other hand, I must congratulate

the sponsor for working through a tremendous number of issues, and it is very gratifying to see a company so devoted to making a product the best it can be, and having touched it and played with it a little bit before the afternoon session, I just have to tell you I think it really does work.

It seems to -- you know, it's a nice weight. It looks nice and all of those good things that go with a good product, but I think that there are still several issues that I have to be very concerned about, you know, regardless of whether this becomes a physician prescription issue or not.

DR. SNYDER: I want to make sure I address all of your questions to the best of my ability.

The first was a discussion regarding the relationship with EMS. One of the things that makes such a discussion so difficult here is that these are state regulations, and they actually vary from state to state, and they're very much in flux.

What I can tell you is that Philips sells a lot of defibrillators. We sell in all states.

We're very used to working with these various state regulations and requirements and support them, and in fact, we often use or work closely with the states themselves in drafting legislation.

What we can do is maintain a database, for example, on the product Web site with information about contacting local state agencies to determine what those requirements are. That can also be available through the telephone customer service.

So the information can be made easily available to the consumer.

I'm trying to remember the second question you had. Can you remind me of your second point? There was the EMS relationship. Storage.

DR. KATO: Storage.

DR. SNYDER: I think the best answer I have for you there is that the technology, the self-test technology that's used in the HeartStart Home is similar to what's used in the ForeRunner and FR-2 products, and we simply have no history of difficulties related to storage of the device. The self-test is actually very good at detecting any

problems that exist and alerting the owner of those problems.

We did, by the way, in the labeling evaluation -- part of the questionnaire, and the questions, I believe, were communicated to you in your panel pack. If not, I know they were in the 510(k) submittal -- many of the questions had to do with maintenance and storage and putting the device into service. So we did to that extent validate the ability of people after reviewing materials to put the device or at least their knowledge of how to put the device into service, how it should be stored, which is near a phone and a visible place, and what steps, how maintenance notification is given to the customer, and the steps that need to be taken when that happens.

ACTING CHAIR LASKEY: We are actually ahead of schedule. So congratulations.

My suggestion, even though we call for a break, is we were here late yesterday, and my suggestion is to move forward. Is that supported?

I have one question before we get to the

questions. You may have answered this in passing, but are you prepared to distribute this device at no cost to individuals who want it and can demonstrate sufficient need?

MR. MORTON: Dr. Laskey, it's me. Isn't that moving into more of the business plan and business aspects of that particular sponsor?

ACTING CHAIR LASKEY: Well, that's for someone else to answer. I've sat here for almost five years now and never been concerned about the inequities, the societal inequities of these deliberative processes. This is the occasion where it actually comes to mind. This is not a prescription. This is out there for purchase over the counter.

So you answer that. To me it's more of a rhetorical question, but I will --

MR. MORTON: My personal answer is I absolutely understand your concern as a caregiver, and I understand how that might be of interest to each of the members of the panel, but I do not believe that this panel is the forum for that

question to be asked.

MS. WOOD: As the Executive Secretary, I'm going to have to say that that's out of the purview of this panel. We do not consider economic considerations for any of the products that we look at. Otherwise it could bias the opinions of these panel members.

DR. MAISEL: Dr. Laskey, could I make a comment?

A related issue, and maybe I'll try to rephrase your question because I have struggled with the same issue, and I think it is relevant because it relates to the prescription question that we are asked to deal with. Maybe a more generic question would be maybe the sponsor could comment on the expectations of availability to lower income populations or just a generic question about the availability of the product by removing the prescription requirement and potentially removing insurance coverage.

So for patients who a physician still feels the device should be prescribed, there will

still be that availability.

That wasn't very well stated, but hopefully you get the gist at the question.

MS. WOOD: I'm sorry, but that's still not the business to be conducted by this panel.

Yes? Yes.

MS. MOORE: I noticed on one of the slides presented by the sponsors that there was an indication that four percent of those persons who were offered the device refused because of cost.

So when I saw that then I said since it was introduced by the sponsor, then maybe this would be a legitimate concern to express knowing that the panel could not deal with it because this is not what we're talking about today, but if, for instance, I were to make a comment now, I would let it be know that I really had concern about that large population out there who would fall in this category of the four percent who would not be able to afford the device.

MS. WOOD: Well, I would have to say that on the other over-the-counter devices I would imagine we have not been able to consider this. We don't

consider cost, and that's the purview of another governmental agency to look at the cost.

DR. KRUCOFF: Geretta or Warren, can I take a third crack at --

ACTING CHAIR LASKEY: This is not about cost. This is --

DR. KRUCOFF: Let me see if I can ask it.

ACTING CHAIR LASKEY: Just let me finish, Mitch. This is not about cost. This is about what we've been referring to is the removal of a barrier. I don't see the prescription and description in this case as a barrier to the acquisition or the allowing of poor, uneducated, lower social run patient, however you want to call this. That actually facilitates the access to this sort of health care, removing this, quote, barrier, which is a facilitator in this case, will represent an impediment to the access to this technology for a significant portion of the patient population, which probably is at greater risk, the LVH patient, and so on and so on. I needn't go into it, but I'm sure everyone on this panel is aware of those individuals in the general

population who are at high risk for sudden cardiac death who have not been part of the system.

DR. KRUCOFF: So can I ask the agency? If a product becomes an OTC designation, does that de facto prevent doctors from writing prescriptions for the device?

DR. ZUCKERMAN: I don't think there would be any need to write that prescription.

DR. RINGEL: Besides the insurance company wouldn't pay for it because it's available over the counter. So it becomes a moot point whether the physician writes the prescription or not.

DR. ZUCKERMAN: Okay, but I do want to reiterate Ms. Wood's comments. Certainly the agency appreciates some of the impact of a device like this on different socioeconomic strata, but that type of line of questioning isn't going to fortunately impact one way or the other on how the FDA makes a decision.

We have to make our decision based on the charge that we defined this morning, which is we have a prescription label right now because at a certain point in time we thought that there was a certain

device complexity that required a prescription label to adequately allow for a safe risk-benefit profile when this device is used.

Through a careful development program the sponsor has tried to move forward and that's really what the agency is asking for this afternoon. Has the sponsor moved forward to a different point now where that prescription label can be removed?

I realize that that's a narrow focus, but it is the focus of this afternoon's discussion.

DR. RUSKIN: May I offer a comment? I think this obviously is a critically important issue, but I think there are some misconceptions here. Current approved indications in which an insurance company will pay for an AED are extremely narrow. So for the vast majority, if I were to write prescriptions for 99 percent of people out there who are likely to want to buy them, they won't be covered. Their insurance will not cover them unless they fit a very narrow spectrum.

In addition, there's no reason to believe that lifting the prescription requirement will

eliminate my ability as a physician to prescribe within those accepted guidelines. For example, if I want to buy a walker, I can go into a pharmacy tomorrow and buy one without a prescription, but if I need one out of medical necessity, it's a piece of durable medical equipment that's covered by my insurance company.

And I don't see anything about this that would differ. I can't speak for insurance companies, but certainly there's no reason to think a priori that this will be treated like an antihistamine and suddenly not covered.

In addition, what is covered at the moment is a minuscule set of indications. It's a tiny, tiny portion of the population.

ACTING CHAIR LASKEY: I understand.

MS. WOOD: Okay.

ACTING CHAIR LASKEY: And lest Geretta has a fit, I think we should probably should abandon this line.

MS. WOOD: This needs to be tabled, yes.

ACTING CHAIR LASKEY: I appreciate your

response though. Thank you.

Okay. Do you want to go through the questions then?

MS. WOOD: Yes.

DR. SOMBERG: Are we going to have a break for a minute?

ACTING CHAIR LASKEY: We voted.

(Laughter.)

PARTICIPANT: He's voting with his feet.

ACTING CHAIR LASKEY: Okay.

MS. WOOD: Let's take a moment to bring the slides up.

The first question regards usability testing and product labeling. In terms of how a lay user would interact with the device, Philips usability testing focused on the ability of untrained users to set up the device to place pads promptly, to deliver shocks safely, and to know when to choose adult or pediatric pads.

Philips' usability testing did not cover other tasks, such as self-training, storage, and maintenance.

Please comment on the adequacy of the testing that was performed to support the notion that lay users can safely and effectively use the product.

ACTING CHAIR LASKEY: All right. Well, the tradition here is I take the lead and you just tell me where I'm wrong or right, but I guess I'm getting a warm and fuzzy feeling that we all seem to agree that Philips has certainly done a commendable job to support the notion that users can safely and effectively use the product.

But there are a number of exceptions. Certainly Norm has just spoken articulately to the maintenance aspect of things, for example, and I guess one thing that still concerns me, and I'd like to hear if this is echoed in the rest of the panel. It is just the patient, the subject population in which this was evaluated. I'm not sure that this is a representative sample of the kind of people who will be looking to buy this.

I didn't want to get down to the nitty-gritty and ask where these three shopping malls were, but I could just see from your bar graphs of the

level of education. That's generally above where we set our own bar, which is somewhat lower in terms of reading ability, comprehension ability.

So just join in, panel. Am I out in left field here? Do I --

DR. RINGEL: Well, I don't see how a physician prescription helps further the goal of educating people in using the device correctly because we might like to think it's all Marcus Welby out there, but it's unlikely that physicians will sit with their patients and then instruct them in its use.

So I don't see the physician prescription protecting people from not understanding the device.

ACTING CHAIR LASKEY: That's not the question we're being asked. The question is to assess the adequacy of the testing that was performed.

DR. RINGEL: Right.

ACTING CHAIR LASKEY: Not compare it to Marcus Welby.

DR. RINGEL: So my point being -- I'm

sorry. I didn't mean to be facetious -- is that I think it is adequate to show that the device would be used as effectively as an over-the-counter product as it is by a prescription product. That's what I meant to say.

DR. NORMAND: Can I comment that I did indicate in my earlier comments that, indeed, I felt that the sample for the simulation studies were not representative of the general population, that the education level was much higher in the numbers that I had seen.

I also commented about the language issue as well, which is also not representative of the population.

ACTING CHAIR LASKEY: Bill and Mitch.

DR. MAISEL: I think there are obvious shortcomings in the testing that was done. I think that the most impressive thing to me was the success rate of this newer device after testing in patients who had no instruction and were able to take it out of the box and use it properly was extremely impressive, I think, due to the diligence of the

sponsor.

I think things could be better, but I'm comfortable with where we are. I guess the only caveat I want to put in is my feeling of personal incompetence to address some of the science of user interface testing. You know, you can look at the numbers. Does it sound rational? Does it make sense?

As a plumber I can give a comment, but I also don't want to over represent the limit which at least I feel competent to comment on how reflective. I think we're all clear that you can't simulate the real event with the stress and that sort of stuff, but there is a whole other science of user interface testing and compatibility that I have to admit is not a personal area of expertise other than a very broad, gestalt answer to some of these questions..

DR. ORNATO: You know, there's another side of this. I'm sort of viewing making a device like this over the counter sort of like consumer electronics in a way. I know I struggle sometimes, and I'm pretty electronically literate, in trying to

figure out, you know, the metaphor, how to program the VCR.

And I'm a little bit concerned that although I understand your perspective and I think it's a fair one, what I'm struggling with is what really is the fair bar to put here. You know, if the fair bar is that 90 percent or 98 percent of the population should be able to use something that's technologically, you know, got some challenges for some individuals, then I think we'll never make progress in this area.

You know, I've been impressed with the steps that have been taken that have gone beyond any of the medical devices that I've personally had any involvement in using as a physician or even as a lay person, you know, if it's outside of my area.

So I think the issues are correct. You know, it certainly would be great to have much bigger samples and much more diverse samples, but I've been really quite impressed that even in the lower, least educational groups it doesn't seem to be a major impediment to using this device.

DR. KATO: You know, in the heart surgery valve area, valves are tested for durability and there are engineering methods used to simulate, you know, years of use. So one of my concerns here is -- and I agree with the sponsor -- these things, I believe, are going to be sitting on, unlike, let's say, the PAD trial or any other trial that's using patients who are at risk; so they're going to have events of sudden death at their house. I think most of the time these devices will be sitting around for years, and I don't believe that we've had enough data to support whether they can effectively survive that long without being shocked, tested every week, rechecked every month to say what's going to happen five years down the road.

ACTING CHAIR LASKEY: That's actually Part B of the question.

DR. KATO: Oh, sorry.

ACTING CHAIR LASKEY: That's okay. Thank you for the segue. But I guess we don't have to have consensus here. You just need to hear our thinking; is that the gist of this?

DR. ZUCKERMAN: We want to try to put things together in the best way possible. So at this point we heard comments that have ranged all over the block. Certainly the panel has indicated that there are certain problems with the adequacy of the testing, the representativeness, et cetera, but, Dr. Ornato or others, would you submit that even given the limitations of the testing together with some of the other external data that you're aware of regarding the PAD trial and other sources of data that together there's enough or does, you know, 1(a) still bother you?

This is a very important question to see if we can get some better consensus.

DR. ORNATO: Dr. Zuckerman, if you're asking for sort of a personal opinion, which I guess is the only thing I can provide. I'm comfortable that although not idea, I think I've seen enough that I'm comfortable that we will likely be doing enough benefit. In other words, enough people, I believe, will likely be able to use this device in the setting for which it appears to be intended that I'm

comfortable, you know, with what I've seen so far.

DR. VETROVEC: To some degree this is a device that once it's off prescription, it is going to be driven by the interest of various members of the population, and I would guess that the survey probably came close to fitting the individuals that will buy this device. And it's not prescriptive, and that may make sense then.

Is the population that we would expect to use this device going to be able to operate it? And I think the answer to that is yes.

DR. SOMBERG: I'm not sure how usability testing and product labeling really changes much from the current device that is approved versus the 510(k) application which takes away the physician prescription requirement, and I think it's the same device out there, and my comment may relate to a lot of other questions. And for the brevity of the meeting, I think we should try to focus on the charge of the committee, which is the recommendation to take that away.

Because I have a lot of comments on the

device and what could be done to make it better, et cetera, and I think some of the things that were said today about the pediatric considerations were very much appropriate, but once again, I can't see how that relates to whether a physician gives a prescription or doesn't give a prescription.

If someone can explain that to me, I will not bring it up again.

DR. ZUCKERMAN: Okay. We're still on one --

ACTING CHAIR LASKEY: Of course, that's not the question, John. The question is has what we heard today met the needs of adequacy of the information base. Let's try and stay focused here.

And the answer seems to be -- yes, Bill. Sorry.

DR. MAISEL: I was just going to add if one of the concerns -- it's not one of mine -- but if one of the concerns is regarding less educated people, perhaps less data than on high school or college educated people, I guess I would ask the question: what if that data did not look as good?

I think the sponsor has done a very good job of making things as simple as possible, and if someone is told to remove their clothes and cut them off, if necessary, and they don't and they still put pads on, those people can't be helped. I mean, I don't know what more you can do.

(Laughter.)

DR. NORMAND: Well, I guess in terms of the question that was raised, and I realize I don't understand the barrier or non-barrier of a prescription. I don't know if there's a selection process that the physician makes about, you know, who's smart enough or facile enough to use the device.

But all I'm saying is that if you were to look at that, that is not representative of the population, and you know, that may or may not have anything to do with the removal of the prescription.

However, that does tell me in a very simulated, pristine experimental setting, I'm going to get an overestimate of it. Those are the numbers. Now, if you're going to tell me they're all going to

fail if I've got a lower educated population, maybe the company might change something and do something a little bit differently.

I'm not saying that they need to or that they must, but surely the fact that the distribution, the demographics of the population that participated in the simulated testing situations were different, and I think that we can't guess, you know, sort of which way it's going to go. I don't make up data.

DR. KRUCOFF: And my understanding of the intent of the question is that if this device is shifted from a physician prescription to OTC, that part of the assurance that we're being asked to evaluate with this question is even if the physician currently isn't doing his job, that's not the issue. Currently if a physician write a prescription, they're in the mix, and some of the responsibility for how the device performs, the physician is in that mix.

If we take the physician out of the mix, is the labeling construct and in this case is the surveys or experiments that have been done to assess

the materials available to the consider sufficient to have them operate the device?

And that is where to me the question on this particular aspect lives, and it seems like we have sort of a range of feelings.

DR. SOMBERG: I must say that I don't see how the physician is in the mix when we talk about the overwhelming majority of uses of the device has been in the public arena. You don't know who you're going to prescribe the device to be used on or who is using the device.

DR. KRUCOFF: No,w John, you're talking about reality thought, and I think what we're talking about is --

DR. SOMBERG: Yeah, that's all I ever do. That's all I ever do. I'm not a dreamer.

DR. KRUCOFF: I think the issue here is a regulatory issue. If you take the physician out of the mix.

DR. SOMBERG: No, but I think what a regulatory issue should be focused on is there any special population we need to protect, et cetera,

special testing that needs to be done, usability, et cetera, that the physician would identify or would have identified, and that would change the device, and I'm just saying, you know, 95 percent of the uses are in the public arena, that the physician really doesn't do any of the screening, is saying the device has worked out very effectively from all data we can get, and it's a lot better than some of the prescription devices we've talked about, even implantable devices, in the past.

So I'm just very impress by that, and I don't see why we should, you know, go over and over. You know, maybe we could be helpful in another forum, but over and over a device that's approved. We're just asking for one thing. Should a physician interpose himself, and I haven't seen any data to suggest that taking that away would place any increased risk, and the experts have testified that it would increase the potential benefit.

ACTING CHAIR LASKEY: Well, you keep going there, John, but we're still trying to answer the question. So that's --

DR. SOMBERG: Well, I can say that the question is --

ACTING CHAIR LASKEY: Yeah, I think Dr. Zuckerman and the agency have probably heard the spectrum of opinions up here on the adequacy of the testing that was performed, which I guess is one way to view this, is just the patient brochure.

DR. KRUCOFF: Warren.

ACTING CHAIR LASKEY: Yeah.

DR. KRUCOFF: Can I risk -- you know, part of the flavor of this to me does suggest that if it was not unduly burdensome that providing some additional similar information in an independent population that maybe leans a little more toward the less educated side would probably be reassuring if it had similar looking profiles to what's been demonstrate.

ACTING CHAIR LASKEY: I'm not sure I'd say less educated. I'd just say more representative, but --

DR. KRUCOFF: Well, I didn't mean that in a derogatory way. I meant in an identifying, you

know, sixth grade level, seventh grade level population, that it would be reassuring.

ACTING CHAIR LASKEY: Perhaps it's tangential. I don't think so, but we've heard the theme repeated that this is not just the box. It's the system here that we need to think about, and the support system, the EMS system, the whole aspect of getting the ancillary care going.

So let's not forget that it's just the box that we're evaluating here. It's also the 911 aspect and all that ensues from that. The box, as someone pointed out, wouldn't work very well without the infrastructure.

And I can't even begin to think of the impact of this on 911 calls, but let's move on.

Since actually, Norm, you already took a crack at (b), is to comment on whether it's necessary to establish other aspects of usability such as self-training, storage, and maintenance as a prerequisite for removing the label.

DR. KRUCOFF: Well, I think that's true. I think there must be more data regarding self-

training, storage, and maintenance before you can removal that label.

ACTING CHAIR LASKEY: I guess my question is: how do you simulate shelf life?

DR. KRUCOFF: I'd have to defer to an engineer about that, but there must be a way to do that.

DR. MAISEL: Or perhaps simply just stating explicitly what the recommendations are would be a step in the right direction.

DR. KRUCOFF: This was one area where I think the track record of the previous platforms actually I found to be helpful, and I'm not an engineer, but we deal a lot from the device side, but I see no radical change in the platform, and at least as the company has reported, their self-test environment seems to be pretty robust over at least the generations of a device sitting on the shelf for years at a time, as long as somebody knows to listen for a beep.

We didn't see data on people listening for a beep, but this was the one aspect that I found,

the longevity of the platform in the self-test environment not having been associated with problems, that to me was a little more interpretable and a little more reassuring.

DR. KATO: I guess my concern was going to be that as the device gets mass produced or produced in greater numbers, then the manufacturing process is going to change also, but right now --

DR. ZUCKERMAN: But that's not the point of the question. Let us assume that the engineering will be fine. It's an approved device right now. the problem is: does the lay user need to have some education, testing about storage, maintenance of this device? It usually sits on the wall.

You know, the actual testing concentrated on a specific component of the device history.

DR. RINGEL: Maybe I missed it on the last round. I apologize if I'm retracing. If this device has been approved, I don't understand how the removing the prescription changes storage and maintenance, for instance. If someone says, all right, if you write the prescription, then there's

going to be some training given, I can understand that when we discuss prescription and training. But I don't understand how prescription and storage and maintenance has a role in our discussion today, whereas it should have been maybe contemplated when the device was originally approved.

So I'm just asking the question again. i know that it was just discussed in Part A, but I don't understand why this was a factor here.

DR. SOMBERG: I'm not going to say anything. I'm sorry.

ACTING CHAIR LASKEY: No, no, no. I think we can let the agency -- it seems that the question was directed to the agency. What's different now than before?

DR. ZUCKERMAN: Well, I think the sponsor would agree with Dr. Ringel, and that's why they concentrated on the adequacy of testing to show that in an acute arrest situation that lay users could use the device appropriately.

However, we're just trying to do our due diligence, cover all of the broad strokes. If you

think that those aspects of potential training covered in 1(b) are self-obviously, then you agree with the sponsor and they don't need to be further demonstrated in this OTC scenario.

DR. RINGEL: So we can review issues that were more appropriate to its approval as a device at all is what you're saying.

DR. ZUCKERMAN: Yeah, the strategy that the sponsor chose was to concentrate on 1(a). We're just asking from the FDA's perspective: is that an appropriate strategy to take here?

DR. KRUCOFF: So that's where I see 1(b) as a beep and a light, that basically they've gotten the system down over the years to a beep or to a light that is not ready, and to me that's probably more likely to be readily translatable to a consumer population than the vicissitudes of call 911, then open the package, then peel it.

So I would support their emphasis in terms of 1(b).

DR. NORMAND: Yes, and I also support their strategy.