

1 DR. VETROVEC: I support it, too.

2 ACTING CHAIR LASKEY: That sounds like
3 consensus.

4 MS. WOOD: let's move on to Question 2.
5 Safe and effective use of the device may depend on
6 the ability of the untrained lay person to determine
7 in what situations the AED should be used. Please
8 comment on the adequacy of the testing that was
9 performed in the product labeling and training
10 materials that are provided to support the notion
11 that lay users would know when to use the product.

12 ACTING CHAIR LASKEY: Yes.

13 DR. SOMBERG: I thought that was very
14 well done, and as I said, I think there are some
15 target populations that could be identified where
16 certain cards could be given, and there's additional
17 work that could be done in this area, as well as
18 areas related to -- I mean, you know, just because
19 this device is approved doesn't mean there's going to
20 be updates and improvement, and I think this company
21 has shown -- what is this, the third generation or
22 fourth of your products? -- I think they're going to

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1 be able to do that, but I think this has been well
2 demonstrated.

3 ACTING CHAIR LASKEY: Well, well
4 demonstrated in the adult population. I guess we
5 should be specific because Rich's concerns are
6 completely valid with respect to the differential
7 diagnosis in a child when they're --

8 DR. KRUCOFF: Well, they're recognizing
9 that this really applies to the user, not the
10 patient, and there, again, I agree with what sounds
11 like other voices, that it's down to patient is down,
12 not breathing right. When in doubt, use it. That's
13 pretty good by me.

14 ACTING CHAIR LASKEY: Fair enough.

15 MS. WOOD: If you do not believe that the
16 testing and/or labeling are adequate in Part A above,
17 please comment on the type of testing or type of
18 labeling changes that would be necessary to support
19 the removal of the prescription label.

20 ACTING CHAIR LASKEY: Well, fortunately,
21 we do believe that it's adequate.

22 MS. WOOD: Okay. Number 3 --

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1 DR. RINGEL: Well, on Number 2 I guess I
2 didn't speak up again because I had said it earlier.

3 I think that there does need to be something
4 included in the package that makes it clear that
5 infants and toddlers are different. Airway,
6 breathing, circulation is the mantra, and I don't
7 think that's been changed at anytime recently. So I
8 think it has to be stated.

9 DR. SOMBERG: Didn't they say that when
10 you put in the pediatric paddles the voice algorithm
11 changes? So isn't that in the system?

12 DR. RINGEL: But it's not in the
13 brochure, and it's not difficult to put it in the
14 brochure.

15 DR. SOMBERG: Oh, no, I agree with that.

16 DR. RINGEL: It's not difficult to
17 include just few lines about infants and toddlers,
18 airway, breathing, circulation. That's all.

19 MS. WOOD: The timing of CPR relative to
20 defibrillation is one concern for this type of
21 device as it impacts survival in certain cases, such
22 as asystole or pulseless electrical activity.

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1 According to the current American Heart Association
2 recommendations, CPR should precede defibrillation in
3 the chain of survival. The Philips device addresses
4 the need for CPR in two ways: by identifying the
5 need for AED CPR training in the labeling and by
6 including device prompts during the defibrillation
7 process that are based on the patient's underlying
8 rhythm, such as normal sinus rhythm, ventricular
9 fibrillation, PEA, asystole.

10 Please comment on whether these
11 recommendations regarding CPR are enough or whether
12 other measures are needed, and please comment on
13 whether the concern is unique to an over-the-counter
14 AED or whether the same concern exists for the
15 prescription version of the device.

16 DR. ORNATO: I'll be happy to start with
17 that.

18 First, the question is flawed. The
19 second sentence is incorrect. The American Heart
20 guidelines do list in the chain of survival early
21 CPR, but it's not meant to imply that that is to
22 precede defibrillation if there's a short bound time

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1 interval.

2 However, the question is, in fact,
3 otherwise a superb question, and is the source, as
4 Dr. Becker and others have pointed out, of intense
5 scrutiny and controversy and discussion and will be
6 materially, I think, dealt with to some degree at the
7 next guidelines conference, which will be occurring
8 within a few months.

9 That said, I think most of us who kind of
10 work in this area basically accept the notion which
11 was presented earlier, which is that there likely are
12 several phases of resuscitation, and that first four
13 or five minutes is an electrical phase, and early
14 defibrillation really appears to be the best
15 intervention that we have. There's really not even a
16 close second.

17 And so in that sense, I think this device
18 and the entire family of AEDs have it correct. I
19 think the real issue is what do you do about the
20 individuals who were down longer than four or five
21 minutes, and right now, none of the devices, none of
22 them, even the ones that we have for medical use by

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1 physicians and paramedics that are FDA approved can
2 really answer the question of when is it time to turn
3 to shocks as opposed to priming the pump with CPR.

4 There is a whole science that has evolved
5 in the last decade looking at the VF waveform, such
6 things as median frequency and other fast 40(a)
7 transforms of the VF waveform that appear to give us
8 somewhat of an index of the state of ATP in the
9 myocardium and whether you should shock or not, and
10 I'm optimistic that in future generations of
11 defibrillators in general will probably have the
12 ability for defibrillators to look at the waveform
13 and then be able to tell whether you need CPR then or
14 defibrillation.

15 But we're not there yet. The science is
16 not quite there yet. So my answer to this question
17 is I think the device is doing all it can do, which
18 is to follow the consensus American Heart and
19 international guidelines on CPR.

20 They may change this year. I think the
21 real issue to me is, you know, can this device change
22 relatively easily to conform to whatever

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1 modifications are made in the guidelines, and that's
2 a technological question.

3 I think we got a hint of it. It sounds
4 like the device has some configurable features now
5 and has the ability to be upgraded by software with a
6 main-in. If that, in fact, is the case, then I think
7 I'd feel comfortable that the device is where it
8 needs to be, given today's science.

9 ACTING CHAIR LASKEY: That being said,
10 nothing in here that we've heard today is stratified
11 by tying down. Should there be some specific
12 language that this is the way to go when it's
13 witnessed or sort of witnessed or within -- there is
14 no language in here that alludes that that and then
15 that leads into do you do CPR.

16 I found it notable that the CPR recording
17 wasn't playing this morning when we saw the demo.
18 That's out of that particular record. So I think we
19 ought to --

20 DR. ORNATO: The current AHA guidelines
21 don't stratify in that fashion. However, the
22 Scandinavian paper, Dr. Wik's paper and Dr. Cobb's

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1 observational report in JAMA a few years ago from
2 Seattle would, in fact, support the notion that the
3 first four or five minutes probably are different
4 than what comes in the next five or six minutes.

5 However, as I've indicated that's a
6 subject that's going to be, I think, greatly and
7 hotly debated at AHA guidelines this year, and it may
8 or may not result in any modification in the
9 guidelines recommendation.

10 So I think, you know, the only standard I
11 think we can reasonably and fairly hold a
12 manufacturer to is what is the current recommendation
13 right now, with the notion that they need to have the
14 flexibility to modify if the AHA and International
15 Liaison Committee on Resuscitation make a substantive
16 change in the recommendations.

17 DR. SOMBERG: Warren, can I?

18 ACTING CHAIR LASKEY: Yeah.

19 DR. SOMBERG: I agree with Dr. Ornato's
20 statement that this device lives up to the current
21 guidelines. I'd also say that if we were a panel and
22 had to make a decision on changing the guidelines for

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1 time, there's such a paucity of data, 200 patients,
2 the study design, the observational study. You'd go
3 crazy. Our statistician would go crazy with that
4 data. So let's not approve something based on that
5 data.

6 And lastly, I would say we have to be
7 careful as a panel not to go from extreme to extreme.

8 We wanted a simple device, a device that the average
9 person could handle with the average education, et
10 cetera, and now we're asking people in a time of
11 emergency where time tends to stop, et cetera.

12 I mean I always have time. Someone comes
13 up to me and says, "You've been coding the patient
14 tangentially on this for, say, 15 minutes or so," and
15 I think it's only three minutes or something like
16 that. So it's very, very difficult to put a time
17 configuration in there.

18 So I'd be very concerned about -- and
19 then maybe the machine went on. Maybe the machine,
20 you know, could go off and then put on again.
21 There's even a timer on a machine might be
22 questionable.

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1 So I would say, you know, this is field
2 tested. It's approved, and what we're asking to do
3 is take away the prescription thing, and therefore,
4 let's not change.

5 I'm afraid any change in device may open
6 it to more problems than less. So a device that has
7 validated itself to this point is the safest device
8 to put out there that will do the most good.

9 ACTING CHAIR LASKEY: Nevertheless, we
10 recognize the need that the IFU may change as the
11 body of evidence changes.

12 DR. SOMBERG: That's right.

13 ACTING CHAIR LASKEY: It's not written in
14 stone.

15 DR. RINGEL: So, again, this is overlap,
16 I guess, with the previous question, but since it's
17 asked, again, the recommendation of CPR and not
18 enough of the peds. should be -- and again, I don't
19 want to make peds. as a broad category, but infants
20 and toddlers -- the comment should be that the
21 documentation is probably not adequate to make it
22 clear that CPR should start before defibrillation.

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1 And then the voice prompt would come
2 already after you've gotten the machine, put it on
3 the kid and so forth. So that would be not the
4 recommendation of the AHA. You start the CPR first,
5 or the American Academy of Pediatrics.

6 ACTING CHAIR LASKEY: Yeah, I guess
7 insofar as (b) goes, the same concern does exist for
8 the prescription version.

9 DR. RINGEL: Correct.

10 ACTING CHAIR LASKEY: Number four.

11 MS. WOOD: Over-the-counter,
12 nonprescription products, such as cold medicines ,
13 typically it's just the layperson in determining
14 whether they need to buy the product by presenting in
15 the outer packaging information describing the
16 intended use of the product.

17 Please comment on the adequacy of the
18 external carton labeling in conveying important
19 information to the lay user that would allow them to
20 know whether this product is right for them.

21 DR. NORMAND: The only comment I'd like
22 to make, and maybe it's already on the package, but

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1 the issue about the Spanish, in the Spanish label or
2 in the English label that the automation is in
3 English because I think that's an important point.

4 DR. KRUCOFF: To me one of the ironies
5 here is what I actually think would belong on the
6 outer part of the box if consumers are going
7 shopping. If you think you need one of these, you
8 probably should talk to your doctor.

9 (Laughter.)

10 DR. KRUCOFF: You may not need a
11 prescription, but at least to alert them to think
12 about it.

13 DR. ZUCKERMAN: Okay. So, Dr. Laskey, is
14 there some consensus on four or were these just
15 comments?

16 ACTING CHAIR LASKEY: Seems to be. I
17 mean we could obviously do due diligence with this
18 one, too, but I think we have consensus that it's --
19 I don't know. What does it say on the outside of the
20 box? If you're deal you open this? What does it
21 say?

22 (Laughter.)

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1 ACTING CHAIR LASKEY: I see the picture.

2 DR. KRUCOFF: No, if you see somebody
3 else dead, open this.

4 ACTING CHAIR LASKEY: Yeah.

5 DR. SNYDER: Actually, to Dr. Krucoff's
6 point, it does say, "If you have concerns about your
7 health or an existing medical condition, talk to your
8 doctor. A defibrillator is not a replacement for
9 seeking medical care." It's right here.

10 DR. KRUCOFF: Yeah, you mentioned that
11 earlier, too.

12 DR. SNYDER: It basically identifies the
13 product. It's the HeartStart Home Defibrillator. It
14 says it's used to treat victims of sudden cardiac
15 arrest who are not responsive and breathing normally,
16 and if in doubt to apply the pads. Treat sudden
17 cardiac arrest by delivering energy to the heart.

18 ACTING CHAIR LASKEY: I mean, I guess --

19 DR. SNYDER: It also reinforces the time
20 of the essence defibrillation within the first few
21 minutes provides the best chance of survival.

22 DR. SOMBERG: Well, you've also got to

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1 remember that you buy it in the carton. It's going
2 to be put in this little carrying pack. It's going
3 to be kept in the carrying pack. Probably the carton
4 -- I mean it's like antiques. You know, antiques are
5 much more valuable if they have the carton because 90
6 percent of them are thrown away.

7 So, I mean, this is what someone would
8 read but not necessarily the user will read.

9 So can I ask you? With that said, what
10 is the little pouch thing? And maybe it's advisable
11 to put all of these good things in the pouch.

12 DR. KRUCOFF: Or a wall mount. Is there
13 a wall mount?

14 DR. SOMBERG: And there was a lot of
15 handouts. So if you tell me it's all on that, I
16 apologize.

17 DR. SNYDER: The labeling on the first of
18 the quick reference guide is check for signs of
19 sudden cardiac arrest. Unresponsive, not breathing
20 normally, and then it has the one, two, three
21 operations of the device.

22 DR. SOMBERG: And I just might suggest on

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1 the cover of that thing, you also have the physician
2 admonition as well.

3 DR. VETROVEC: This is an interesting
4 point because a cold tablet is inside the box, and
5 there's no reason that someone would have it outside
6 the box. So you'd get other information when you
7 were looking at it in a drug store. It's likely Wal-
8 mart would have this open so you could look at the
9 product, and you wouldn't necessarily read the box
10 when you were looking at it, and maybe the compromise
11 here is the information that's on the box should be
12 displayed prominently at the advertising site.

13 MS. MOYNAHAN: Can I make a comment?

14 This is Megan Moynahan.

15 The question was worded specifically to
16 ask you whether you felt that the external carton
17 labeling would allow users to know whether the
18 product was right for them, meaning should they buy
19 it at all, and the reason we're asking that question
20 is because there may be some considerations they
21 should think about. For example, if they do live
22 alone, this might not be the best product for them.

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1 Can they physically work with the product? Do they
2 know that they have to get down on their knees to
3 help the patient? Do they know that they have to be
4 able to listen to audible alarms or things like that?

5 And this is more the question of can the
6 user in a store situation determine for themselves
7 whether they need to buy the product?

8 DR. VETROVEC: Well, if you're really
9 asking that question, it seems to me that then the
10 statement needs not so much the disclaimers of where
11 it might not be useful to the person, but maybe it
12 ought to have some statement about the incidence of
13 sudden death and people unsuspecting or something
14 like that and increasing with age.

15 That would be the sort of information
16 that might be important to a user.

17 DR. RINGEL: When I had looked at the
18 materials, I must admit I hadn't thought of it in
19 exactly that way, but if you're asking the question
20 of can you get an education of who needs the product
21 by looking at the box, I don't think the answer is
22 yes. I think most people at that level of education

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1 would not know what defibrillation means.

2 It doesn't say anything about heart
3 attacks, which is what most people think. It says
4 things like sudden cardiac arrest, you know, or
5 something like that. Most people, I guess, wouldn't
6 know what that is. I mean, most people only know the
7 term "heart attack."

8 And I think many people don't know what
9 defibrillation is. They know what shock is, but I
10 don't know that they know what defibrillation is.

11 So if you ask purely not knowing anything
12 else and you just look at the box, I think it might
13 be a problem.

14 What does the rest of the group think?

15 DR. MAISEL: I was just going to say I
16 think if you asked what is the single piece of
17 information a person should most have if they're
18 about to buy the product, for me it would be what is
19 my risk or the risk in my environment of needing to
20 use the device.

21 In other words, what is the risk of
22 sudden cardiac death if it's for themselves or their

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1 family.

2 DR. RINGEL: Do they understand? Do your
3 patients understand sudden cardiac death as opposed
4 to heart attack?

5 DR. MAISEL: Well, they don't have to.
6 It's just of needing the device. Whether they
7 understand that it's a heart attack or a sudden
8 cardiac death, I don't know that there's an easy way
9 to present that on the outside of the package, other
10 than perhaps some graph or chart of, in people with
11 no prior medical history, of unanticipated sudden
12 cardiac death by age or something like that, but I
13 don't know that that's a realistic option on the back
14 of a package.

15 DR. KRUCOFF: I guess what I'm hearing is
16 more like does there need to be a bullet list on the
17 side of the package like what does it take to operate
18 this thing and you need two double A batteries and a
19 flashlight and a wrench, and that that somehow --
20 you're forewarned of that so that you don't buy
21 somebody a Christmas present that when they open it
22 they can't use it.

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1 So, you know, I think some of the
2 ergonomic features, if that's really the question --
3 I wouldn't want to substitute that for having on the
4 front where they got it, but you know, you probably
5 should talk to your doctor, but maybe on the side, if
6 there is a bullet list of specific ergonomic
7 features, that would mean if you buy this thing and
8 somebody in your house arrests, you're not going to
9 be able to use it, that that wouldn't be a bad bullet
10 list to put on the side, and it doesn't sound like it
11 would be too much more complicated than the things
12 you all had pointed to. You may have to operate it
13 on the floor to maintain it. You may have to be able
14 to hear a beep. You may need a sixth grade
15 education, you know, to play the --

16 ACTING CHAIR LASKEY: There's a lot of
17 writing on this box right now. So I --

18 DR. SOMBERG: But can I? This is a very
19 involved device. It's going to take more than the
20 outside reading of a box. I think the manufacturer
21 has spoken to its confidence in trying to deliver the
22 message to the person by giving them 30 days to look

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1 through this.

2 I mean it's not that you buy it and
3 you're stuck with it. You have 30 days to go through
4 that and you can --

5 DR. KRUCOFF: You can generally use it in
6 those 30 days.

7 DR. SOMBERG: well, you may use it the
8 next day. That's not true. You'd be surprised how
9 many people run out, especially if their physician is
10 away at an FDA meeting, right?

11 But the point is I think there's a whole
12 manual there. Someone has to go through it, and what
13 we've heard, we've each learned a little about this
14 device today. Nobody can understand it in a minute
15 by looking at the box, and I think you have to read
16 the manual and it will tell you that, you know, you
17 need people at home. You need people that can handle
18 this. You need to host things, and some people are
19 going to be overwhelmed, and then they'll give it
20 back, and in fact, what's the incidence of people
21 giving it back?

22 Less than one percent. Well, obviously

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1 there are a lot of cognitive dissidences they'll tell
2 you in marketing school, but --

3 DR. KRUCOFF: -- by airports. I mean, if
4 you get into homes, it may be different.

5 DR. SOMBERG: That's a good point, too
6 because it's a live public access. The building or
7 the airport doesn't give it back. You're right.

8 But I would say go to the manual for this
9 type of info. That's my message to the FDA.

10 DR. KRUCOFF: Well, I would respectfully
11 disagree. I think a bullet list on the side that had
12 specific ergonomic features, that if you can't do
13 this, you can't use this, would be simple,
14 reasonable, and for all the writing could be discrete
15 enough to be useful.

16 DR. KATO: Yeah, and I'd like to agree
17 with Mitch. I mean, many of the products that we buy
18 now all have that. Software, hardware for computers
19 has very explicit listings of what you have to have
20 in order for it to work. I think that's reasonable.

21 ACTING CHAIR LASKEY: How would people
22 feel about a bullet list that said you may be at

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1 increased risk of sudden cardiac death if you --
2 bullet, bullet, bullet, bullet, have had a heart
3 attack?

4 DR. VETROVEC: I would agree with that.
5 I think the ergonomic issues, I think you need to --
6 if the goal is to make it like cold remedies on the
7 supermarket, then you need to tell people who might
8 benefit from it.

9 ACTING CHAIR LASKEY: And you have to
10 have a cold, and I think that's the problem here.
11 These people don't have a cold, and they haven't been
12 survivors of sudden cardiac death. They are at risk
13 of, but we can't quantitate the risk. Nobody can.

14 So I think that's just opening up a
15 hornet's nest. I mean, we all agree it's for the
16 treatment of someone that drops dead, but to go home
17 and to ask that person to do some risk stratification
18 in their household for who is at risk for sudden
19 cardiac death is (a) unfair, (b) impossible, and I
20 just -- the language here of is it right for them is
21 just so vague, and I think if we cleaned up the
22 language a little bit in the question, we might be

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1 able to help you more.

2 But I think that's ultimately what the
3 morning's discussion was about, was the inability to
4 quantify the risk. You know it's there. It's
5 greater than zero, but how do you do that and how do
6 you do it without making the buyer hysterical?

7 DR. RINGEL: I think I mostly agree with
8 that. The only thing is as I look at the packaging,
9 it really -- for such a big life saving product I
10 really now looking at it have to admit there's a real
11 dearth of any usable information. The only thing it
12 says, and it's in about the smallest print on the
13 package, it says, "Used to treat victims of sudden
14 cardiac arrest who are not responsive and breathing
15 normally. If in doubt, apply the pads. Treat sudden
16 cardiac arrest by delivering energy to the heart."

17 Very small print, and that's it. So I
18 guess I hear what the other panelists are saying, and
19 it seems like maybe a little bit more information
20 could be -- again, if the FDA is asking the question,
21 and I hadn't thought of it until we asked the
22 question. If they're asking the question is it like

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1 a cold remedy that tells you why you need this
2 product, this is even less than, you know, allergy
3 medicine gives. That's all. It could be a little bit
4 more.

5 DR. ORNATO: But it -- I'm sorry to keep
6 this going -- but it comes down to this fundamental
7 issue of is this a medical device or is this a safety
8 device, and that's really what I'm hearing out of
9 this discussion that we're struggling with. If this
10 were to be viewed in the traditional paradigm of a
11 medical device, then we would need all of those
12 things, and it's perfectly understandable that our
13 instincts are telling us to put those things for all
14 of the reasons that you've nicely articulated.

15 But what I've had to I think keep
16 reminding myself as the day has gone on is that this
17 problem of sudden death is totally unpredictable. We
18 don't know who the victim is. We don't know who is
19 going to be in the household when this happens, and
20 ultimately 80 percent of the events occur in the
21 household. So if ultimately we're going to make a
22 dent in this problem, it's very similar to the fire

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1 extinguisher issue.

2 You know, I will have to go back and look
3 at the ones that are in my house, but I don't think
4 on the label of a fire extinguisher it tells you to
5 re-stratify what you're likelihood is of having your
6 house catch on fire.

7 And although I don't want to make light
8 of the comments that have been made, I think the
9 difference is where we physicians and health care
10 providers are in the mindset always of viewing this
11 as the traditional paradigm of a single patient, a
12 single device that we're prescribing.

13 This is really a different animal, and I
14 think that that's why we're having this discussion
15 back and forth. Maybe that will help.

16 DR. RINGEL: Even a small comment, I
17 mean, because I've listened to what you guys are
18 saying, and many people here feel the importance of
19 making sure that the lay public is aware that they
20 need to activate EMS and that this only buys some
21 time, that it's not even a mention on the box.

22 So someone could think, "Oh, all I need

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1 to do is take this. We're going to go climb, you
2 know, Mount Everest. I'll take it up there and then
3 we'll be fine."z

4 I mean, that's why I said a little bit
5 more labeling. You could even say, you know, it
6 gives you the extra time needed before the paramedics
7 arrive.

8 All I'm saying is it's really a dearth of
9 information for a big product. I'm not saying it has
10 to label everything, and I know what you're saying.

11 It's a public safety thing. It doesn't have to list
12 all of the conditions that you might have, but it's a
13 little bit sparse on information.

14 DR. KRUCOFF: Actually I kind of like
15 that. If they could wordsmith something that would
16 on the front say that this thing is an adjunct to the
17 knowledge of CPR and the use of 911 EMS services for
18 in the home, you know, but actually if you could
19 emphasize that it's important for you to know CPR and
20 to know how to dial 911, and that this is an adjunct
21 to that that you can keep in your home that, you
22 know, bridges that little time period that can be so

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1 critical, I think that would be a really interesting
2 way to put what it is right on the front of the box.

3 MS. WOOD: Number five, Philips is
4 seeking over-the-counter status for this AED to be
5 used with both adult and pediatric pads. Both the
6 adult and pediatric pads are already FDA cleared with
7 prescription status.

8 In support of the usability of the device
9 with pediatric pads, the sponsor has provided the
10 results of simulated use testing of pediatric
11 electropatches with the AED performed on ten
12 subjects. The purpose of the test was to determine
13 whether users could recognize the need to change from
14 adult pads to pediatric pads.

15 Please comment on whether this testing is
16 sufficient to remove the prescription only label on
17 the pediatric pads.

18 ACTING CHAIR LASKEY: So we'll defer to
19 Dr. Ringel for the consensus.

20 DR. RINGEL: I was really hoping honestly
21 that you guys would start because I'm really torn
22 here. A trial of ten is almost nothing.

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1 I was reassured by the comments after I
2 asked the questions. I still am troubled by the
3 pediatric pads. On the one hand, I would love to
4 have the kids, the babies and infants and toddlers
5 included in the over-the-counter use. On the other
6 hand, maybe there should be a discussion with their
7 pediatrician about, you know, their child who they're
8 worried about sudden infant death or their child who
9 they're worried about, you know, this or that, and
10 maybe they should discuss it with a pediatrician who
11 can then tell them what to do.

12 I don't know. I'd really like to hear
13 what the other panelists say because I'm torn on that
14 one.

15 DR. SOMBERG: I would say if you don't
16 take away the prescription for pediatric pads and
17 just did it for adults, then you have a default mode
18 and that you would vitiate the use of the pediatric
19 because people who wanted to buy it would go ahead
20 and buy the adult.

21 And I am very concerned, and unless you
22 correct me if I'm wrong, but let's say it was used in

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1 the infant population. You're giving 150 Joules to
2 an infant. Would that not have the potential for
3 myocardial damage?

4 So I'd rather someone who is concerned
5 about this have the same admonitions as the adult
6 population. You know, consult a doctor, and I also
7 recommend strongly a pediatric card there to give a
8 little more information about the use of this, et
9 cetera, and I certainly wouldn't object if they order
10 the pediatric paddle, you know, that this is all
11 recommended.

12 But if we just have the adult panels
13 available to buy over the counter, then people are
14 going to buy that and use the adult for the
15 pediatric, and that is, I think, not as good as
16 having the pediatric available.

17 DR. RINGEL: That was part of why I'm on
18 the fence here, is the issue. It goes like this. I
19 ask them why not include the pediatric paddles. They
20 say cost issue.

21 Okay. Then we go through, well, what are
22 the chances that someone who's an adult and doesn't

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1 have any kids in their house are going to need
2 pediatric paddles. The answer is very limited, but
3 then if you say people are buying it specifically
4 because they have an infant who has been diagnosed as
5 having sudden infant death or someone who has long
6 QT, well, then they are plugged into the physician
7 system anyhow, and they could get that prescription
8 and get the pediatric paddles.

9 On the other hand, the chances that apart
10 from those rare conditions long QT or whatever,
11 it's -- these are primarily respiratory events, and
12 the chances of getting VF that would then meet an
13 algorithm and get a shock is so small, and if you do
14 get it, it's better just to shock the kid. You may
15 fry the heart a bit, but its' better just it's better
16 just to show them.

17 So it's tough. If they're not going to
18 include the pediatric pads, the chances that someone
19 who does not have an infant that they're worried
20 about in the house is going to spend the extra money,
21 order the other pads and get them sent it small.

22 I don't know.

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1 DR. SOMBERG: I see your point. I'd just
2 add one more thing. The one thing that really does
3 disturb me in the last hour of the conversation, or
4 two hours or three, is that they're not having the
5 pediatric pads because once again, that adds a level
6 of a complication, and I think although you buy it
7 for the home use, et cetera, I can see how especially
8 in neighborhoods -- I live in a country where there's
9 a few acres between houses -- but if you're living
10 where 50 feet down i the next house and the next
11 house, someone knows you have the defibrillator. A
12 child has a problem. It may be used on a child.

13 So I really think the company, unless I'm
14 misunderstanding it adds two, three, \$400, but I
15 really think that both sets of pads should be
16 considered. That's my personal opinion here.

17 But, once again, this prescription
18 removal, that's what we're here for today, and I
19 would say if someone wants to buy it for the child
20 and they decided not to consult the physician and
21 they go ahead and buy it for the child and they only
22 can get the adult, then they'll use the adult, and

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1 that's something we're making them do what we
2 shouldn't make them do.

3 You know, the companies have argued this.
4 We've argued this. We don't know who it's going to
5 be used on. We don't know who is going to use it and
6 for what, you know, whether it's in their house or
7 someone else's house. It should have both components
8 to be reasonable, and I think both components are the
9 pediatric and the adult because the machine only
10 works partially. It doesn't work giving you the
11 other algorithm if it doesn't have those pediatric
12 panels to convert it, and you need those voice
13 prompts to be able to go to the ABC approach for
14 pediatrics airway to be told.

15 So I think it's an incomplete device if
16 you don't give those pediatric pads.

17 DR. ZUCKERMAN: Dr. Ringel, are you any
18 more convinced one way or the other?

19 DR. RINGEL: I really hate for this to be
20 a sticking point because I think it is a very, very
21 small point, and frankly, my major problem before
22 with the pediatric pads had been my concern about

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1 them being erroneously used on larger people.

2 I'm not sure that three cases of a seven,
3 eight year old and a ten year old convinces me that I
4 don't have to worry up at the upper end, but the
5 company seems very certain that this is the best way
6 of providing pediatric defibrillation as opposed to
7 any other techniques.

8 Down at the lower end I must admit I
9 don't have very much concern. I think that parents
10 who are going to bring it into the house for their
11 infant or toddler, I know these parents. They are
12 way plugged in medically, and they will get the pads
13 one way or the other, whether it's prescription or
14 over the counter. They will buy them. They will
15 hook them up. If that's why they're buying the
16 machine, they will get it.

17 So I guess it's okay for over-the-counter
18 use as long as the rest of the panel is not concerned
19 about the upper end, which is you know bringing us up
20 to having child pads in and then being used on
21 adults, child pads in and then being used on the
22 large eight year old. If that doesn't bother anyone,

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1 then I think it's okay.

2 DR. KRUCOFF: Well, let me make the
3 argument from the other side, which would be if the
4 OTC version was really one format. I mean maybe
5 that's actually a whole lot smarter. Just make the
6 OTC version with the adult pads, recognizing that if
7 you need something for an under 50 pound child that
8 that's a parental or institutional decision that
9 could involve a doctor where there's going to be a
10 motivation to involve the doctor.

11 What that interestingly takes away is the
12 potential complexity and the general use that
13 somebody with a sixth grade education actually gets
14 confused and ends up putting the pediatric -- you
15 know if you have both sets of pads in every unit, the
16 potential is to get confused, and maybe what we could
17 do is take away that opportunity for confusion, let
18 the OTC version be one size and to --

19 DR. RINGEL: Well, there's no reason to
20 deprive the pediatric population of an OTC device.
21 If you make the pads by prescription that's all you'd
22 have to do. You don't have to disable the whole

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1 device.

2 DR. KRUCOFF: Well, that's what I'm
3 saying. My understanding of this question is that
4 one of the regulatory options here would be to make
5 the whole device OTC, however make the pediatric pad
6 configurations by prescription. Same box, et cetera,
7 but is that what's being suggested here, Bram, that
8 that is at least an option?

9 DR. ZUCKERMAN: Well, it could be
10 considered, but the easiest would be to make
11 everything OTC if felt appropriate.

12 DR. MAISEL: I don't understand the
13 rationale for making pads, pediatric pads which are
14 markedly less complex than this complex device by
15 prescription. I think we can debate whether they're
16 packaged with the device or not, but it seem
17 ludicrous to me to make that by prescription and not
18 the device by prescription.

19 DR. KRUCOFF: You could just package them
20 separately.

21 MR. MORTON: Excuse me. Could we go back
22 to Megan?

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1 Excuse me. It's me, Mike. I'm sorry,
2 Megan.

3 What is the configuration of the device
4 now? Because that's really what we ought to be
5 looking at is what they have submitted, what the
6 sponsor submitted as to be reviewed for 510(k). Is
7 that an ancillary device, the pads? Are they
8 different models, pediatric and adult?

9 MS. MOYNAHAN: It's the same unit with
10 different kinds of pads, and right now the home used
11 system which has a prescription offers both adult and
12 pediatric pads. What the sponsor is asking for is
13 removal of the prescription for the unit and the
14 replacement adult and pediatric pads.

15 MR. MORTON: Okay. I was just confused.

16 DR. SOMBERG: Well, that confused me.
17 You mean the current unit that is now available for
18 prescription when you get a prescription and you
19 purchase the unit, it has both the adult and
20 pediatric pads in it?

21 The sponsor is saying no. It only has
22 the adult, and you must request and purchase the

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1 pediatric material.

2 MS. MOYNAHAN: Right.

3 DR. SOMBERG: I must submit from my point
4 of view it's hard to confuse. You know, if the adult
5 pads were connected, and that's the way the machine
6 is configured and then it came in a box just as my
7 camera comes with a lens or something else tucked in
8 the back, pediatric pads, I don't think people would
9 be very confused. It's just those individuals who
10 want the flexibility, you know.

11 You have one neighbor who's potentially
12 at risk, you think. You have another neighbor that
13 has an infant, and then you bought it for your spouse
14 who had an MI. I mean, you know, that's the options,
15 and when you pay this much money for a device, you
16 would probably want the maximum -- and we want to get
17 the most out there, you know, the public health
18 thing. We want to get the most out. So, I mean, you
19 can make up all sorts of weird scenarios, but I think
20 just having all options available makes the most
21 sense to me.

22 DR. MAISEL: I don't feel that strongly

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1 about whether the pads are with the device or not,
2 but if they're not with the device, then I think the
3 packaging should be clearly marked that pediatric pad
4 is not included.

5 PARTICIPANT: That's a good suggestion.

6 MS. WOOD: Number six, according to the
7 AHA, the first link in the chain of survival is to
8 activate the EMS system calling 911. The sponsor has
9 addressed this concern by placing a prominent
10 sticker, call 911, call EMS on the AED case. Please
11 comment on the adequacy of this approach.

12 DR. VETROVEC: I'll make at least the
13 first comments. I've made comments before. I think
14 this is the single most important point to get across
15 because this is where the individuals really are
16 going to be the help they need in addition to what
17 they can provide themselves.

18 So having that on the way as soon as
19 possible has got to be communicated critically. I'm
20 not sure. I still think electronically it would be
21 better to do it.

22 DR. KATO: I'd just like to see that the

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1 sticker be made permanent, etched on printing on the
2 package. When I was looking at the package before, I
3 think that the sticker is part of the name, that you
4 can write on it, which means that potentially you
5 could lose it or if you give it to somebody else,
6 they're going to want to put their name on it.

7 So I'd like to see a permanent 911 paint
8 job on the red bag.

9 DR. KRUCOFF: Yeah, I would agree with
10 Norm. I would like to see bigger, more prominent
11 call 911 before use, but as elegant as the digital
12 solution sounds, I mean, in my own home I don't have
13 a cell. My cell phone does not work in my own home,
14 and the potential with the level of technology that
15 we have available to think that you're called 911 or
16 think this thing is going to call 911 for you when,
17 in fact, it's in a dead cell I think would be very
18 hazardous.

19 But I do agree with norm. It's so
20 important, and it's so simple to do. Just make the
21 darn thing the biggest lettering on the box the way
22 it would hang on the wall by the phone. Just write

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1 right on the surface when you look at that, I think
2 what you should see is, "Call 911 before use," while
3 you're there at the telephone, and hopefully the
4 instructions suggest as you guys suggested. Keep it
5 by a phone, mount it by a phone. Start with 911 and
6 then grab it and go. I think that would be my
7 suggestion.

8 ACTING CHAIR LASKEY: Pretty
9 straightforward. Is that there on the record? If
10 forgot. When the recording starts, is that the first
11 thing that comes up?

12 DR. KRUCOFF: No, there's a reminder
13 later, after the first cycle.

14 DR. SOMBERG: WE had a conversation
15 specifically. They figured that if you were the lone
16 one, you don't want to call 911. You don't want to
17 be running back and forth

18 DR. SNYDER: Correct. The first layer of
19 labeling is the sticker. In the event that someone
20 does that and we have no data in our experience with
21 defibrillation to suggest that that's what's going to
22 happen, but should it happen, what we're trying to

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1 avoid is causing the responder to have to go back and
2 forth between the patient and the phone, all the time
3 the patient not receiving either circulatory support
4 or defibrillation. So if they're not activated, we
5 want them to deliver first shocks. Then they get a
6 reminder to go back and activate EMS.

7 DR. RINGEL: Just once again for my
8 unintended consequences, so when somebody puts this
9 in the house, this is going to become their reference
10 for CPR, their reference for all sorts of CPR issues
11 and, again, call EMS is not the first stage for
12 single responder for kids.

13 So when you do that, whatever card,
14 whatever plaque, whatever you're going to do for the
15 pediatric response, they have to be reminded that
16 that's not the first link in the chain for pediatric
17 resuscitation. At least not yet. It's do the
18 breathing, get a minute in, then go to the phone. So
19 we just have to remember that if it's going to be
20 marketed for kids.

21 ACTING CHAIR LASKEY: Just give BLS cards
22 to everybody that wants one of these. That's

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1 basically what.

2 DR. RINGEL: Yeah, and I'm not asking for
3 much. Just make sure it's in the documentation.
4 that's all.

5 ACTING CHAIR LASKEY: Good.

6 MS. WOOD: Number seven, automatic
7 external defibrillators are currently track devices
8 by FDA regulation. Tracking requires the sponsor to
9 have processes in place to promptly identify users in
10 the event of a recall. At this time removing the
11 prescription labeling will not alter the tracking
12 requirement for these devices.

13 In Philips response to this question,
14 Section 4 of the FDA review memos of the panel pack,
15 Question 6, they state that they have submitted a
16 petition requesting a waiver of the tracking
17 requirements for its AEDs.

18 Please note that the panel is not being
19 asked to comment on the merits of such a petition.
20 Please comment on the adequacy of Philips'
21 description of the methods they have in place to
22 identify users in the event of a recall.

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1 DR. SOMBERG: Warren.

2 ACTING CHAIR LASKEY: Yes, John.

3 DR. SOMBERG: I think it's important that
4 there has to be a very detailed tracking system, and
5 I don't know why that -- and I'm very disturbed about
6 46 percent being able to be identified. I really
7 don't understand why if you purchase this you don't
8 get the card filled out immediately. If the device
9 is given to someone else, that is a problem, and
10 you're probably only going to get feedback when they
11 need some part of some maintenance, but at least get
12 the name of one person and probably to suggest that
13 if it's transferred a second for the warranty, you
14 know, to sustain itself and to get an extra discount
15 or something, you need to fill out another card.

16 But it seems to me there should be a
17 mandatory card filled out similar to a gun, and we k
18 now that ATF has a lot of troubles tracing guns, but
19 at least they know who the first purchaser was..

20 DR. KRUCOFF: I agree. You know, I just
21 think whether you did it at the time of sale, at
22 least tracking through the first point of sale. What

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1 if protocols really do change and you've got a big
2 sticker on the front of all of these things that say
3 call 911 for a pediatric purpose or don't call 911
4 for a pediatric purposes and the recommendations
5 change? I mean, I think at least that first --

6 ACTING CHAIR LASKEY: And it needs to be
7 a much tighter surveillance, and it's interesting how
8 in the last sentence you left out the qualifier
9 "promptly" because I liked that in the second
10 sentence, but the mechanism to identify patients
11 promptly.

12 DR. VETROVEC: I think it's important to
13 emphasize, too, that the key may not be only
14 identifying who purchased it. It's conceivable some
15 of these will be purchased as gifts, and so somehow
16 you've got to have the question right or so forth as
17 to who the user is going to be and the contact for
18 the user.

19 MS. WOOD: Number eight, FDA develops an
20 understanding of how devices are performing in the
21 post market period by the reports that come into FDA
22 through the medical device reporting or MDR system.

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1 The sponsor has described the measures they have
2 taken to encourage use of FDA's MDR system in Section
3 4, FDA review memos of the panel pack Question 12.

4 Please comment on the adequacy of the
5 response.

6 DR. SOMBERG: Warren, I thought the post
7 marketing data was quite informative, and it's once
8 again, I think, important to try to keep information
9 on who has the device and every effort should be made
10 to that, but I don't think that was the loosest link
11 in the chain here.

12 DR. KRUCOFF: I actually think there's a
13 huge Pandora's box that I have to admit I guess i see
14 as burdensome here. As this moves into a consumer
15 population, we can't get doctors to fill out MDRs.
16 You know, as we move to consumers, I think the burden
17 to dump this on the company, you know, I think to
18 make efforts to track what's going on, I think one of
19 the built in reporting at least data gathering
20 mechanisms that they have, that they seem to have
21 some real spirit toward maintaining is when a part
22 replacement comes in, to go find out how it was used,

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1 how it did, what happened. That would be very
2 valuable data, and you might be able to get your
3 hands on something interpretable.

4 But you know, to talk to my grandmother
5 about how it went when she defibrillated my
6 grandfather or to ask her to fill out an MDR if he
7 died, we can't get doctors to do that. How can we
8 expect them to get that in a consumer population?

9 I just can't imagine.

10 DR. MAISEL: I do not think it's
11 unreasonable to ask users to call an 800 number in
12 the case of malfunction or suspected malfunction, but
13 I agree with what you said.

14 ACTING CHAIR LASKEY: Yeah, it kind of
15 segues into number nine. I guess number nine has got
16 more potential meat to it than number eight, but I
17 think it's just not feasible, number eight.

18 MS. WOOD: The sponsor has proposed to
19 conduct a post market evaluation of this device.
20 Section 5-7. The primary objective is to assess the
21 safety and effectiveness after use of the device.
22 Please comment on the adequacy of this proposal to

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1 collect information about the device used in a post
2 market period.

3 ACTING CHAIR LASKEY: And we certainly
4 applaud the efforts of Philips to come forth and
5 propose a post market evaluation. That's a key
6 interest of the agency, and obviously as we go over
7 the counter with this product in terms of the
8 adequacy of the proposal, first of all the fact that
9 you're doing it is a credit. It wonderful. It's
10 probably the only way we're going to get information
11 on the use of the device.

12 Any other comments about the program?
13 Yes.

14 DR. SOMBERG: I just have one comment,
15 and you know, taken as a totality, this package, I
16 just want to say I think it's unique to this
17 particular product and not necessarily generalizable.

18 ACTING CHAIR LASKEY: What is unique?

19 DR. SOMBERG: All that we've talked about
20 today, including the post marketing follow-up, et
21 cetera.

22 Do you want me to elaborate more on that?

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1 I think Bram is understanding my particular comment
2 that this is -- I think you need to be this system
3 and not necessarily generalizable to every
4 defibrillator in terms of the safety, in terms of the
5 validations, in terms of everything else, and really
6 since this is an important issue, it would have to be
7 gone through with each different item.

8 DR. ZUCKERMAN: Right, but now we're
9 trying to define the goals of the post market study,
10 and although the sponsor has indicated that they will
11 commit themselves to a post market study, we've heard
12 today how there are a lot of extrapolations being
13 applied here because the data in the intended patient
14 population isn't quite there.

15 So what goals does the panel have in the
16 collection of these 200-odd uses? There aren't any
17 hypotheses defined in the last section of your panel
18 pack. Are there certain questions that you would
19 like answered?

20 For example, going back to Question 1 of
21 the FDA questions, there's really a lack of data
22 perhaps when use of this device is looked at as a

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1 function of educational level. That could be looked
2 at more closely. In this post market study proposal
3 so far, the prescription and OTC device uses are
4 being combined.

5 Is that what the panel really wants to
6 see or do we want to see a series, an adequate series
7 of OTC cases that can be compared to a prescription
8 control to make sure that all of these extrapolations
9 that have been talked about today can be confirmed?
10 What are some reasonable goals here for this post
11 market experience?

12 DR. KRUCOFF: My prediction, Bram, in a
13 realistic sense is that with a diligent effort
14 supported by the sponsor, you might get some
15 information on the former, on the 1(a) confirmed in
16 real use, in real world use. Do people at different
17 educational levels actually know where the yellow
18 pads are? And can they get it to operate?

19 I think as much as all of us would love
20 to have the data of something more elegant, like a
21 comparative with and without prescription, I think
22 the likelihood that you could get that meaningfully,

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1 in my opinion, meaningfully out of a post market
2 experience would be a huge clinical trial.

3 You know, what we might hope would be
4 that some of the NIH sponsored data that might give
5 us some explanation, although the flip side is if
6 this goes OTC, it may undermine the NIH's ability to
7 do this trial altogether. So not that that's the
8 issue for this panel, but I think realistically in
9 the post market environment that learning more about
10 1(a), the operational, can people use it, do they get
11 confused, and relating that to educational level or
12 other things would be learning something.

13 ACTING CHAIR LASKEY: I think we need to
14 be extremely modest in our expectations, but there
15 are some glaring gaps in the information base, which
16 can be obtained at minimal cost, I would think, but
17 we do need to be modest in the expectation. So
18 certainly general use as a registry approach to this
19 , just one cross-sectional swipe or, better yet, just
20 a look at the beginning and a look after a year, but
21 you'd have to evaluate the cost of doing that, but I
22 think we've outlined enough areas where we need

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1 filling in without designing a parallel cohort.

2 DR. ZUCKERMAN: Right. MY comment was
3 not to design a parallel study. the way the protocol
4 reads right now, it's unclear in this case series of
5 200 uses how many would have to be OTC. It's a
6 pooling of prescription of uses and the relevance of
7 the prescription data I'm not sure is what is needed
8 right there. Or I may be wrong. That's where I'm
9 going.

10 Mitch.

11 DR. KRUCOFF: Well, okay. So good point,
12 and I really missed it. I mean, one thing would be
13 to simply start the data gathering during that
14 overlap period, and then you're going to get to a
15 point where you're going to have pure OTC data.
16 That's not a randomized experience obviously or even
17 a parallel experience. It's just done by calendar
18 time from point of release. Would that add
19 importance? I mean, unfortunately I think what to me
20 a lot of the message of today is is that the
21 prescription component of this gadget has been to
22 some degree a barrier or let's say more a barrier

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1 than a thoughtful addition to how the device is used
2 or who it reaches.

3 So I guess my expectations that somehow
4 the prescription versus OTC versions would actually
5 look any different if using the same device are -- I
6 like Warren's word -- I would be very modest in my
7 expectations of what we learned across that boundary.

8 ACTING CHAIR LASKEY: Well, and even more
9 directly, we're assured of the safety of this device.

10 If you could get some effectiveness, that's really
11 what we're after. We don't have a handle on
12 effectiveness by geography, by age, by class, by so
13 much. That would be helpful.

14 DR. NORMAND: If I could say something, I
15 know we're not supposed to be designing anything, but
16 it looks like you're going to use the telephone
17 research as well, and I would urge you to have
18 information on the missing data. This is standard in
19 any analysis that is conducted. So we're going to be
20 modest. We're going to collect data on geographic
21 distribution, educational and some demographics on
22 the population that are using this. Just standard

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1 that you should be thinking about collecting
2 information and it being reported back to you.
3 You've got the numbers and things such as that.

4 I'm not sure about the prescription and
5 OTC, and I'm not sure if you're sort of wasting
6 resources by getting it on both groups of patients.
7 I understand the desire to have both, and it would be
8 nice to have both pieces of information, but I'm not
9 sure where the 200 came from.

10 Did you say 200 sample size?

11 DR. ZUCKERMAN: It's not defined right
12 now. It was derived.

13 DR. NORMAND: Okay. Because I don't know
14 where that --

15 DR. MAISEL: It does state 200 in the --

16 DR. NORMAND: I don't know the
17 justification for that particular sample size. I
18 don't know what that's based on. It's pulled out the
19 air in my mind.

20 But in any event, if you wanted to
21 estimate something, wouldn't it make more sense to
22 use to make it for the OTC population? I feel like

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1 you're going to be wasting some money and we're going
2 to get little information on both groups. So focus
3 on one and do it well I would suggest.

4 DR. MAISEL: I agree with that, and I
5 think it should specify home use. I don't think we
6 need more information about use of this in public
7 access areas, you know, in a shopping mall or
8 something.

9 DR. KRUCOFF: I agree with that.

10 DR. VETROVEC: This may be too mundane,
11 but it would seem to me if you're calling people and
12 finding out how to use certain information, the
13 obvious things that you would like to know is were
14 there any difficulties with using the device or what
15 information would have been helpful to you to know
16 ahead of time.

17 You might be able to learn a lot about
18 how to reconstruct the information going forward. So
19 I wouldn't be --

20 DR. KRUCOFF: You know, that also
21 triggers towards in Sharon-Lise's sort of emphasis.
22 I think one of the critical pieces in gathering some

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1 of these data is to find out the patient's outcome
2 because if the people who don't respond to your
3 survey are the ones who are depressed because they
4 die, the use died, boy, would that be the wrong kind
5 of slant.

6 So, you know, I think at some point
7 putting the energy into making this a meaningful data
8 set would be extremely valuable if you can keep your
9 arms around it.

10 ACTING CHAIR LASKEY: Okay.

11 DR. RINGEL: I'm sorry. I've missed this
12 before, and I just have to ask this quickly. On the
13 front cover you have a little thermometer, and I had
14 meant to ask this early one, and it says that if it's
15 stored under 50 degrees less tha 48 hours. Does that
16 mean the whole thing has died in two days if it's
17 left out in your car in Minnesota nine months out of
18 the year?

19 DR. KRUCOFF: Yeah, but everybody is so
20 hypothermic they live forever. So it doesn't make--

21 (Laughter.)

22 ACTING CHAIR LASKEY: Dan Power.

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1 MR. POWERS: The indicator on the box is
2 really about shipping and how you would treat the
3 device. We don't want it just sitting out on
4 shipping docks where it's very hot because heat
5 affects pads and battery shelf life.

6 DR. RINGEL: So it's not in actual use.

7 MR. POWERS: At 48 hours it's not going
8 to like suddenly vaporize or anything.

9 ACTING CHAIR LASKEY: Okay. We are
10 moving into the home stretch here. The last portion
11 of our session today is the open public hearing.

12 DR. KRUCOFF: Warren. I'm sorry.

13 ACTING CHAIR LASKEY: Yes. Sorry.

14 DR. KRUCOFF: Can I? Just before we
15 leave questions. I just want to suggest wording
16 going all the way back, but just to wordsmith a
17 suggestion on what might go on the front of the box,
18 who buys this thing. It might say for emergency use
19 in conjunction with CPR of unresponsive subjects
20 while awaiting 911 rescue response.

21 I just wanted to suggest a ballpark of
22 wording of if you want to know who ought to buy this

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1 thing or what it's about, but something in that
2 flavor which is just what we are talking about. I
3 just wanted to put that on the record.

4 DR. VETROVEC: The definition of what it
5 is, I'm not sure it still addresses who ought to buy
6 it. I think it still needs a list of at least the
7 people who are at greatest risk and the concept that
8 half the people who die suddenly didn't know they
9 were sick.

10 ACTING CHAIR LASKEY: I think we've
11 raised enough issues for the agency and the sponsor
12 to ponder for quite some time. So if we can now
13 again move to the open hearing, the first speaker
14 this afternoon that has requested time is John
15 Gregoire.

16 I hope I've pronounced that right.

17 MR. GREGOIRE: Yes. It's John Gregoire.

18 That's a tough one there.

19 Good afternoon. I appreciate the time to
20 speak with you folks today. My name is John
21 Gregoire, and I'm a sudden cardiac arrest survivor.

22 Philips is paying my travel expenses.

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1 MS. WOOD: Just keep the mic close,
2 please.

3 MR. GREGOIRE: Okay. Philips is paying
4 my travel expenses for attending this event today. I
5 live in Dallas, but I took a day off from my family
6 vacation in Hilton Head, left them there to attend
7 this event because it's very important to me.

8 I'm here to void my support for the
9 elimination of the prescription requirement. I know
10 first hand the importance of this technology. On
11 June 23rd, 2002, while working out at the Plano YMCA
12 with my two sons and wife, I experienced sudden
13 cardiac arrest.

14 A heart surgeon who happened to be
15 working out at the club at the same time recognized
16 that that was what had occurred with me and began
17 applying heart massage as well as CPR.

18 Due to that early intervention, I have no
19 heart damage, brain damage, actually any evidence of
20 even the event occurring.

21 He asked the club if they had a
22 defibrillator. The YMCA in Plano had bought one just

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1 a couple of months prior. They used it to restore my
2 rhythm, and you know, clearly was very blessed and
3 lucky to be in that place with someone who gave that
4 care, as well as having the technology.

5 Unfortunately many other people aren't so
6 lucky. The survival rates for SCA, as everyone
7 knows, are low primarily due to two reasons: time
8 and technology. Additionally, the public safety net
9 of paramedics and ambulances can't get to victims'
10 locations and time. So the elimination of the
11 prescription requirement in my opinion will get more
12 defibrillators out and available to where these
13 events occur and will save lives.

14 Now, in my particular case, I had 99
15 percent, 99.9 percent blockage in one of my major
16 arteries, and 50 percent in a second artery that two
17 stents today now keep open nicely. The problem for
18 many people, including me, is there were no symptoms,
19 no pain, no shortness of breath, no warning of any
20 kind.

21 Even when SCA occurred, it was like a
22 light switch. There was no pain. there was no chest

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1 clutching. Just darkness.

2 So even after this event happened to me,
3 I waited 18 months believe it or not before I got a
4 home defibrillator. After such a traumatic event,
5 you're in denial that it's necessary, that it's
6 important, and other barriers, such as the
7 prescription requirement, makes it even easier to
8 ignore.

9 Relatives and friends that looked into
10 purchasing a defibrillator for me when they ran into
11 the prescription barrier just kind of moved side and
12 didn't take that next step.

13 Today I bring my defibrillator to my
14 office daily.

15 So in conclusion, lives can be saved with
16 the availability of defibrillators. The removal of
17 the prescription obstacle will allow consumers to act
18 on their needs and have this proven, safe technology
19 available for themselves, as well as others.

20 Thank you.

21 ACTING CHAIR LASKEY: Thank you, sir.

22 Next on the roster is Dr. Graham Nichol,

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1 or at least a statement from Dr. Nichol.

2 DR. NICHOL: Good afternoon. I'm Graham
3 Nichol. I'm here as a representative of the American
4 Heart Association. I currently chair the Heart
5 Association's Automated External Defibrillator Task
6 Force.

7 Before I make the core of my remarks, I'd
8 like to declare some potential conflicts of interest.

9 I have a clinical practice in the emergency room of
10 Harborview New Medical Center in Seattle. I am
11 Director of the University of Washington, Harborview
12 research and training center for pre-hospital care,
13 and also my associated with University of Washington
14 clinical trial center. Both of those centers enroll
15 patients or coordinate trials in a number of
16 industries and agency sponsored trials evaluating
17 resuscitation, interventions.

18 I also hold an investigational device
19 exemption from the FDA for a randomized trial of
20 wearable cardioverter defibrillator. And I
21 previously received grants from several AD
22 manufacturers for an out-of-hospital cardiac arrest

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1 registry.

2 However, I hold on relevant to equity,
3 and I've never taken any salary support, speaker fees
4 or consulting fees from any device company or from
5 the Heart Association. The Heart Association does
6 not endorse any drug or device, but we endorse all
7 efforts to reduce death and disability due to
8 cardiovascular disease, obviously a major cause of
9 cardiovascular disease is out of hospital cardiac
10 arrest, which is common, lethal, debilitating, and
11 costly.

12 Many of those events, as you have heard
13 earlier, occur in the home and most EMS systems, if
14 they arrive quickly are able to get good results, but
15 are not able to arrive quickly.

16 So in 1992 we previously challenged
17 manufacturers to make small, simple, easier to use,
18 automated external defibrillators that could be made
19 available to lay responders to use at the onset of
20 cardiac arrest before the arrival of the MES
21 providers.

22 The National Heart, Lung, Blood Institute

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1 and American Heart Association and others sponsored
2 the public access defibrillation trial or PAT trial
3 to test whether defibrillator by lay responders in
4 public settings was effective and cost effective.
5 The results of the primary analysis will be published
6 shortly in the New England Journal of Medicine.
7 Included in the study were community units, for
8 example, shopping malls, recreational facilities and
9 apartment complexes randomized to receive either
10 structured and monitored emergency response system
11 with lay responders receiving training in CPR or CPR
12 and AED capability. About 20,000 volunteers
13 participated in the study. There was a significant
14 important difference in survival observed in these
15 CPR and AED group compared to CPR alone.

16 This demonstrated that training,
17 equipping, and maintaining volunteers to provide
18 early defibrillation within a structures response
19 system improved survival to hospital discharge from
20 cardiac arrest in public locations.

21 Currently the National Heart, Lung, and
22 Blood Institute and Philips are sponsoring the HAT

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1 trial to test whether defibrillation by lay
2 responders in the home setting is effective and cost
3 effective. However, regarding device safety as part
4 of our ongoing review of the scientific literature to
5 update our emergency cardiovascular care guidelines,
6 we recently systematically reviewed Medline and M-
7 BASE from 1966 to the present to identify any adverse
8 effects associated with use of defibrillators. There
9 were actually six published cases. In one case the
10 individual who was shocked inappropriately died. In
11 five other cases there was no adverse effect.

12 Also, in 1990, Gibson and Eisenberg
13 reported eight accidental shocks to EMS providers in
14 King County, Washington. Most of those were the
15 result of accidental contact with the patient. There
16 were no fatalities.

17 Note, however, that both the intentional
18 and unintentional inappropriate shocks that I just
19 described were all with manual defibrillators. There
20 is no published or unpublished evidence that we are
21 aware of which demonstrates harm with inappropriate,
22 intentional or unintentional shocks.

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1 And also in the PAD trial, which Dr.
2 Ornato and Dr. Becker and others have alluded to
3 today, there were no adverse effects associated with
4 inappropriate shocks from the AEDs.

5 Therefore, we recommend that use of AEDs
6 by lay responders in public or home settings should
7 include training and device maintenance.

8 To summarize, we are unaware of any
9 published or unpublished evidence that the
10 requirement of a prescription prior to dispensation
11 of an AED increases the likelihood that a responder
12 will be able to use an AED better, nor are we aware
13 of any published or unpublished evidence that the
14 prescription requirement decreases inappropriate use
15 or adverse effects.

16 Therefore, we support removal of the
17 prescription requirement for automated external
18 defibrillators.

19 Finally, as I was listening to the
20 comments today, perhaps we may make some
21 extemporaneous remarks about the notion of physician
22 prescription and Web dispensation of AEDs. That

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1 makes as much sense as the notion of physician
2 prescription and Web dispensation of pharmaceuticals.

3 It is not getting you what you want. It makes no
4 sense. We think the prescription requirement should
5 go away.

6 Thank you.

7 ACTING CHAIR LASKEY: All right. Thank
8 you.

9 Next up is Michael Willingham.

10 MR. WILLINGHAM: Good afternoon. Thank
11 you for the opportunity to speak before the panel
12 today on behalf of my company, Medtronic.

13 My name is Mike Willingham. I am the
14 Vice President of Regulatory Affairs for Medtronics
15 Emergency Response Systems Division, formerly known
16 as Physiocontrol.

17 I have no financial interest in the
18 sponsor. My salary is paid by Medtronics, and my
19 expenses to travel here today are covered by the
20 company.

21 I should also mention that I also serve
22 as the co-chairman of the American National Standard

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1 Committee for Performance and Safety of External
2 Defibrillators.

3 Medtronic is the leading producer of
4 external defibrillators and AEDs. The company
5 conducts research, designs, manufacturers, sells, and
6 services its defibrillators, and we have been doing
7 so for nearly 50 years.

8 We introduced the first AED model
9 specifically designed for lay users in the home in
10 1986 and received FDA 510(k) clearance for that use.

11 The LifePack 100 was sold to physicians and
12 prescribed to individual patients with high risk for
13 sudden cardiac arrest.

14 The physicians trained the patient's
15 spouse or caregiver in CPR skills and the AED
16 operation. The device was nicknamed the HomePack
17 defibrillator. It was very small in design and
18 similar to today's AED designs. It was small,
19 lightweight, simple to operate, and had instructional
20 prompts to guide the user through a resuscitation
21 attempt

22 However, this device was ahead of its

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1 time. While it was effective for its intended use,
2 public awareness of sudden cardiac arrest and early
3 defibrillation programs was still years off, and as a
4 result, the sales of LifePack 500 were limited, and
5 the production was discontinued just a few years
6 later after introduction.

7 Nonetheless, this device demonstrated
8 that AEDs could be used safely and effectively by lay
9 persons. Fortunately today public awareness of
10 sudden cardiac arrest and the willingness of the
11 general public to volunteer as a rescuer for a sudden
12 cardiac arrest victim has increased dramatically, and
13 while tremendous effort and progress has been made in
14 recent years, the survival rates for sudden cardiac
15 arrest, as everyone here has mentioned, are still
16 abysmal.

17 Hundreds of thousands continue to die
18 every year, and we encourage FDA to keep the enormity
19 of this public health issue in mind as we consider
20 the relative risks and benefits of over-the-counter
21 availability of AEDs.

22 Medtronics supports any movement to

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1 increase the awareness of sudden cardiac arrest and
2 to promote the methods and tools to treat this
3 disease. We encourage the FDA to thoughtfully
4 consider removing the prescription requirement for
5 certain models of AEDs that are designed and proven
6 as safe and effective devices for lay users.

7 AED designs have continually improved in
8 recent years, and several clinical studies have shown
9 very promising results in public access
10 defibrillation programs with dramatically improved
11 survival rates.

12 Large scale studies of home AED use are
13 already underway, and we should all be encouraged by
14 these developments.

15 The Emergency Care Research Institute,
16 based in Pennsylvania, issued a comprehensive report
17 in June 2004 evaluating and comparing the majority of
18 AED models on the U.S. market today.

19 ECRI is an independent, nonprofit
20 research company and serves as the consumer reports
21 for the medical device industry. ECRI considered
22 several factors in evaluating these AEDs for use by

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1 lay users. The report provides an excellent detailed
2 review of each model for comparison, and ECRI
3 concluded that several models of AEDs are appropriate
4 and safe for lay use.

5 We recommend that FDA review this report
6 and its assessment of over-the-counter sales for
7 AEDs.

8 AEDs today are already being sold with
9 prescription and increasing numbers to individuals
10 and organizations that have never owned a
11 defibrillator before. We understand that consumers
12 and non-medical organizations need help in
13 establishing early defibrillation programs, and we
14 offer support services through companies that include
15 medical direction, CPR and AED training, device
16 registration with local EMS, post event medical
17 review, liability protection and, if needed,
18 physician prescription for the sale of an AED.

19 It's our experience that obtaining a
20 physician prescription is relatively a minor
21 consideration in cost in the overall consumer
22 purchase of an AED. From the purchaser's

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1 perspective, there are many considerations.

2 Nonetheless, FDA authorization to market
3 an AED without a prescription would give the consumer
4 more confidence the device is safe for use by the
5 general public, and hopefully it would encourage
6 wider adoption, and we encourage the FDA to consider
7 this benefit.

8 Federal prescription requirement is just
9 one of many controls placed on AEDs today. Consumers
10 must also consider state legal requirements, and
11 nearly all states have Good Samaritan liability
12 protection laws around the ownership and use of AEDs.

13 Some states also require prescription for the sale
14 of AEDs, and nearly all states require a state
15 licensed physician to be involved in the AED program,
16 and require users to attend approved training.

17 We currently offer most of these support
18 services. However, they add cost and complexity to
19 the purchase, and they inevitably impede the adoption
20 and deployment of AEDs.

21 We encourage legislators and regulators
22 to balance the need for these controls; that the need

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1 to increase availability of AEDs to aggressive
2 improve nationwide survival rates from sudden cardiac
3 arrest.

4 My final point would be that earlier this
5 year FDA publicly proposed to reclassify AEDs from
6 Class III to Class II. Per the regulation for Class
7 II, FDA intends to provide guidance for special
8 controls to AED manufacturers in the near future.
9 Special controls may include labeling requirements
10 conformance to recognized performance standards and
11 post market surveillance.

12 A new edition of the American standard
13 for external cardiac defibrillators was published
14 just last year. The standard includes specific
15 requirements for AEDs, including those designed for
16 infrequent use and public access in home settings.
17 It includes requirements for ECG analysis algorithm
18 performance and defibrillator waveforms.

19 Medtronic encourages FDA to develop a
20 special control guidance document for AEDs and to
21 provide the industry with a common set of
22 requirements for future market clearance of AEDs.

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1 This guidance document should provide the foundation
2 for any unique controls for OTC AEDs.

3 ACTING CHAIR LASKEY: Mike, excuse me.
4 We're well over the allotted time. So if you can
5 summarize or wrap up.

6 MR. WILLINGHAM: And I am done. Thank
7 you very much.

8 ACTING CHAIR LASKEY: Oh, great. Thank
9 you very much. It's just in fairness to all the
10 other speakers today who are trying to adhere to the
11 allotted schedule.

12 The next scheduled speaker is Mary
13 Newman.

14 MS. NEWMAN: Good afternoon, Dr. Laskey
15 and members of the panel. Thank you for the
16 opportunity to speak here today.

17 I represent the National Center for Early
18 Defibrillation, which is based at the University of
19 Pittsburgh, and with me today is Dr. Vince Mosesso,
20 the Medical Director for the National Center for
21 Early Defibrillation, who is also an associate
22 professor at the University of Pittsburgh School of

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1 Medicine, Department of Emergency Medicine.

2 In the interest of disclosure, our
3 organization is funded by two corporate foundations,
4 seven AED companies, and two private foundations.

5 The remarks I'm about to share with you
6 have been provided to you in your packets, and also
7 I'd like to mention that Dr. Mosesso co-authored
8 these remarks.

9 The National Center for Early
10 Defibrillation, a nonprofit, vendor neutral,
11 information clearing house and resource center based
12 at the University of Pittsburgh, supports a change in
13 the Food and Drug Administration to enable over-the-
14 counter sales of AEDs to consumers for personal use.

15 The rationale for this recommendation follows.

16 Number one, sudden cardiac arrest is the
17 leading cause of death in the United States affecting
18 about 1,000 people every day. It affects more people
19 than the number who die from breast cancer, prostate
20 cancer, AIDS, handguns, house fires, and traffic
21 accidents combined.

22 Number two, despite the fact that

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1 efficacious therapies exist, only seven percent of
2 sudden cardiac arrest victims survive. This dismal
3 survival rate is due to the fact that most victims do
4 not receive effective treatment, that is, a
5 combination of CPR and defibrillation in a timely
6 manner, and as you know from all the other remarks,
7 this has to occur within minutes for it to be
8 successful.

9 Without treatment sudden cardiac arrest
10 leads to death.

11 Number three, AEDs are safe, user
12 friendly, computerized devices, things to voice and
13 visual prompts that can be used effectively by
14 trained and lay persons. While training is
15 recommended, the devices have also been used
16 effectively by untrained lay persons.

17 Further, AEDs cannot harm patients. They
18 will not deliver defibrillatory shocks to individuals
19 who do not need to be shocked.

20 Number four, while some individuals at
21 high risk for sudden cardiac arrest can be identified
22 in advance and these individuals may benefit from

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1 implantable cardioverter defibrillator therapy, most
2 cases of sudden cardiac arrest are unpredictable.
3 Sine sudden cardiac arrest occurs most often in the
4 home and sudden cardiac arrest is predominantly
5 unpredictable, it stands to reason the consumers who
6 are aware of this information who are conscientious
7 about family health and safety and who wish to
8 prepare for sudden cardiac emergencies may seek to
9 purchase AEDs and have these devices available in
10 their homes and personal vehicles.

11 Currently consumers first have to get a
12 prescription to purchase the device, which is an
13 unnecessary impediment to optimal resuscitation
14 readiness.

15 Number five, despite the increasing
16 attention to deployment of AEDs in public locations,
17 most cases, 70 to 80 percent of cardiac arrests occur
18 in private residential settings, and research
19 indicates that when sudden cardiac arrest does occur
20 in the home, the event is witnessed in 54 percent of
21 cases.

22 Therefore, in about half the cases that

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1 occur in the home, someone would be available to
2 administer defibrillation, potentially leading to
3 many more lives saved than the penetration of all
4 public venues with AEDs.

5 Number six, the concept of medical
6 oversight is beneficial in specific settings. AED
7 programs and community-wide and large public or
8 private facilities are strengthened when there is
9 strong medical oversight.

10 However, medical oversight of home AED
11 programs is impractical and not warranted. The
12 benefits of medical oversight can be provided through
13 appropriate labeling and inclusion of instructional
14 and reference materials with the device.

15 Further, the typical medical oversight
16 prescription model does not apply to consumers and
17 their families since both the victim and rescuer are
18 unknown.

19 Number seven, a change enabling over-the-
20 counter sales of AEDs to consumers has the potential
21 to have a strong positive impact on sudden cardiac
22 arrest survival nationwide, without incurring any

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1 risk to future sudden cardiac arrest victims or their
2 rescuers.

3 We do not believe that the prescription
4 requirement provides significant efficacy or safety
5 benefit for personal purchase and use of AEDs and,
6 indeed, is an impediment to more widespread
7 availability of this life saving therapy in the
8 setting where it occurs most often.

9 However, we also feel that with the
10 elimination of the prescription requirement there
11 should be comprehensive user friendly instructional
12 materials. These should clearly and thoroughly
13 explain and demonstrate device operation and
14 maintenance.

15 For all of these reasons, the National
16 Center for Early Defibrillation urges the FDA to
17 eliminate the prescription requirement for purpose of
18 AEDs for personal use.

19 Thank you.

20 ACTING CHAIR LASKEY: Thank you.

21 The next scheduled speaker is Carol
22 Spizzirri.

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1 MS. WOOD: Actually she sent in a
2 statement to be read into the record. This is from
3 the Save a Life Foundation.

4 "Dear Ms. Wood:

5 "Although AEDs are a valuable tool in the
6 resuscitation of lives, they should be lower in cost
7 and more available. They should be managed by the
8 medical community so a fear factor is not created in
9 purchasing them without an educational component and
10 CPR and their use, including the general maintenance
11 of the unit so they work when needed with regular
12 practice to create a comfort level by the user.

13 "Lastly, it is important to redefine the
14 Good Samaritan law and promote it at the national
15 level to protect individuals against frivolous
16 lawsuits."

17 This is signed by Carol J. Spizzirri,
18 R.N., President/Founder, and Mark Mitchell, D.O.,
19 Chairman.

20 ACTING CHAIR LASKEY: I guess you're
21 going to read a statement from Mr. Grogan then?

22 MS. WOOD: Yes.

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1 ACTING CHAIR LASKEY: Okay.

2 MS. WOOD: This is dated July the 13th.
3 "I am writing this letter to convince you that the
4 FDA prescription requirement for the purchase of AEDS
5 is an impediment to their deployment and, by
6 extension, risks the lives of future sudden cardiac
7 arrest victims.

8 "More than a quarter of a million
9 Americans suffer an SCA each year. Only five percent
10 survive. I am one of the chose few.

11 "My life was saved on November 16, 2002,
12 on board United Airlines Flight 1540. Dr. Hocksell
13 (phonetic) Garcia began immediate CPR and United
14 Airlines attendant Michael Braddock brought my heart
15 back to a normal rhythm through the use of an AED.

16 "I am a member of Sudden Cardiac Arrest
17 Survivor's Network. SCASN's parent organization is
18 the National Center for Early defibrillation, NCED,
19 which is located at the University of Pittsburgh.

20 "Since my sudden cardiac arrest, I have
21 developed myself to promoting greater public access
22 to defibrillation. This crusade has taken me into a

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1 wide array of venues: Silicone Valley companies,
2 fitness centers, police departments, as well as other
3 public and private organizations.

4 "In addition, given the fact that 70
5 percent of all sudden cardiac arrests take place in
6 the home, I have also been a strong proponent of
7 greater private access to defibrillation.

8 "SCA survivors all have one thing in
9 common. An AED was available to them in their time
10 of need. Therefore, anything that inhibits AED
11 deployment is life threatening to future SCA victims.

12 "I have seen the chilling effect when
13 people learn that they must have a doctor's
14 prescription in order to purchase an AED. The
15 prescription requirement does nothing to improve the
16 ease of the use or the life saving potential of AEDs.

17 "At the very best, all that can be said
18 about this regulation is that it makes it more
19 difficult for anyone to acquire and deploy an AED.
20 In other words, this regulation stifles the
21 proliferation of this miraculous piece of medical
22 equipment.

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1 "The calculus of SCA is simple and
2 indisputable. As we increase the number of AEDs
3 available in public and private venues, the SCA death
4 rate will diminish. Unfortunately the FDA
5 prescription requirement is an impediment to this
6 noble goal.

7 "In conclusion, I strongly urge you to
8 revoke the FDA regulation that requires a
9 prescription for the purchase of AEDs. By taking
10 this step, you will improve the SCA survival rate.

11 That's from Jack Grogan in San Jose,
12 California.

13 ACTING CHAIR LASKEY: Thanks, Geretta.

14 And if you have any more stamina left,
15 you can read the last statement from Dr. Kellerman.

16 MS. WOOD: This is dated July 12th. "To
17 Whom It May Concern:

18 "I regret that I will be unable to attend
19 the upcoming meeting of the panel. I am writing to
20 express my opposition to the proposed premarket
21 notification submission. I am Professor and Chair of
22 the Department of Emergency Medicine, Emory School of

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1 Medicine in Atlanta, Georgia.

2 "I have conducted research on out of
3 hospital cardiac arrest and the use of automated
4 defibrillators. My former mentor, Dr. Mickey
5 Eisenberg and I, published opposing editorials on
6 this topic in the September 20th, 2000 issue of JAMA.

7 A copy of my editorial is attached to this letter.

8 "I have been employed by Emory University
9 since 1993. I own no stock in any device
10 manufacturer, nor have I accepted salary support or
11 honoraria from any manufacturer. One manufacturer,
12 Leardahl Medical Corporation, donated the devices
13 that were used in my study of fire fighter
14 defibrillation in Memphis, Tennessee.

15 "Another company, Medtronic/Physio
16 Control, recently agreed to loan my current
17 institution equipment to study the utility of
18 acquiring 12 lead ECGs in the field to improve the
19 outcome of patients suffering from acute myocardial
20 infarction.

21 "The argument in favor of over-the-
22 counter sales of automated defibrillators goes

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1 something like this. Number one, heart disease is a
2 major cause of death.

3 "Two, ventricular fibrillation is a major
4 cause of death due to heart disease.

5 "Three, rapid defibrillation is necessary
6 to save victims in VF.

7 "Four, AEDs allow rescuers with minimal
8 training to deliver defibrillatory shocks.

9 "Therefore, widespread deployment of AEDs
10 in homes will save thousands of lives following
11 cardiac arrest.

12 "There is solid scientific evidence to
13 support statements one through four. There is no
14 scientific evidence to support statement number five.

15 Published studies on use of automated defibrillators
16 by first responders, fire fighters, police officers,
17 and other public safety personnel have yielded mixed
18 results. Interestingly clinical trials that have
19 included a control group, as well as a treatment
20 group, do not demonstrate the same degree of benefit
21 reported by before/after studies that use historical
22 controls.

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1 "When I was a member of the faculty of
2 the UT-Memphis School of Medicine, I led one of the
3 first major controlled clinical trial of first
4 responder defibrillator by fire fighters. Rather
5 than equip all of our fire companies with AEDs and
6 compare their performance to historical statistics, I
7 equipped half of our companies with AEDs and
8 retrained the other half to perform excellent quality
9 cardiopulmonary resuscitation until the paramedics
10 arrived.

11 "During our two-year study period, the
12 rates of cardiac arrest survival in our treatment or
13 AED group was twice what we had observed in our
14 historical controls. However, survival doubled in
15 the CPR, the control group, as well.

16 "If we failed to include a control group,
17 we would have reached the erroneous conclusion that
18 AED use doubled Memphis' cardiac survival rate. It
19 didn't. Simply conducting the study boosted cardiac
20 arrest survival because it motivated everyone to do a
21 better job.

22 "In another study, researchers examined

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1 what happened when 19 urban and suburban communities
2 in Ontario, Canada enhanced their emergency care
3 system by equipping first responders with AEDs.
4 Following this innovation, cardiac survival increased
5 from 3.9 percent to 5.2 percent, a modest but
6 statistically significant difference.

7 "However, most of this improve was due to
8 a higher rate of survival from pulseless electrical
9 activity, PEA, a condition that does not respond to
10 early defibrillation.

11 "Again, it wasn't the introduction of
12 AEDs that made the difference, but probably better
13 CPR. The data on the benefits of widespread
14 deployment if public access to defibrillators is even
15 weaker than that reported for first responders. The
16 two most widely cited studies involved placing AEDs
17 in casinos and on commercial aircraft. Both are
18 singular environments that they are little
19 resemblance to the real world.

20 "Casinos are an idea location for AEDs.
21 They are covered by surveillance cameras, feature
22 roaming security officers who are trained to perform

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1 CPR and operate an AED, and they are filled with
2 thousands of overweight, chain smoking patrons losing
3 lots of money.

4 "This environment bears little
5 resemblance to Main Street, USA. The widely cited
6 study that put AEDs on the fleet of American Airlines
7 saved six lives. To achieve this benefit, the
8 company trained more than 24,000 flight attendants
9 and transported over 70 million passengers.

10 "What do studies tell us about the
11 benefits of placing an AED in the home? Well, there
12 aren't any. To the best of my knowledge, the only
13 published trial of placing a defibrillator in the
14 homes of high risk cardiac patients produced negative
15 results. A larger study is presently underway, but
16 its findings are not yet available.

17 "For patients at significant risk for
18 sudden cardiac death, an implantable defibrillator
19 makes more sense because it operates itself
20 automatically. For the rest of us the odds that we
21 will ever need a defibrillator are quite small. If
22 that time comes, the odds that someone will be nearby

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1 and know where the AED is kept are smaller still. A
2 clever salesman might argue that purchasing an AED
3 for the home is no different than purchasing a fire
4 extinguisher. It is better to have one and not need
5 it than to need one and not have it.

6 "It is worth noting, however, that having
7 an AED in the home might actually impair a person's
8 odds of survival. Will the family of a cardiac
9 arrest victim lose precious minutes searching for the
10 device rather than calling 911? Will they focus so
11 intently on operating the AED that they forget to
12 perform CPR? Will people who buy an AED place undue
13 confidence in the device and either skimp on
14 preventative care or fail to dial 911 at the onset of
15 cardiac symptoms?

16 "Obviously these are hypothetical
17 concerns. At this point the putative benefits of
18 over-the-counter sale of AEDs are hypothetical as
19 well. The FDA simply doesn't have the data it needs
20 to reach an informed conclusion one way or the other.

21 "Clearly, this is an instance when the
22 commercial imperative to sell AEDs has outpaced

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1 scientific research on this subject. With nothing
2 more than device performance data you are being asked
3 to authorize the unrestricted sale of a very
4 expensive lottery ticket.

5 "Thanks to the movie Jerry McGuire,
6 Americans are familiar with the express 'show me the
7 money.' Before members of the FDA Circulatory
8 Systems Device Panel authorize over-the-counter sale
9 of AEDs, they should shout, 'Show us the data.'"

10 And that is signed Arthur L. Kellerman,
11 M.D., MPH, Professor and Chair, Department of
12 Emergency Medicine, Emory School of Medicine.

13 ACTING CHAIR LASKEY: All right. Geretta,
14 take a break.

15 Is there anyone else in the audience who
16 wishes to address the panel today?

17 I'm sorry. How many -- I'm sorry. Just
18 so we can reschedule our time we're here. Well, we
19 heard from one this morning, right?

20 If you want to come forth, sir. Yes.

21 So there are two additional? Yeah,
22 great, thank you.

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1 MR. BROWN: Dr. Laskey and members of the
2 panel, my names is Richard Brown, and I am a survivor
3 of sudden cardiac arrest. I am also President of the
4 Sudden Cardiac Arrest Survivor Network.

5 My life was saved because of the
6 proximate availability and rapid deployment of an
7 automated external defibrillator, but it could easily
8 have been otherwise. My SCA due to an artery
9 blockage happened in a health club where
10 approximately two months before another man died
11 before my eyes. He died because there was no AED at
12 the facility at the time, and it took 45 minutes for
13 an ambulance to arrive after 911 was called.

14 My health club responded to my request to
15 install an AED, and as good fortune would have it, I
16 was the first upon whom it was used.

17 On the day of my SCA, an emergency call
18 to 911 from the health club generated a busy signal.

19 A member of the club who saw me go down ran across
20 the street to the fire station and was told that they
21 could not respond. The station was in a different
22 response district.

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1 Notwithstanding these impediments to
2 saving me, the availability and rapid deployment of
3 CPR and of an AED by some of the club's physical
4 trainers saved my life.

5 As President of the SCA Survivor Network,
6 I have had the happy experience of meeting and
7 talking to scores of others who have a similar story
8 to tell. I know survivors who have been rescued
9 while at an airport, while at school, while at home,
10 while at health clubs or a gym, while acting on
11 stage, while at work, and while engaging sports.

12 Easy was lucky to be near a defibrillator
13 that was rapidly put into use. Today you have the
14 power to significantly take luck out of the equation.

15 If we simply contemplate where we spend most of our
16 time, it is at home. About half our time is spent
17 there and on the average, that is where we can expect
18 the majority of SCAs to occur.

19 Elimination of the prescription
20 requirement making the device a simple consumer
21 purchasing opportunity will make AEDs more readily
22 available to consumers and thus, to SCA victims where

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1 they most often need it.

2 I'd like to think of this opportunity as
3 not one confined to home use, by more broadly to
4 personal use. For the consumer defibrillator, it's
5 not likely to be confined to some wall in the
6 basement or attic. It will go on family vacations.
7 It will be taken to children's football soccer and
8 basketball and hockey games and to swim meets and all
9 other sporting events.

10 There will emerge a two defibrillator
11 family, one to keep at home and one to keep with you
12 wherever you go.

13 Who will be affected? Contrary to what
14 one might expect, the average age of our survivors in
15 our group is relatively young, in the early 50s, and
16 14 percent of our group is comprised of teenagers.

17 Survivor demographics span the highest
18 level of consumer purchasing power in America. SCA
19 survivors are representative of an immense population
20 that is in danger of dying of SCA. At the same time
21 they represent the group that is very likely to
22 purchase personal AEDs. That is why your decision is

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1 so critically important. Since SCA cuts across all
2 ages and is most likely to occur at home or where
3 consumers are likely to take his or her person AED.

4 Your decision to improve the availability
5 of an AED as a consumer product will immediately save
6 lives. As more AEDs are sold in the consumer market,
7 the price barrier will also diminish. Look at the
8 history of cell phones, of VCRs, DVDs and flat screen
9 TVs. The retail prices have dropped dramatically as
10 more and more consumers learn about them and begin to
11 appreciate your usefulness.

12 And I hope that provides some insight,
13 Mr. chairman, as to your concern before about this
14 being available to people who cannot afford the
15 present price.

16 Removal of the prescription requirement
17 for the sale of automated external defibrillators
18 will have an immediate positive outcome in saving
19 lives throughout the country. Therefore, the Sudden
20 Cardiac Arrest Survivor Network of NSAID urges the
21 expeditious removal of this requirement.

22 Thank you for your time.

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1 ACTING CHAIR LASKEY: Thank you, sir.

2 MR. BAUM: My name is Jim Baum. I
3 primarily live in Lodai, California.

4 I'm here today to urge that you drop the
5 requirement for prescriptions to purchase AEDs, and
6 I'm going to tell you the story of how the ones I
7 purchased for my personal use saved my life.

8 I read Monday's Wall Street Journal
9 article. Late Tuesday afternoon I was in my summer
10 home up in northern Washington, and I got thinking
11 about it, and I got thinking about it, and I thought,
12 you know, we have to get more of these AEDs out where
13 people can use them and save lives just like they
14 saved mine.

15 So I called Philips, and they said please
16 get on the "red eye" last night. "Come out here and
17 tell your story."

18 Last September I was going through O'Hare
19 Airport on my way to somewhere that's not important,
20 and I saw my first AED, that I had never seen any
21 before, and I looked at that and I thought, you know,
22 my neighbor on the west side of me in Lodai is 84

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1 years old. I own a winter home in Porta Vallarta,
2 Mexico. My neighbor on the north side that is 87 and
3 his wife is 82, and the one on the south side is 78.

4 And I'm looking at my own friends, and
5 we're getting older, too, my friends around me. I've
6 got my own tonsils, my own appendix. The worst thing
7 I've ever had in my life is a cold. I go for a
8 check-up every couple of years. No indication of any
9 kind of heart problem whatsoever, any blockages of
10 any kind.

11 I got on my airplane and didn't think
12 anything more about it, took my trip, came back, and
13 as luck would have it a doctor friend of mine and I
14 were having a cocktail one night at the bar, and he
15 says, "Jim, I've got to buy an AED for my house. Do
16 you want one?"

17 I looked at him, and I said, "Yeah, I
18 want three, one for my house in Washington, one for
19 my house in California, and one for my house in Porta
20 Vallarta."

21 Okay. So in a week come three cardboard
22 boxes. I had never even touched one. The one in the

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1 O'Hare airport was behind glass and said if I opened
2 it a siren would go off and I would be arrested, you
3 know. So I looked at the thing, and I shook the box,
4 and I got busy, and I threw the boxes over in the
5 corner of the bedroom.

6 Well, the three of them sat there for --
7 oh, I don't know -- probably three weeks. We made
8 our first trip down to the home in Puerto Vallarta in
9 late October and we had a bunch of stuff to go. So
10 my wife didn't put one in the suitcases.

11 We came back, and we went down again for
12 Thanksgiving, and she had some room, so she threw one
13 of these cardboard boxes in the suitcase. And we go
14 to Puerto Vallarta and got our shorts on and the beer
15 out and the tequila, and threw the box up on the top
16 of the dresser in the bedroom and thought nothing
17 more of it.

18 So it sat up there for ten days. In the
19 Saturday after Thanksgiving, it was kind of boring
20 and I thought, "Oh, I've got to see what that thing
21 looks like."

22 So I got a box cutter, took it out on the

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1 patio with a cup of coffee, cut the box open, got the
2 thing out. Well, here's an instruction book, started
3 reading the instruction book. Well, you've got to
4 install the battery to make it work. It's not
5 functional until you do that. So I take the little
6 bit off.

7 And to make a long story short, I sat
8 there and played with it. I got my wife out there
9 and showed her how to use it, and we had a house
10 guest and his wife who as luck would have it, he was
11 an oral surgeon, and the four of us sat out there and
12 played with that thing and listened to it talk to us,
13 and I was just amazed at the piece of equipment, how
14 heat it was.

15 And by that time it's cocktail time. So
16 it goes in and sits on the dresser again. the next
17 morning my friend and I took a long walk up the beach
18 and had a good time, and came back. We had our
19 breakfast in a restaurant, and just as we got done,
20 our wives came in. Well, they wanted to eat, and I
21 thought, "I don't want to sit here for an hour while
22 they eat," and I'm feeling kind of punky and I don't

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1 really feel very peppy, and I said, "Guys, you go
2 ahead and set. I'm going back and lay down and take
3 a nap.

4 So I go back and I laid down, and the
5 longer I laid there the worse I felt. Pretty soon my
6 wife and the two house guests came in, and I got my
7 wife in there, and I said, "You know, something is
8 not right here. I don't feel good."

9 She says, "Well, let me get Bob in here."

10 Well, Bob hears the story. Bob reaches over to take
11 my pulse, and just as he's reaching out to take my
12 pulse, I died. Head goes back, eyes roll back, froth
13 at the mouth, become incontinent. I'm dead.

14 Bob says, "Hand me the defibrillator over
15 there, would you?" He gets the defibrillator. He
16 turns it on, he sticks it on me. The machine says,
17 you know, "Stand back and defibrillate," and he
18 pushes the button, and I woke up, and I looked around
19 and I thought, "I went to sleep here while three
20 people were talking to me. How rude," and I started
21 trying to pick up the conversation, and I became
22 aware my left arm was shaking.

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1 And I said to my wife, "Why is my left
2 arm shaking?"

3 And she said, "We had to defibrillate
4 you."

5 Well, I let out a couple of four-letter
6 words and said, you know, "That's stupid. Don't play
7 with me like that." I looked down and, "Oh, my."
8 She was right.

9 If I hadn't had that defibrillator I
10 would not be here today. And so I would urge you to
11 reduce, to eliminate the requirement of having to
12 have a prescription so that we can get defibrillators
13 out where they will save lives in people's hands.

14 Thank you.

15 DR. ZUCKERMAN: Sir, for the record, have
16 you noted all of your potential conflicts of
17 interest?

18 MR. BAUM: I don't think I have any.
19 Nobody has paid me anything. Philips paid for my
20 ticket last night to get out here, but they're not
21 paying me here.

22 DR. ZUCKERMAN: Thank you.

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1 MR. BAUM: I'm self-employed. I don't
2 make any money out of it.

3 ACTING CHAIR LASKEY: Thanks very much.

4 MR. McNELLIS: Good afternoon. My name
5 is Bill McNellis. I'm from Stewartsville, New
6 Jersey.

7 I came here today, thanks to the Philips
8 Corporation. They invited me here to speak in front
9 of this panel, and I thank you for the opportunity.

10 We've just celebrated a two year
11 anniversary of a gentleman who I work with who
12 suffered a massive heart attack, and I use layman's
13 terms because I am a layman at this issue. As it
14 stands right now, I'm probably more nervous standing
15 here talking to you at the panel and the people in
16 the room than I was when I used the AED.

17 But as it stands my story goes we were at
18 work one afternoon or evening about ten after six at
19 night when one of the clerical staff came into my
20 office and told me that one of our clerks was in the
21 back in the computer room clutching his chest and he
22 was profusely sweating and complaining of a lot of

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1 pain.

2 So I immediately got up out of my office
3 and went back and checked on our clerk. Needless to
4 say he had a vice grip on his chest so hard I
5 couldn't hardly even move his arms.

6 At that point in time I realized he was
7 having a heart attack. I contacted an associate of
8 mine and told him to get the AED. Our AEDs in our
9 offices are located in such an area that they're
10 accessible to all of our employees.

11 I work in a food distribution warehouse,
12 and our AED is located right outside on the floor,
13 right outside of our office.

14 So when I called on the radio to get the
15 AED, my associate, a fellow supervisor of mine
16 actually thought I was joking because we've had more
17 incidences as the alarm, as people have stated
18 before, on the box going off by people bumping it
19 than we had any use for it. We never had any use for
20 it in our building

21 Obviously at that point in time of the
22 second request for the AED, he realized I was really

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1 serious. So he ran in with the AED to me, gave it to
2 me, and at that point we got our Mr. Duddar down on
3 the ground, opened up his shirt, and applied the
4 paddles.

5 At that point he was still conscience.
6 With the expedience sake of using the AED and having
7 it set up and ready to go, we applied he paddles
8 prior to him actually going out.

9 At that point it kind of more or less was
10 a monitor, monitoring the event. As time went on, he
11 was complaining more and more of pain. He kept
12 telling me what he was going to die. We had a
13 lengthy conversation about that, and I told him there
14 was no way he was going to die.

15 At that point in time, he threw his head
16 back, his eyes rolled, and he actually died. At that
17 point the AED did do its job and did shock the
18 victim. At that point we pushed the button and
19 shocked the visit.

20 At that time, within seconds after the
21 shock, he came back to life, and the first thing out
22 of his mouth after he told me he saw a bright light

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1 was, "I remember everything you said. What
2 happened?"

3 So actually at that time we had the
4 paramedics on the way, but unfortunately they went to
5 our mailing address versus our actual address. So it
6 did take a little extra time for the paramedics to do
7 there.

8 At which time we were almost in a stage
9 of CPR and reshocking the individual, but luckily at
10 that point the paramedics did show up.

11 After reviewing the situation, the
12 company and the paramedics, they took the AED with
13 them and they downloaded all of the information at
14 St. Michael's Hospital in Newark, New Jersey, which
15 from what I was told was very helpful because it did
16 give them insight to the whole event and exactly what
17 did happen.

18 When I spoke to the doctor the day I went
19 to see Mr. Duddar in the hospital, the doctor said to
20 me, "If it wasn't for the AED, Mr. Duddar would not
21 be here today."

22 The type of heart attack he had was

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1 massive, and that the idea of the AED being applied
2 so quickly saved his life.

3 So I'm very thankful for the AEDs.
4 Again, when Mr. Duddar and I talked, the first thing
5 we did was a big hug and we love each other. I mean,
6 we were friends prior to this. We are best friends
7 now, and I will never let him forget the fact that,
8 you know, you have to look at me and said, "I saved
9 your life. So don't screw up again."

10 But as it goes, having the AED in a place
11 of employment or in an airport is very, very
12 important, but I also feel by being a rescuer that
13 it's also important to have it available to the
14 general public at home or anywhere, even in a
15 vehicle. You never know what may happen at home or
16 you may never know what you may come across as a
17 rescuer on the outside.

18 So I do agree with taking the
19 prescription plan off of the AED and having it
20 available to all of the people.

21 I thank you.

22 ACTING CHAIR LASKEY: And thank you.

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1 Are there any other requests to address
2 the panel?

3 (No response.)

4 ACTING CHAIR LASKEY: If not, I'd like to
5 close the open public hearing and just kind of
6 quickly wrap up here and ask Dr. Zuckerman: does the
7 agency have any additional comments or questions at
8 this point?

9 DR. ZUCKERMAN: No.

10 ACTING CHAIR LASKEY: Does the sponsor
11 have any final comments or questions?

12 DR. SNYDER: No.

13 ACTING CHAIR LASKEY: Ms. Moore, do you
14 have any?

15 MS. MOORE: You don't want to hear my
16 dissertation, do you? Just joking because I am still
17 concerned about that underserved population, but
18 getting to the point, I do feel that the presentation
19 was really quiet impressive, and as a lay person and
20 a consumer, I believe that the use was simplified to
21 the point that even the people who may be less
22 educated than the test subjects should be able to

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1 understand what to do because of the voice prompts
2 and the diagrams. I think that they are really the
3 thing that makes this really simply to use.

4 I am concerned though about the box
5 labeling. I don't think that I would be prompted to
6 purchase it just as it's labeled because you know
7 when you go to the pharmacy or wherever you're going
8 to buy it, the first thing you do, you read the box
9 to see what it says, and I'm not convinced that the
10 ordinary citizen would feel compelled to purchase
11 this if that's all the information they have.

12 However, if there is very aggressive
13 marketing so that everybody knows what this is, then
14 of course I believe the people would be compelled to
15 buy.

16 But I do feel that it was a very good
17 presentation, quite, quite well presented, enough for
18 even the lay members here to understand exactly that
19 you are proposing to do, and I'm very please, but I'm
20 still concerned about those people who may not have
21 access to this lifesaving device.

22 And once again, we would say that the

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1 underserved remain those persons who have less health
2 care than the more affluent members of our society.

3 ACTING CHAIR LASKEY: Mike?

4 MR. MORTON: No comments from me.
5 Thanks.

6 ACTING CHAIR LASKEY: Well, it's my
7 privilege then to ask for any final recommendations
8 from the panel. I think we've certainly given the
9 agency lots of recommendations, but these are meant
10 to be final recommendations, Mitch.

11 DR. KRUCOFF: I may step out of bounds,
12 so Geretta, you can slap me, but this is actually to
13 the ANA and other representatives of professional
14 societies, and I speak as an embarrassed physician,
15 that I think our professional societies need to do
16 some education of doctors to get in the loop instead
17 of being an obstruction to the loop, and I think we
18 can follow that up in another venue.

19 ACTING CHAIR LASKEY: I certainly support
20 that.

21 All right. Well, then I'm pleased to
22 adjourn this meeting. I would like to thank, first

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1 of all, the speakers who came forth out of their own
2 time and energy and provided testimony for the panel.

3 I'd like to compliment and thank the sponsor,
4 Philips. That was just an outstanding presentation
5 and thanks for hanging in there with us.

6 And lastly, I want to thank my colleagues
7 here at the panel. They were just truly
8 inspirational and supportive today. So thanks.
9 Thanks, all.

10 This concludes the recommendations of the
11 panel regarding the over-the-counter use of Philips
12 Medical HeartStart Home External Defibrillator.

13 (Whereupon, at 5:55 p.m., the meeting was
14 concluded.)

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