

1 These are three studies all published in
2 the New England Journal of Medicine that I'd like to
3 just talk about for a minute. The first is the
4 American Airlines program. In that study, you'll
5 note that they had 15 patients up in the air with
6 ventricular fibrillation, a survivor rate of 40
7 percent, and no adverse outcomes.

8 In our own study in Chicago O'Hare and
9 Midway Airports, we basically placed AEDs about a
10 minute walking through the terminals of O'Hare and
11 many airports have followed suit. The result that we
12 had was a nearly 61 percent survival rate, 11 of 18.

13 I might add that ten of those individuals were alive
14 a year later.

15 Many of these defibrillations were done
16 by lay people. Half were done by people simply
17 walking through the terminal. There were no adverse
18 events. In the Las Vegas study, in the casinos,
19 you'll see again a 60 percent survival to discharge,
20 and again, no adverse events.

21 Now, I want to point out that the airline
22 study and the casino study are sort of individuals

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1 using the AED who have a duty to use the AED. It's
2 part of their job. In the O'Hare experience, ours
3 was more mixed, particularly with people simply
4 walking through the terminal, but the study that I
5 think has really given us a great deal of information
6 is the recent public access defibrillation trial.

7 I have to highlight that the principal
8 leader of that study, Dr. Joe Ornato, is here on the
9 panel and can probably speak to it in more detail
10 than I will, but the basic question here was would
11 AEDs plus CPR improve survival compared to CPR alone,
12 and this was a large NHLBI sponsored study, 20,000
13 lay responders trained, 23 cities, 1,000 sites, and
14 the results were that in the arm that had the AED,
15 survival was doubled compared to CPR alone.

16 Importantly, there were no serious
17 adverse events associated with AED use, and there
18 were no recorded instances of EMS not being called or
19 a failure, a failure of EMS to be notified.

20 Individuals retained their skills during
21 this study, and that was measured, and the
22 conclusions really were -- and I think it's very

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1 important for this panel -- that layperson can use
2 AED safely to provide early defibrillation.

3 So if we try to summarize those, it's
4 clear that rapid response is what saves lives, that
5 the time is critical, and that early defibrillation
6 is highly effective and we want to do it as early as
7 possible, and so a primary question for this panel
8 is: can the HeartStart Home Defibrillator be used
9 safely by lay people.

10 And I'd now like to share the simulated
11 data that we generated in Chicago in an attempt to
12 provide some information on that question.

13 Our study had two primary hypotheses.
14 The first was that the HeartStart Home Defibrillator
15 and the FR-2 are safe and safe even in the absence of
16 training. We were designing essentially a worse case
17 scenario, someone who had never seen the device and
18 who did no training whatsoever.

19 Our second hypothesis was the HeartStart
20 Home and the FR-2 would have high usability when
21 used with primary labeling components, including the
22 voice prompts that you've heard David demonstrate and

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1 watching the trainee video.

2 The methodology that we used is a mock
3 cardiac arrest scenario with a fully clothed manikin
4 and an AED, and the details of this are in your
5 packet. It's much like the demonstration actually
6 that David performed up here earlier.

7 I'd like to share with you the
8 enrollment. You can see that for the two devices,
9 there were both naive and video trained individuals.

10 Of note, for the FR-2 here, that videotape was an
11 eight minute videotape that those individuals
12 watched, and then all volunteers went to a simulated
13 use.

14 For the HeartStart Home, a three minute
15 videotape was watched by the volunteers, and they
16 then went to the simulated test.

17 Our primary endpoints, first they were
18 safety and successful use, and I want to define
19 those. Safety meant that there was no touching of a
20 patient in a manner that it could result in a shock
21 across the rescuer's chest.

22 Successful use meant that they had to

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1 complete a whole series of adequate deliverables, and
2 those including power the unit on, attaching the pads
3 with the appropriate placement, allowing the device
4 to analyze, if necessary plugging in the pads, and
5 then defibrillating within five minutes.

6 Our secondary endpoints that I'll be
7 sharing include the time that it took from when the
8 volunteers stepped into the room, from when pads were
9 placed successfully, and how long it took for them to
10 then deliver the shock.

11 Results of the study, for the FR-2 are on
12 this slide, and I first want to highlight that you'll
13 note that in terms of safety, both the naive users
14 and the video trained users were completely safe, and
15 as you'd expect, when we look at successful use, you
16 can see here that about 50 percent of the naive users
17 were able to actually operate the FR-2 without any
18 instructions or any training by listening to voice
19 prompts.

20 After watching the videotape, you'll
21 notice that this improves to 86 percent, and this was
22 not at all surprising to me.

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1 If we look at the data on pad attachment,
2 we can see that, again, there's a beneficial effect
3 to watching the videotape with the pads being
4 attached faster and the shock delivered in a more
5 timely fashion.

6 Now, as we look at the HS-1, the Home
7 Start, we see that again the safety was complete for
8 both devices, rather, for both naive users and video
9 trained users, and what I want to highlight in this
10 successful use is that we see what to me appear a
11 difference in the naive users. Eighty-seven percent
12 of the naive users, that is, individuals who had
13 never seen the device before, were able to
14 successfully use this device in the five-minute
15 period. When they watched the videotape it only
16 increased to 89 percent, which is not statistically
17 different.

18 And I just want to add that it was this
19 observation that made me first aware that not all of
20 the devices would function the same in terms of human
21 use, and it was for this reason that it is the
22 HeartStart Home that is being brought forward today

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1 as an acceptable over-the-counter device.

2 When we look at the effect of the video
3 on improving pad placement and the time to shock,
4 again we see that while there was no difference in
5 successful use, there indeed was some improvement in
6 the amount of time that it takes, and of course, it
7 is everyone's intention and suggestion that we hope
8 that individuals who use these devices will be
9 totally trained and fully trained with a formal
10 course.

11 We, indeed, got these results under what
12 we would consider to be fairly adverse conditions.

13 Now, like all studies, there are
14 limitations to this, and I want to be forthright
15 about those. The simulated use cannot simulate
16 everything in a real use. The chaos and noise and
17 uncontrolled setting of someone falling down and
18 dying in front of you, and I might add that you can't
19 take volunteers and subject them to that. It is not
20 ethical.

21 So the ability to do a simulated test
22 where you would actually have a real person with a

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1 naive -- you know, it would just be totally
2 unethical. So there are limitations to simulations.

3 Our demographics were those that were due
4 to convenience. We picked to very different places,
5 an urban emergency department and then a parochial
6 school after school program, and those were the
7 people who we studied. And of course, another
8 limitation was that real human anatomy is far more
9 varied than one will find on a manikin, and that's
10 another limitation.

11 But what I want to tell you all is that
12 despite these limitations, this was and is the state
13 of the art of doing simulation studies, and I think
14 there are some important things that we can learn
15 from this.

16 The first is that in terms of safety we
17 can see that both devices were used safely in all
18 cases. We note the significant improvement that took
19 place with the FR-2 when individuals watched that
20 videotape. They improve significantly in their
21 ability to successfully use the device.

22 But importantly, the HeartStart Home

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1 Defibrillator was successfully used by both naive and
2 video trained volunteers at a rate of 87 and 89
3 percent, very high. And I want to try to draw one
4 conclusion from this, which is that most of our data
5 right now on the effectiveness of defibrillators is
6 based on the FR-2 device, and as we see, the superior
7 human characteristics, the use characteristics in the
8 HeartStart Home, it seems to me that we have very
9 good data to suggest that the experience with the
10 HeartStart Home will be certainly as good and very
11 likely better than our experience has been to date
12 with the FR-2, which has been highly successful in
13 previous studies.

14 I thank you, and would now like to have
15 David continue with the labeling evaluation and the
16 other surveys.

17 DR. SNYDER: Thank you, Dr. Becker.

18 There are three studies that I would like
19 to present to you, actually two studies and a
20 continuation of an existing study. The first is a
21 labeling evaluation and simulated use.

22 We did undertake some validation studies

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1 to gauge the ability of people to read and comprehend
2 additional labeling components that were developed
3 for the product, and then we continued on to
4 simulated use very much like Dr. Becker just
5 described.

6 We also have conducted a survey of likely
7 lay users of our earlier products, the ForeRunner and
8 the FR-2. Now, it's important to understand that
9 these products from the very beginning have been sold
10 to lay operators and even into homes. There's been
11 no prohibition on that, and physicians have certainly
12 prescribed them for that application.

13 So we made an attempt to contact as many
14 of those people as possible and find out what issues
15 they may or may not have had with the use of their
16 product.

17 And finally I want to describe a post
18 market study which was already underway. It was
19 launched with the FDA clearance of the HeartStart
20 Home Defibrillator for home use to look for specific
21 issues that may come up in home use.

22 To begin with the labeling evaluation,

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1 the purpose of the study was to test the
2 comprehension ability of the public basically to read
3 these additional labeling materials, comprehend them.

4 We gave them a written examination to see how well
5 they understood the materials.

6 These materials specifically are the
7 owner's manual, the quick reference card which you
8 saw in the case of the device when I demonstrated it,
9 a training video which ships with the product and the
10 quick start poster which is a guide to assembling the
11 device and putting it into service.

12 In addition, for two of those pieces we
13 proceeded on to a simulated use in order to
14 demonstrate safe and successful use after reviewing
15 only one aspect of this additional labeling, and
16 these are the pieces of labeling that are actually
17 included in the defibrillation case and would be
18 accessible in the event of an emergency use.

19 I want to show you what these look like.

20 the owner's manual is right here. It has the same
21 form factor as the quick reference card that you saw
22 in the demonstration, and it's inserted in a pocket

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1 behind the quick reference card and is actually not
2 visible when you first open the case.

3 This is the training video, standard VHS,
4 and the quick start guide, and as you can see in some
5 of the graphics, it demonstrates how to open the
6 battery in the pads' cartridge and assemble them into
7 the device.

8 A methodology involved recruitment of
9 volunteers in three geographically diverse shopping
10 malls. We sought people with no medical or
11 defibrillator training and having received no CPR
12 training within the prior two years.

13 This was a precaution against, again,
14 accidentally enrolling people that had been exposed
15 to AEDs because so many CPR courses within the last
16 two years had begun teaching AED skills as well.

17 We saw a broad age range in this
18 enrollment and were successful in recruiting
19 volunteers over the range of 21 years to 74 years of
20 age. Forty percent of our volunteers were in the 45
21 to 65 age group, and 20 percent approximately were in
22 the 66 to 74 percent age group -- excuse me -- 66 to

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1 74 year age group.

2 The hypothesis for the comprehension test
3 -- this was a little tricky. So I want to be careful
4 with it -- was that the labeling materials were well
5 understood, and what we sought to show was that 90
6 percent of these people could achieve a passing
7 grade. If you refer back to your grade
8 school experience, a passing grade was 70 percent of
9 questions answered correctly, or a C, and you'll see
10 that in the slides. So we wanted 90 percent of these
11 people to be able to get a passing grade on the
12 written exam, and we powered the study to establish a
13 lower confidence limit on those results of 80
14 percent, given the presumption of a 90 percent
15 passing grade.

16 The hypothesis for simulated use was that
17 the HeartStart Home Defibrillator is safe and that
18 the HeartStart Home Defibrillator can be successfully
19 used by lay persons to deliver defibrillation shock,
20 and this was powered for a noninferiority test
21 against a presumed success rate of 90 percent, with a
22 ten percent detection margin.

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1 I want to say that this is an arbitrary
2 goal. There are no gold standards for either of
3 these tests, either the reading comprehension or
4 performance and simulated use. We tried to set a
5 high bar, and I'll point to the public access
6 defibrillation trial. They recorded in abstract that
7 three months following initial training approximately
8 89 percent of the people still had adequate AED
9 skills.

10 So we used that as kind of our benchmark
11 for what we wanted people to be able to achieve in
12 the simulated use.

13 This diagrams the enrollment
14 randomization for the study. the study was first
15 stratified according to how much time the volunteer
16 had to spend with us. If they had 15 minutes
17 available, they were randomized into the reading
18 comprehension only arms and either viewed the
19 training video or reviewed the quick start poster and
20 then took a written comprehension exam.

21 If they had 30 minutes to spend with us,
22 they were stratified into a randomization between

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1 either owner's manual or quick reference. Again, the
2 materials that are in the case, should you use the
3 device in an emergency, they took the written
4 comprehension test and then proceeded to a simulated
5 use test.

6 Primary endpoints were essentially the
7 same as those reported by Dr. Becker: safe, meaning
8 no touching of the patient in a manner that could
9 result in a shock delivered across the rescuer's
10 chest; and successful, meaning shock delivered with
11 pads positioned in a manner likely to defibrillate,
12 and the activities necessary to do that were turning
13 the device on, deploying the pads in proper position,
14 allowing the device to analyze without interruption,
15 and delivering the defibrillation shock.

16 Secondary endpoints as for the Chicago
17 study were time to pads on and time to shock.

18 The written comprehension test, first of
19 all, the labeling materials themselves are written to
20 a sixth grade reading level or lower according to a
21 Flesch-Kincaid score. Topics for the test included
22 what is the definition of a sudden cardiac arrest.

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1 Is it different from a myocardial infarction, stroke,
2 so forth?

3 Questions regarding set-up of the device,
4 the importance of training, how is the device
5 properly stored; rescue steps; post shock care and so
6 forth.

7 These are the results of the reading
8 comprehension test. A C grade is shown here. This
9 was our goal. We wanted 90 percent of people to get
10 a C grade or better, and what you'll see is the
11 median scores on all four of these pieces of material
12 were actually in the 90 percents.

13 Now, this slide does contain some
14 information which has been provided to the FDA, but
15 not reviewed, and I want to draw attention to that.
16 We have shown interquartile ranges, the 25 and 75
17 percentiles. That was not originally submitted to
18 the FDA in our 510(k), and we've also shown the 90
19 percentiles which are these -- excuse me -- ten
20 percentiles, which are these dots.

21 And you can see that in all cases 90
22 percent of the people achieved a C grade or better,

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1 and in fact, the medians were in the A grade range.

2 These are the results of the simulated
3 use test. Our lower confidence limit goal is shown
4 here, the 80 percent. And in the case of the owner's
5 manual we did not meet our predefined goal. You can
6 see that the lower confidence limit actually extends
7 somewhat below the 80 percent lower confidence limit
8 goal.

9 In the case of the quick reference card,
10 however, we actually achieved an observed successful
11 use rate of 97 percent among these volunteers with a
12 lower confidence limit that easily exceeded and a
13 highly significant non-inferiority result.

14 Median time to show is similar as that
15 reported in the Chicago study as 104 seconds
16 following owner's manual, 89 seconds following quick
17 reference. This is from entry to room now. This is
18 not once you've turned the device on. This is entry
19 to room to deliver of shock.

20 Limitations to the study are clearly the
21 same as associated with the simulated use study
22 performed at the university of Chicago. Given those

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1 limitations we conclude from the study that all of
2 the labeling was well understood. At least 90
3 percent received a passing grade, 70 percent correct
4 or better, and the lower confidence limit on passing
5 grades was actually greater than or equal to 88
6 percent in all cases.

7 The defibrillator was used safely in all
8 cases. That was 178 mock arrests, and successful use
9 was achieved by 97 percent of the individuals with a
10 lower confidence limit of 92, following review of the
11 quick reference card, which is the recommended
12 labeling for emergency use.

13 Now, we did take some follow-up actions
14 as a result of this study. I want to show them to
15 you here. First of all, we added information to the
16 training video and the quick start poster regarding
17 the intended use of the various labeling materials,
18 and in particular, we modified the cover of the
19 owner's manual to clarify its purpose as a guide to
20 set up maintenance and accessories as opposed to an
21 emergency use piece of labeling.

22 I'd now like to briefly describe the

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1 results of the lay user survey I mentioned. The
2 purpose of this study was to determine if lay use of
3 Philips AEDs resulted in any previously unreported or
4 not understood problems.

5 The method was to establish a contact
6 list of all people who had owned an AED at least a
7 year and in an environment in which a lay use may
8 have occurred. We specifically excluded all medical
9 professionals.

10 We were able to identify 145 homes and
11 almost 2,700 businesses and public facilities where a
12 lay use may have occurred. We then attempted contact
13 via a phone center and seven attempts were made for
14 each person or installation that had been identified.

15 A brief interview was conducted, and in
16 particular, we asked if the defibrillator had been
17 used by a layperson. If the answer to that question
18 was yes, we requested a detailed interview between a
19 medical professional and the lay user of that device.

20 The results of that survey were that we
21 were able to contact 78 homes and 1,645 businesses.
22 No problems were reported. Two hundred and nine of

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1 the businesses or 13 percent had used their AED at
2 least once to respond to a suspected cardiac arrest.

3 This doesn't mean that the paths were necessarily
4 attached to the patient or that shocks were
5 delivered, but a patient collapsed. It was suspected
6 to be cardiac arrest and a person responded.

7 We also identified nine uses in home or
8 home offices. We were able to conduct 11 detailed
9 interviews regarding incidents in which paths had
10 been applied to unresponsive patients by lay
11 responders. EMS was called in every case. Three
12 patients appropriately received no shocks. They were
13 not in VF. Eight patients did receive shocks, of
14 which six survived a hospital admission and four
15 received shocks solely by lay responders, and all
16 four of those survived to hospital admission.

17 Now, these are anecdotal data. I don't
18 want to draw too much attention. The real purpose of
19 the study was the first sub-bullet up here, which was
20 that no problems with use of the product were
21 reported.

22 In conclusion, a limitation to the study

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1 are obviously that it was a survey interview.
2 Participation is voluntary and bias is, therefore,
3 possible, but we conclude from what we observe that
4 no harm or injury to users by standards or patients
5 was reported. No malfunctions or problems were
6 reported. All users expressed willingness to use a
7 defibrillator again should they suspect a sudden
8 cardiac arrest, and finally no safety or
9 effectiveness issues were reported.

10 To wrap up, I'd like to talk a little bit
11 about the post market study that's currently underway
12 for the HeartStart Home Defibrillator, and we do
13 propose an extension to that study should over-the-
14 counter clearance be granted for this product.

15 The purpose of the study is to evaluate
16 lay uses of the HeartStart Home Defibrillator for
17 safe and appropriate application. The methodology is
18 similar to the phone survey you just heard about.
19 Philips is generating contact lists following one
20 year of ownership for using the one year in order to
21 allow some opportunity for an event to have occurred.
22 There's not point in calling people one month after

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1 they purchased their defibrillator because it's very
2 unlikely it will have been used.

3 We're also enrolling people in the study
4 should they contact Philips for accessory
5 replacement. Certainly if a customer calls us for a
6 new set of pads there's a possibility that those pads
7 had been used in a rescue. Through both of these
8 avenues, we then asked was the AED used. If the
9 answer is yes, similar to the other survey, we
10 request a detailed interview with a medical
11 professional.

12 We propose to extend the study by an
13 additional four years should we be granted OTC
14 clearance for the HeartStart Home Defibrillator, that
15 is, we will continue this process for four years
16 following receipt of the clearance or terminate it
17 should we record 200 home uses of the HeartStart Home
18 Defibrillator, results to be reviewed by a data
19 safety and monitoring board and reported annually to
20 the Food and Drug Administration.

21 I'd now like to introduce Dr. Jeremy
22 Ruskin, Director of Cardiac Arrhythmia Service,

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1 Massachusetts General Hospital.

2 DR. RUSKIN: Thank you.

3 Good morning. It's a privilege to
4 participate in this important discussion. I'm Jeremy
5 Ruskin. I'm here as a paid consultant to Philips
6 Medical. I own no equity.

7 I also consult for Medtronic on
8 implantable arrhythmia control devices, and I've been
9 asked to make a few comments about the HeartStart AED
10 and the problem of sudden cardiac arrest from a
11 clinical perspective.

12 Just by way of introduction, I want to
13 underscore what you heard from Dr. Becker, but from a
14 slightly different perspective. When I began my
15 academic career in the 1970s, my colleagues and I
16 focused on evaluating the electrophysiologic and
17 anatomic substrate of survivors of out of hospital
18 cardiac arrest.

19 And we understood from risk
20 stratification schema that patients who were at
21 highest risk for cardiac arrest were those with prior
22 myocardial infarction, left ventricular dysfunction,

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1 heart failure, and spontaneous ventricular
2 arrhythmias.

3 What we learned from our own observations
4 and also from those of Drs. Eisenberg and Cobb and
5 his colleagues in Seattle, that in fact the profile
6 of survivors was somewhat different from that of the
7 high risk subset that we just described, and that is
8 that prior infarction was present in only about 50
9 percent of survivors. More than a third had normal
10 or near normal left ventricular function. Fifty
11 percent had no clinical or prior historical evidence
12 of congestive heart failure, and about half had no
13 spontaneous arrhythmias.

14 And the question then is what explains
15 this seeming paradox, and it is explained by what
16 you've heard from Dr. Becker, and that is that many
17 cardiac arrest survivors, in fact, are drawn from an
18 undetected high risk patient pool who are not
19 definable prior to the event. These are patients in
20 whom sudden cardiac arrest is the first manifestation
21 of their underlying heart disease, and this
22 represents a failure of our risk stratification

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1 schema.

2 This subset is now at least beginning to
3 be addressed from a primary prevention standpoint
4 with implantable cardioverter defibrillators. But
5 from an epidemiologic and preventive medicine
6 standpoint, we have no approach to this subset at the
7 present time, and it is this group that is targeted
8 by more widespread availability of AEDs.

9 This slide depicts for you the
10 dissemination of defibrillator technology from
11 physician delivered, hospital based defibrillation in
12 the 1960s to emergency medical systems in the 1970s
13 and '80s, to public access defibrillation in the
14 1990s, and most recently to the concept of
15 defibrillation as a lay procedure in the early 2000s.

16 With the evolution of this technology and
17 thinking, it is perhaps reasonable to think about the
18 device under discussion today as a piece of time
19 critical safety equipment, much in the way that we
20 think of air bags fire extinguishers, smoke alarms,
21 and seat belts.

22 All safety equipment has benefits and

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1 limitations. We know that smoke alarms reduce the
2 risk of dying in a fire by as much as 40 percent, but
3 that, in fact, alarms may be deactivated because of
4 nuisance factors.

5 Seatbelts save approximately 11,000 lives
6 per year and reduce the risk of death in car
7 accidents by as much as 45 percent, but we also know
8 that they are not used as much as a third of the
9 time.

10 Air bags reduce the risk of a fatal event
11 in a head-on collision by as much as 30 percent and
12 have saved large numbers of individuals since their
13 widespread implementation.

14 But we also know that they may cause
15 injury or even death in children and small adults.

16 This slide depicts for you the absolute
17 numbers of deaths attributable to motor vehicle
18 injuries in the green line and sudden cardiac arrest
19 in the red line for the year 1999 as a function of
20 age group. And as you can see, even in the mid-'40s,
21 the risk or the numbers that toll from sudden cardiac
22 arrest begin to exceed those from accidents, and in

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1 fact, you see the curve rise very steeply into the
2 mid-'60s. Still a relatively young group of
3 individuals, many of them not known to be at risk,
4 and experiencing cardiac arrest as the first
5 manifestation of their underlying heart disease.

6 This slide depicts the ten-year
7 probability of experiencing any number of emergency
8 events, including reportable fires, air bag
9 deployment, sudden cardiac arrest in all households,
10 and sudden cardiac arrest in households over the age
11 of 45, and you can see that the ten-year probability
12 of a household over the age of 45, experiencing a
13 sudden cardiac arrest is three times that of a
14 reportable fire, and substantially higher than that
15 of air bag deployment in a motor vehicle.

16 The benefits of removing the prescription
17 requirement would include broader access to a safe
18 and effective technology that constitutes the only
19 definitive treatment for a sudden cardiac arrest and
20 thereby provide an opportunity to save some of the
21 lives that would otherwise be lost to this public
22 health problem.

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1 The question that arises in proposing
2 this kind of a change in thinking and change in
3 practice is whether or not the AED can, in fact,
4 cause harm. In addressing this question, it's
5 important to underscore that the HeartStart AED is
6 intended for the same user and patient population as
7 the currently cleared prescription device.

8 And as you've also heard, this device is
9 designed with safety first and foremost in mind, and
10 some of the critical safety features include an
11 extremely sensitive and specific ECG analysis
12 algorithm, an extremely robust artifact detection
13 algorithm, and the absence of a manual override to
14 preclude the delivery of inappropriate or incorrect
15 shocks.

16 The safety of this device of the Philips
17 AED line is supported by the use experience. These
18 are estimates of use. You've heard of these from
19 David Snyder, including an estimated more than one
20 million patient applications, with an estimated
21 approximately 200,000 individuals requiring shocks,
22 with only one known inappropriate shock in this vast

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1 experience and no complaints about shock
2 effectiveness.

3 This overriding commitment to safety is
4 verified by an established history of safe use and
5 the demonstrated fact that the HeartStart AED can be
6 used safely for its intended purpose based upon its
7 labeling alone by lay responders.

8 A number of theoretical risks have also
9 been raised with regard to the OTC AED concept. One
10 is whether or not an OTC AED would interfere with
11 appropriate medical care.

12 Clearly, an OTD AED is not a substitute
13 for any kind of medical care. Risk factors continue
14 to need to be addressed. Care and prescribed
15 therapies for preexisting conditions need to
16 continue. Physicians will retain the option to
17 prescribe AEDs in cases of medical necessity. And
18 finally, the target populations, particularly those
19 in comparison with those who require ICDs, are
20 entirely different, as Dr. Becker emphasized and I
21 did earlier.

22 Another issue that's been raised is

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1 whether or not the OTC defibrillator will interfere
2 with the EMS response. We know that the sudden
3 cardiac arrest survival rate is abysmally low, less
4 than five percent, precisely because defibrillators
5 logistically cannot be delivered in time to victims
6 in a vast majority of instances.

7 Philips supports calling EMS in its
8 labeling, as you've heard, and in verbal prompts and
9 recognizes that early defibrillation is only one
10 part, but a critical part of the emergency response.

11 Finally there's no evidence that a
12 prescription requirement would in any way enhance an
13 EMS response.

14 In approaching an issue of an OTC home
15 defibrillator, it's important to consider this with
16 realistic expectations. Sudden cardiac arrest is an
17 epidemic and major public health problem of enormous
18 proportion. It is the most common cause of death in
19 adults.

20 We know also, as you've heard innumerable
21 times this morning, that current survival rates are
22 unacceptably low, in the range of five percent.

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1 It's also important to recognize that an
2 AED is not considered by anyone to be a cure for the
3 problem of sudden cardiac arrest. As many as 40
4 percent of arrests are likely to be unwitnessed.
5 Devices will in some instances be used incorrectly,
6 and there will be some device failures.

7 There will also be human and logistical
8 factors that will interfere with effective use.

9 Those limitations notwithstanding, OTC
10 defibrillators represent a paradigm shift and a step
11 towards wider access that will provide the potential
12 to save some lives that will otherwise be lost. It's
13 important to consider that long term with widespread
14 dissemination, even a small impact, perhaps salvage
15 of as few as five in 100 cardiac arrests would double
16 current survival rates.

17 Ultimately the prevention of sudden
18 cardiac arrest lies in the prevention of coronary
19 artery disease, but until this goal is achieved,
20 current strategies for addressing this public health
21 scourge include risk factor modification by life
22 style changes and appropriate medications,

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1 revascularization and implantable defibrillators in
2 the highest risk patient subsets, and widespread
3 availability of on site rapid defibrillation.

4 Defibrillation is one of the most
5 important therapeutic advances in the history of
6 medicine. Over the last five decades we've come to
7 take this therapy for granted in a medical
8 environment. We now have a technology that is
9 designed specifically and cleared for use by lay
10 responders.

11 Removal of the prescription requirement
12 will provide broader access to a safe and usable
13 technology and thereby provide the opportunity to
14 salvage some lives that in the absence of prompt
15 defibrillation will otherwise be lost.

16 Thank you.

17 DR. SNYDER: And that is the completion
18 of our presentation.

19 ACTING CHAIR LASKEY: Great. Thank you.

20 I would just ask the panel members if
21 there are any queries at this point.

22 Dr. Kato.

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1 DR. KATO: One other reason that the
2 sponsor is going to eliminate the or desire to
3 eliminate the prescription requirement is to broaden
4 the availability of these devices to the public. Do
5 you have an estimate for what you think the annual
6 growth would be in terms of AED deployment sine
7 you're already seeing a 20 percent growth per year?
8 At least that's what you presented.

9 You know, on a cursory review last night,
10 it seems that you can get these things over the
11 Internet now.

12 DR. SNYDER: It's a good question, and we
13 don't have specific data on any anticipations of
14 growth rate, given removal of the prescription
15 requirement.

16 We have, however, in conversations with
17 people who have attempted to purchase home
18 defibrillators via our phone contact system, we've
19 discussed with them the problems that they've had in
20 obtaining prescriptions, and we do have data on that,
21 and it has not been submitted as part of our 510(k).

22 If you would like to view some of that, I

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1 could show you the data.

2 I would like to also mention that the
3 internet sites that you're referring to are actually
4 doing it under prescription. It's not a methodology
5 that we really endorse because no benefit is being
6 provided by that prescription. If an individual
7 contacts Philips to purchase a home defibrillator, we
8 actually walk them through the process of learning
9 about the product, and we do ask them to visit their
10 own physician, set up an appointment, and we perform
11 follow-up after that appointment to see if they were
12 able to get a prescription or not, and again, we do
13 have the data for those that were refused
14 prescriptions to tell you the reasons that they were
15 refused.

16 And I'd be happy to share that with the
17 permission of the Executive Secretary if the panel
18 would like to see it.

19 DR. KATO: So currently you're involved
20 in a fairly elaborate system of education of these
21 patients as they obtain these AEDs from your company,
22 right?

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1 DR. SNYDER: Correct.

2 DR. KATO: So what is the advantage of
3 just being able to purchase one of these at Save-on
4 (phonetic) without that educational benefit?

5 DR. SNYDER: Well, first of all, over the
6 counter doesn't necessarily imply Save-on, but we
7 would continue to sell the product through the
8 channels we're using now. It's certainly an
9 eventuality, but the educational materials provided
10 with the product do educate the purchaser about the
11 problem and the possibilities.

12 In addition, if someone is to purchase a
13 HeartStart over-the-counter defibrillator, they do
14 have a 30-day, fully money back, no questions asked
15 guarantee.

16 So even if they purchase it without
17 studying, after reviewing the materials if they
18 decide it wasn't a purchase they desire to make, they
19 can get a full refund on that.

20 But the issue we're really attempting to
21 address is the fact that there is very significant
22 fallout in people how have made committed decisions

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1 to purchase a defibrillator when they contact their
2 physician and attempt to get a description, a large
3 number are denied those prescriptions.

4 DR. KATO: So you have data that
5 physicians are actually denying these prescriptions
6 now?

7 DR. SNYDER: That's correct, yes.

8 DR. KATO: What happens if this device is
9 used at a pool or at the beach?

10 DR. SNYDER: It's an excellent question,
11 and it's a problem we have had concerns about. We
12 actually performed a study on this, which was
13 published last year. What we found was that even
14 defibrillation and wet environments on wet surfaces
15 was entirely safe to the responder. We actually
16 instrumented a surrogate. It was actually a turkey,
17 and we attached defibrillation pads and set out a
18 grid so that we could do electrical measurements and
19 only very small voltages were present.

20 And I can tell you that I personally have
21 defibrillated a patient in the pouring rain with no
22 adverse consequences. It's actually a very safe

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1 thing to do.

2 DR. KATO: Was the turkey alive or dead?

3 Is there a difference with --

4 (Laughter.)

5 DR. KATO: Well, I mean, is there a
6 difference in resistances?

7 DR. SNYDER: No. The turkey was dead,
8 but it was selected to present a reasonable
9 approximation of a human impedance.

10 ACTING CHAIR LASKEY: It was fresh
11 killed, Norm.

12 DR. SNYDER: It was one of the more
13 embarrassing studies we've ever published.

14 DR. RINGEL: I have a number of questions
15 regarding the pediatric usage.

16 DR. SNYDER: Yes.

17 DR. RINGEL: I would like to point out
18 that even though you have suggested that this will be
19 labeled for pediatric usage, none of the speakers
20 talked at all about any of the pediatric issues, the
21 algorithms, the pads or anything like that. So
22 you'll have to bear with me because there are a lot

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1 of questions to follow.

2 We can start off with the question as to
3 why you are suggesting the system with two sets of
4 pads. I think it has potential for a great
5 confusion, and you don't explain how these pads would
6 interact. For instance, I don't think your tests
7 tested removing an adult cassette, put it in a
8 pediatric cassette and then using the pediatric
9 cassette. I'm not sure you give guidelines to tell
10 people how to figure out if someone is 55 pounds or
11 less.

12 I'm confused by one of the statements in
13 your brochure when you say, "Note. If you're not
14 sure about the child's exact age or weight or if
15 infant child pads are not available, do not delay
16 treatment. Use the adult pads, but place them on the
17 child's chest and back as shown in using the
18 HeartStart."

19 So if that's the case and you can use the
20 adult pad effectively, why not just have one set of
21 pads and avoid the confusion?

22 I also have concerns about the fact that

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1 most small child and infant arrests are respiratory
2 arrests. They are not fibrillation or cardiac
3 arrests, and there's no mention about or study about
4 how this delay in fiddling or fumbling with the AED
5 might delay appropriate respiratory care.

6 There are more, but you can start at any
7 time.

8 DR. SNYDER: All right. I'll attempt to
9 answer all of them in order. If I miss one, please
10 let me know at the end.

11 DR. RINGEL: Sure.

12 DR. SNYDER: First of all, with regard to
13 cartridge exchange, we did perform a design
14 validation on people's ability to do this.

15 Slide up, please.

16 We performed a design validation with ten
17 volunteers, and I want to admit right up front that
18 clearly this aspect of the product has not been
19 validated to the same standards as the primary use of
20 the product, which is adult defibrillation.

21 But we have performed validations. We
22 sought ten volunteers. These were people who had

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1 previous adult AED training, but no training on this
2 particular product. So they had never seen this
3 product before. Nor had they received any prior
4 training in pediatrics.

5 The sample size was based on an FDA
6 guidance document called "Do It by Design" from '96.

7 All volunteer viewed a training video,
8 which included a pediatric chapter on pediatric
9 application of the device prior to the test. The
10 scenario was that upon entering the room they were
11 presented with a toddler manikin, and an AED with an
12 adult cartridge installed. A pediatric cartridge was
13 available in the AED case.

14 Next slide, please.

15 The results of the validation are tha t
16 all ten of the volunteers were able to recognize the
17 need for exchanging the cartridge. Ten out of ten
18 Retreat the pads cartridge or knew where it was
19 located in the case and seven out of ten of those
20 were able to exchange the cartridge, remove the adult
21 cartridge and insert the pediatric cartridge with an
22 average time to do so of 40 seconds.

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1 And of the seven that successfully
2 exchanged the cartridge, all seven were able to
3 deliver defibrillation shock with adequate pads
4 placement.

5 Now, I want to emphasize that these
6 people had never had an opportunity to operate the
7 release latch of the cartridge. So, again, they had
8 never seen the product. They had never inserted or
9 removed a cartridge, yet 70 percent were able to
10 succeed. That's an admittedly small sample size, and
11 it's obviously a limitation that the panel needs to
12 take into consideration.

13 With regard to the next question,
14 guidance on 55 pounds or less, I'll show you the
15 labeling we have in the quick reference guide. Slide
16 up, please.

17 The statement is zero to eight years,
18 less than 55 pounds use the pediatric pads, and it
19 chose adult pad placement adjacent.

20 Now, the guidance we give in the owner's
21 manual is if uncertain about whether they're 55
22 pounds or greater, to go ahead and use the adult

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1 cartridge. We believe this to be an entirely safe
2 does, and it's consistent with current AHA
3 recommendations on pediatric defibrillation if
4 pediatric defibrillation is unavailable, go ahead and
5 use an adult does with the biphasic therapies.

6 We have selected the anterior posterior
7 positioning because we also did a validation on pad
8 placement. I don't have specific data with me, but
9 we found that in very small children, ability to
10 place anterior-anterior pads was quite poor because
11 people go the pads adjacent, not providing a good
12 defibrillation vector. But we found very high
13 success rates in placing anterior-posterior pads. So
14 that is the recommended placement, and for
15 simplicity, we wanted to keep the pad placement
16 consistent for all infant child application even if
17 you were using the adult pads.

18 The next question was with regard to
19 respiratory arrest. Your statement is correct that
20 there is no discussion of respiratory arrest, and I
21 think that this is an issue of some controversy in
22 the resuscitation community today as to what the

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1 proper sequence of rescue is, given perhaps lack of
2 information about the nature of arrest.

3 So for that we really have to defer to
4 our policy and recommendation body, such as the
5 American Heart Association. What we're trying to do
6 here is to provide the opportunity to defibrillate,
7 but I think it would be out of place for a
8 manufacturer to make some specific recommendations in
9 that regard.

10 Did I address all of your questions?

11 DR. RINGEL: Many of them. I think that
12 some of the others we can discuss this afternoon.

13 DR. SNYDER: Okay.

14 DR. RINGEL: That will be fine. Thanks.

15 ACTING CHAIR LASKEY: Dr. Somberg.

16 DR. SOMBERG: Is there a population the
17 manufacturer has identified that would not be
18 appropriate for this device? For instance, and I'm
19 not suggesting it is an inappropriate population, but
20 I'm just using it as an example patients diagnose and
21 with current epilepsy, for instance, who are prone to
22 seizure disorder.

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1 is there any population that has come to
2 the fore from your consumer queries, et cetera, that
3 suggest caution should be identified in that group?

4 DR. SNYDER: If you'll give me a moment,
5 I'll consult with my team and give you an answer on
6 that.

7 DR. SOMBERG: Or maybe for the sake of
8 time you might want to come back at a later point.
9 Is that what our chairman would like?

10 ACTING CHAIR LASKEY: He may have the
11 answer.

12 DR. SNYDER: I have the answer. The only
13 group that we've really identified as inappropriate
14 is that for people with certain medical conditions,
15 this is out of our owner's manual, who are likely to
16 suffer SCA, an implantable cardioverter defibrillator
17 may be advised. The HeartStart is not intended as a
18 substitute for an ICD.

19 Now, the other group I would say that
20 could not really derive benefit from a
21 homodefibrillator or would have minimal benefit, it's
22 not necessarily an inappropriate market, would be

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1 people in single persons households. Obviously if
2 they live alone, the only time another responder
3 would be available in the event of sudden cardiac
4 arrest is if they were a guest in the home.

5 DR. SOMBERG: Where is the concern about
6 having an ICD in place? Located that's in the manual
7 you said?

8 DR. SNYDER: That's correct. It's page 2
9 of the owner's manual.

10 DR. SOMBERG: So that's just probable the
11 only instance where a physician's place in the chain
12 might be a benefit to discern whether someone has an
13 ICD or not?

14 DR. SNYDER: Well, remember there's
15 specific labeling on the outside of the carton, as
16 well as in the owner manual and the pre-sales
17 material saying if you have concerns about your
18 health or a medical problem, that this is not a
19 substitute for medical care and that you need to
20 contact your physician.

21 On the specific language, if you have
22 concerns about your health or an existing medical

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1 condition, talk to your doctor. A defibrillator is
2 not a replacement for seeking medical care. This
3 message is repeated throughout our labeling
4 materials.

5 ACTING CHAIR LASKEY: Dr. Krucoff.

6 DR. KRUCOFF: I'd just like to follow the
7 quick question on not so much the indication for an
8 ICD, but in patients who collapse in public settings,
9 is there any instruction to the responder in how to
10 identify that the patient who is on the floor has an
11 ICD, or do you have any experience with if you
12 defibrillate both externally and internally
13 simultaneously how the two devices are likely to
14 interact?

15 DR. SNYDER: We do not have specific
16 instructions, and I would like to defer to Dr.
17 Becker to address the question of interaction between
18 internal and external.

19 DR. BECKER: We don't have a lot of data
20 on that. I mean, not quantitative data that's really
21 going to answer the question. What we do know is
22 that numerous individuals have had the device applied

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1 to them who have internal devices, and the device is
2 operated normally.

3 The specific scenario that you're
4 suggesting, the possibility that the internal device
5 is about to shock and a shock is delivered is one
6 that I have yet to see report as any kind of
7 adversity.

8 DR. KRUCOFF: I guess as Jeremy pointed
9 out, on the one hand, you know, a third of the folks
10 who are sudden death survivors don't have low EFs and
11 indications, but I think we have to recognize that
12 there is a skyrocketing number of individuals who are
13 now candidates for permanently implantable
14 defibrillators. So that population is going to be
15 more and more a part of our population.

16 We can talk a little bit more about that
17 this afternoon.

18 MR. MORGAN: I had one other just quick
19 question as to whether --

20 DR. SNYDER: Can I add just one comment
21 on that? I think it's important to point out that in
22 the presence of an AED or ICD by the time you could

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1 retrieve an AED and get it applied and get to the
2 point of a shock, there's multiple opportunities for
3 internal defibrillation shocks and the possibility
4 certainly exists that the ICD has failed or is not
5 defibrillating. In that case shock by an AED would
6 be an appropriate activity.

7 DR. KRUCOFF: Yeah, I guess it's a
8 crossover. If while you're running to get the AED
9 the patient on the floor has their internal
10 defibrillator fire but they don't convert, I mean, a
11 lot of the safety margin of your device is based on
12 its not shocking rhythms that are inappropriate to
13 shock.

14 DR. SNYDER: That's correct.

15 DR. KRUCOFF: The population I'm thinking
16 of are patients who actually would potentially have a
17 shockable rhythm, and without a layperson's
18 appreciation, we now have the potential for two
19 devices, each appropriately going after that same
20 rhythm.

21 So this is one of the places that I just
22 think we can talk about more later this afternoon.

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1 I had one quick question just on your
2 anticipation of what the removal of the prescription
3 feature would do. I guess if it's not so much Dr.
4 Kato's answerable rate of growth, most of the data
5 that we've seen today have by a power of ten or more
6 public access type, you know, shopping malls,
7 airports, airline systems.

8 Do you all have a sense or have you
9 examined the ramifications of without prescription
10 how much more a private home presence is likely to
11 eventuate or whether you think the proportion that
12 we're seeing in the data currently reported would be
13 maintained?

14 DR. SNYDER: The proportion of home
15 deployment versus public deployment?

16 DR. KRUCOFF: Right.

17 DR. SNYDER: No, I'm afraid we don't have
18 any projections. Really what we're operating on is
19 I'm going to fall back on the mission of our company,
20 which is to make defibrillation available to as many
21 people as possible as quickly as possible, and we
22 have identified the home as a way to do this, and we

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1 have identified the prescription requirement as a
2 barrier to the purchase of these products.

3 We really are unable to extrapolate
4 beyond that because we don't know how well accepted
5 this will be accepted by the public, and it's
6 certainly a sensitive --

7 DR. KRUCOFF: Well, that's the point,
8 isn't it? If you remove the barrier, what happens
9 next? If it's different from the basis of what we're
10 thinking about as a good reason to remove the
11 barrier, what happens next is different than how do
12 we know what happens next.

13 DR. SNYDER: Well, it will only be
14 different potentially in the extent of the
15 deployment. Is there a specific concern that you
16 have that I might be able to address?

17 DR. KRUCOFF: Well, for instance, in a
18 public access area, if there are 100 people standing
19 around in the middle of an airport and somebody
20 collapses, there's likely to be an EMT or a nurse or
21 somebody who steps forward in the use in addition to
22 other laypeople or a calmer lay person as opposed to

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1 ten people who panic. Because, as you say,
2 simulating these events in the types of simulations
3 any of us could do is simply not possible.

4 In a home there may be a single
5 individual. It may be a teenager. It may be a
6 spouse, and I think some of the performance
7 characteristics when you have people step forward in
8 a lay environment out of a public may, in fact, be
9 quite different than if you have one individual in
10 the house, and at least the data that I'm looking at
11 and aware of, that we have very little knowledge
12 about a lot of home use. Even though we keep calling
13 this a home use, the vast majority is really public
14 access use.

15 DR. SNYDER: Yes. I do have a small
16 amount of data I can share with you. You're correct
17 there's not very much.

18 Slide G-11, please.

19 MR. MORTON: Dr. Laskey, Dr. Laskey. Let
20 me ask the sponsor. Let us not lead you into
21 economic and business results that you might present.
22 We've got some legitimate questions, but you need to

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1 protect that information for yourself.

2 DR. SNYDER: Yes, thank you.

3 DR. KRUCOFF: I'm sorry. I had no
4 intention of going there. In fact, I'm not
5 interested in the business. To me the real
6 ramification is the user.

7 MR. MORTON: It's just the penetration.

8 DR. SNYDER: Yes, I understand the
9 question.

10 If we can have the slide up, please.

11 There are a limited number of studies
12 that have looked at this. I can draw your attention
13 to these three. They're all home use studies. In
14 1987, Chadda and Cammerer reported on experience with
15 AEDs in the home. In the study they saw five
16 arrests. Two of five were converted to sinus rhythm.

17 One use was by a spouse, and there were no adverse
18 events reports.

19 They concluded that AED use was feasible
20 by family members and lay persons.

21 Another study by Swenson trained 48
22 families of sudden cardiac arrest survivors. In

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1 their study they observed five arrests, four uses by
2 spouses. Three of the individuals were resuscitated.

3 These are very admirable survival rates, by the way.

4 Again, no adverse events reported, and
5 concluded that AED was far easier to learn and
6 maintain than CPR.

7 And finally, Dr. Eisenberg who spoke this
8 morning has done a study in which they observed two
9 VF arrests in home. One patient was resuscitated and
10 no adverse events were reported.

11 I would also on this question like to
12 defer to Dr. Jeremy Ruskin.

13 DR. RUSKIN: May I first offer a response
14 to something that Dr. Krucoff raised earlier about
15 ICDs? Since I'm standing here, I'll take the
16 opportunity.

17 It's unusual for a patient with an ICD to
18 lose consciousness these days. The detection and
19 charge times are so fast that for a patient to
20 actually go down and stay down long enough for
21 somebody to think about getting an AED would suggest
22 that something is wrong.

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1 And in that circumstance, at least in an
2 in hospital environment, we routinely recommend that
3 standard external defibrillation be performed without
4 any hesitation or question, and I'd be interested in
5 Bill Maisel's thoughts about that since he's got
6 plenty of experience as well.

7 DR. MAISEL: My only other comment is
8 that we routinely defibrillate patients in the EP lab
9 during ICD testing. If they fail internal
10 defibrillation, we routinely defibrillate patients
11 for atrial fibrillation who have ICDs, and the
12 general recommendation is simply not to put the pads
13 directly over the device.

14 I noted in the user manual that that's
15 mentioned. If that person has a known pacemaker or
16 defibrillator, not to put it over the device.

17 DR. KRUCOFF: Actually, Bill, I'd like to
18 come back to that this afternoon because, you know,
19 that to me would be the key piece, is just to make
20 people aware that if there's a lump, you know, under
21 the skin somewhere, put the pad somewhere else.

22 DR. RUSKIN: That said, and that is

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1 absolutely in agreement, I think, with everybody's
2 current procedure. There's precious little evidence
3 that you can actually do damage to these devices.
4 It's not impossible, but it's difficult to do.

5 With regard to your second question, I'm
6 going to interpret it in a very broad sense, and that
7 is the issue of whether or not there is effectiveness
8 data on home use of the type that we'd all like to
9 see as academics and clinical investigators.

10 And I think the answer is no. We don't
11 have clinical trial data to direct to the question
12 that you've asked, and it's a critical question. And
13 I've struggled with this, and the conclusion that
14 I've come to in trying to construct in my own mind
15 some sort of benefit risk assessment is really to
16 raise the question of what the stakes are and then
17 what the risks are.

18 And on the risk side, I think you've
19 heard very solid data from a randomized control trial
20 to three other uncontrolled trials, to field
21 experience, to simulated use data, that with this
22 device at least there are simply no safety issues

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1 that have been raised. I mean there just is no
2 evidence of harm to an individual victim or to a
3 user, and there are no theoretical concerns right now
4 for which there are signals in the experiential
5 database with regard to safety. That's my own
6 personal interpretation.

7 I think the safety is on very solid
8 ground. You look as if you disagree with that.

9 DR. KRUCOFF: Well, my only real concern
10 because the issue we're here to discuss is if you
11 pulled a physician prescription out of the loop, then
12 the 40 to 60 patient type family cohorts that we have
13 data on, these are all selected patients and
14 presumably I would think a physician was probably in
15 that loop of identifying them as good candidates for
16 inclusion in these studies, for instance, as one.

17 And what I'm literally sitting here and I
18 think we're probably all going to have to balance is
19 what is the burden of requiring the prescription and
20 having the physician in the loop versus what happens
21 if relative to the 45 well selected homes, 45,000
22 families who can go to Target, you know, and buy one

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1 of these things go out and start buying these things.

2 What happens next?

3 DR. RUSKIN: Well, I think that's a
4 critical question, and my own bias is that, one, no
5 harm will come to anyone because I can't find in any
6 of the data from all the trials and the field
7 experience and the simulated use studies evidence of
8 a safety concern, which for me is the most important
9 question if you're going to expand access.

10 then the next question is what can you
11 expect on the benefit side, and the answer is we
12 don't know with certainty, but if you take a
13 fraction, just a tiny fraction of current survival
14 rates and you extrapolate that to a broader
15 application of this technology, there will be some
16 lives saved, and the question is really what's the
17 benefit or -- excuse me -- what's the risk. What's
18 the target, which is a 95 percent lethal condition
19 and what is the experience to date outside the home?

20 All of those, I think, add up to an
21 overwhelming benefit risk assessment, but we can't
22 put a number to it with regard to the home

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1 application for precisely the reason that you've
2 raised. We don't have that experience in the home.

3 The question is: is that achievable?
4 And personally I don't think it is. I don't think
5 you can do a study that's large enough with an event
6 rate so low in the general population to answer the
7 question. It's not dissimilar to the QT issue that
8 keeps coming up on the drug side. It's not
9 answerable in a clinical trial.

10 So where are you left? You're left with
11 trying to construct the best benefit risk ratio that
12 you can from the available data. It's not a perfect
13 situation, but my own bias is that with a situation
14 in which we're losing 95 out of 100 victims and we
15 know that defibrillation in every other scenario it
16 has been tested works, even if the success rate is a
17 tiny fraction of what it is at O'Hare Airport, close
18 to 40 percent and 60 percent in other studies, take
19 that down to five percent or take it down to one
20 percent. I think you're still going to save some
21 lives.

22 DR. KRUCOFF: Yeah, I don't think there's

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1 going to be any argument about that from anybody,
2 Jeremy. I think the real question is what's the
3 burden of the physician in the loop versus what's the
4 concerns about taking the physician out of the loop.

5 ACTING CHAIR LASKEY: We're going to come
6 back to this subject, this language, I'm sure. I
7 would suggest we take a break so we can at least hear
8 the FDA presentations before lunch.

9 But I have just about noon. If we could
10 take a ten minute break and resume at 12:10.

11 Thank you.

12 (Whereupon, the foregoing matter went off
13 the record at 11:58 a.m. and went back on
14 the record at 12:13 p.m.)

15 ACTING CHAIR LASKEY: The plan here is to
16 have the FDA presentation followed by some short
17 questioning, hopefully very short, and then we'll
18 break for lunch.

19 DR. TOVAR: Well, during this
20 presentation, I am going to show a brief summary of
21 the regulatory history of the HeartStart Home
22 Defibrillator. Next I will present the regulatory

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1 context of a prescription device followed by a
2 summary of the review. The panel questions are going
3 to be presented in the afternoon.

4 At this time I would like to present the
5 members of the review team. Dr. Lesley Ewing was
6 the primary clinical reviewer. Michael Mendelson,
7 peter Carstensen reviewed human factors. Gay Kamer
8 is statistics. Dr. Victor Krauthamer, risk analysis,
9 and Ms. Beverly Gallauresi, post market.

10 And I will use some of the clinical
11 aspects of this submission as well. I was the lead
12 reviewer.

13 The purpose of this submission is to
14 remove the prescription requirement from the Philips
15 HeartStart Home Defibrillator prescription label.
16 This is a summary of the regulatory history for the
17 HeartStart Home Defibrillator that the sponsor
18 presented previously. In September of 1996, the FDA
19 cleared the ForeRunner AED. In May 2001, the FDA
20 cleared the FR-2 defibrillator with attenuated
21 defibrillation paths for pediatric use with
22 prescription caution.

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1 In November, 2002, the FDA cleared the
2 HeartStart Home Defibrillator designed for home use.

3 All the three previous were always with the
4 prescription caution.

5 In April 2004, Philips submitted a 510(k)
6 proposing removal of the prescription caution from
7 the labeling.

8 As I mentioned before, this device has
9 had a prescription caution that reads, "Caution.
10 Federal law restricts this device to sale by or on
11 the order of a physician."

12 The Code of Federal Regulations defines a
13 prescription device as a device which, because of any
14 potentiality for harmful effect or the methods of its
15 use or the collateral measures necessary to its use
16 is not safe, except under the supervision of a
17 practitioner licensed by law to direct the use of
18 such device and hence for which adequate directions
19 for use cannot be prepared.

20 The present regulations do not describe
21 requirements for removing the prescription language.

22 However, the definition of prescription device

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1 suggests that two elements must be met to remove the
2 prescription language.

3 One, the device is safe to use without
4 supervision of a licensed practitioner, and adequate
5 directions for use can be created.

6 Therefore, the FDA's review has focused
7 primarily on the device labeling and human factors
8 evaluation, and those are the summaries that I'm
9 going to present.

10 First, I would like to talk about the
11 device itself, the automatic defibrillator. Philips
12 Medical Systems states that the HeartStart Home
13 Defibrillator and its accessories, including this
14 510(k), are the same as the HeartStart Home
15 prescription defibrillator. The previous was the
16 over the counter.

17 And these similarities are in the way
18 from therapy, the sign, functionality, technology,
19 software, manufacturer processes, acceptance
20 criteria, and packaging with some modification to the
21 text of the written materials. The target
22 populations is going to be the same, adults and

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1 children.

2 In summary, this device is the same
3 device already used and comes with a prescription.

4 These are the indications for use of the
5 device. The HeartStart Home Defibrillator is
6 intended to be used to treat someone who the rescuer
7 thinks may be a victim of sudden cardiac arrest. A
8 person in sudden cardiac arrest does not respond when
9 shaken and he's not breathing normally. If in doubt,
10 apply the pads.

11 For children eight years or older or who
12 weighed 55 pounds or more, use the defibrillator with
13 the adult pads that come with it. For younger
14 children or those who weigh less than 55 pounds, the
15 special infant child pads should be used if
16 available.

17 Next I'm going to present the summaries
18 of our review.

19 Around 80 percent of sudden cardiac
20 arrest occur in homes. However, the greater
21 experience with 80 is in public places, like for
22 example the PAD trial in the Chicago area airport,

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1 the casinos study, et cetera.

2 Cardiac function, the ventricular
3 fibrillation deteriorates rapidly with time. This
4 fibrillation in function is associated with rapid
5 decrease of survival of sudden cardiac arrest
6 produced by ventricular defibrillation.

7 A victim of cardiac arrest loses
8 approximately ten percent of the probability of
9 survival, which means that state in VF has been
10 previously presented.

11 Therefore, rapid access to a
12 defibrillator addresses this problem, and in some
13 instances might be sufficient. A recent report
14 presented previously by Dr. Baker proposed that if
15 the duration of ventricular defibrillation is less
16 than four minutes, the electrical phase, a
17 defibrillation shock could be sufficient to compare
18 VF to a normal sinus (phonetic) rhythm. Between four
19 and ten minutes are the circulatory phase. CPR
20 should proceed or you might need it for
21 defibrillation.

22 Beyond ten minutes of ventricular

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1 defibrillation of the metabolic phase, other
2 additional measures like control reperfusion,
3 cooling, et cetera are required.

4 In an effort to increase survival from
5 sudden cardiac arrest, the American Heart developed
6 the chain of survival. If a person is un responsive
7 to links and the chain of survival are early access
8 or call 911 or the EMS because other conditions can
9 cause unresponse in victim, for example, stroke,
10 choking, et cetera.

11 We have a question for the panel on this
12 issue. Early CPR is the next link, pump and blow,
13 and the defibrillation. Use the AED followed by
14 early advanced care or care provided by EMS
15 personnel.

16 The timing of CPR relative to
17 defibrillation is one concern for this type of
18 device. CPR should precede defibrillation in the
19 chain of survival according to the American Heart,
20 according to the guidelines from 2000.

21 However, we are aware of the dynamics of
22 this sequence. When the chain of survival was

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1 established, the arrival of the defibrillator to the
2 victim would take some time, and research suggests
3 that even changes can be done to CPR. That means the
4 weight of CPR is done. We are aware of all these
5 changes, and we want to recognize that.

6 But so far this is the sequence.
7 However, the design of the device allows that if the
8 victim collapse is witnessed, there is a reasonable
9 probability of a prone application of the AED and
10 shock delivery within four minutes and probably no
11 need for CPR.

12 If the victim collapses, is a witness,
13 there is a high probability of longer duration of
14 defibrillation and pressing of non-shockable rhythm,
15 and in this situation the device should not deliver a
16 shock and even call CPR.

17 Of course, with this examples, I am not
18 trying to cover every single situation during a
19 rescue attempt. I am trying to put the extremes of
20 the spectrum, and we have also a question for the
21 panel on this issue.

22 The next studies were presented by

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1 Philips previously, and I'm not going to repeat all
2 of the results, and the next studies that I'm going
3 to just mention were simulated tests with the manikin
4 or comprehension tests to study appropriate and
5 timely use, speed of application of the elctropads of
6 the AED, as well as safety and effectiveness of the
7 defibrillator, and this were the three studies, the
8 safety and the civility study, the Liberty label
9 (phonetic) user survey and the signed validation.

10 The Sarapo Infant/Child Cartridge was a
11 study to show the ten users who had viewed the
12 training video could recognize the need to change
13 from adult pads to infant/child pads and successfully
14 change the cartridges. This was one of our concerns
15 and is one question for the panel.

16 The labeling, label evaluation was a
17 written test. The purpose was to assess the
18 participants' comprehension of one of four labeling
19 items. There was a simulation part with 190 subjects
20 were tested on how to set up and place pads based on
21 their understanding of the labeling. We have, again,
22 another question for the panel. And there was a

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1 marketing survey.

2 The comments or concerns that we have are
3 -- actually our main concern on the previous test was
4 that testing was preceded by a script read to the
5 subject informing them that the manikin was a
6 simulated victim of sudden cardiac arrest; that the
7 victim required immediate help, and then that an AED
8 might be used to help the victim, and also the EMS
9 has been already called.

10 Survival rates and adverse events with
11 home use of AEDs have not been directly evaluated.

12 The full performance summary, Philips
13 reported 150,000 units distributed with approximately
14 200,000 uses and reported 59 devices among functions
15 that are represented here, and at the time of our
16 review there were four AEDs, and specifically the FR-
17 2s that fail in a use related event. That means that
18 you compromise delivery of therapy.

19 The sponsor dates are different from ours
20 because they are including the reports up to date.
21 That's why they presented six. One case was a case
22 that it was believed it was a simulated case, and it

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1 turns out to be that a patient was involved.

2 Human factors. Human factors examines
3 all aspects of assistance interface that are
4 necessary for safe and effective use. The definition
5 of use includes the installation, calibration,
6 operation, maintenance, repair and ultimately the
7 disposal of the system or its components.

8 Training and labeling are part of the use
9 interface of a device. In this context, delivery of
10 medical care is only one part of a device's use. In
11 devices for emergency use, as this one, concerned
12 with preparing a device at maintained readiness are
13 extremely important. For the HeartStart
14 Defibrillator, it appears that the user must
15 accomplish the following basic activities: set up
16 training, operation, storage, and maintenance of the
17 device.

18 The actions needed for the operation of
19 this device includes determine that a patient is
20 unresponsive. Notify 911. Turn on the device.
21 Expose the patient's chest. Place electrodes.
22 Respond to the device's instructions, possibly

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1 pressing a shock button and possibly perform CPR.
2 And attend to the patient until arrival of emergency
3 personnel.

4 Philips' testing covers some aspects of
5 device wrap (phonetic) and device operation.
6 However, Philips' testing did not cover training,
7 storage, or maintenance.

8 And we have two questions for the panel
9 on this issue. FDA considered this a track device
10 requiring the sponsor to have processes in place to
11 promptly identify users in the event of a recall.
12 The sponsor proposes the use of a registration card
13 to build a database of shipment records.

14 However, in the case of a recall,
15 multiple methods of identification will be used, like
16 Web sites, collaboration with consumer organizations,
17 public warnings. We have a question for the panel
18 regarding this issue.

19 For the post market surveillance, Philips
20 is planning to continue with the NDR reporting as for
21 the prescription device and also has a follow-up
22 survey of post market study that consists of a

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1 follow-up survey of U.S. customer after one year of
2 after-years of the device, whichever come first.
3 Purpose: assess safety and effectiveness following
4 use of the nonprescription device and also a strategy
5 that ties the direct reordering of pads.

6 Our final comments are uncertainty
7 remains regarding the public's ability to safely use
8 AEDs given the increased access, and we have conveyed
9 this concern in some of the questions. The sponsor
10 has presented data that characterizes the human
11 factors attributed to the device and labeling.

12 However, survival rates and adverse
13 events with home use of AEDs have not been directly
14 evaluated.

15 Thank you.

16 ACTING CHAIR LASKEY: Let's see. Is
17 there anybody else from the agency who's presenting?
18 Is that it?

19 Okay. Anybody have a comment? Yes,
20 John.

21 DR. SOMBERG: I'm going to ask the same
22 question to the FDA group here as I did to the

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1 sponsor, and that is in your review have you
2 identified a population, a subpopulation that you
3 think would be placed in some degree of jeopardy by
4 the use of this device?

5 And if you have identified that
6 population, would the physician link in the
7 prescribing obviate that problem?

8 DR. TOVAR: No, we didn't identify that
9 population

10 ACTING CHAIR LASKEY: Yes, Dr. Vetovec.

11 DR. VETROVEC: A somewhat different
12 question, but in the experience of the agency with
13 other devices, I recall that there has been approval
14 of the Heart Card for monitoring heart rhythm that
15 patients can elect to do. That does require at least
16 not a prescription but physician input, but is there
17 any other model that the agency has dealt with in
18 which prescriptive authority has been removed from a
19 medical device? And what has been the experience
20 with that?

21 DR. TOVAR: As far as my knowledge, I
22 don't recall anything on that, but probably Megan

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1 could help me with this.

2 MS. MOYNAHAN: Megan Moynahan, FDA.

3 Our primary experience with over-the-
4 counter products has been with over-the-counter
5 diagnostics, blood tests, urine tests for pregnancy,
6 ovulation, glucose monitoring, and that. I think
7 there is something called a liquid bandage, which is
8 considered a therapeutic device, but besides that,
9 our primary experience has been with over-the-counter
10 diagnostics.

11 ACTING CHAIR LASKEY: I thought I saw
12 your hand up earlier, Mitch.

13 DR. KRUCOFF: No.

14 ACTING CHAIR LASKEY: No? Okay.

15 Well, then I apologize for our premature
16 break. I didn't realize we'd be so brief.

17 That brings us to the lunch hour, which
18 we've been smelling for the last hour.

19 (Laughter.)

20 ACTING CHAIR LASKEY: We've been trying
21 to do something about that with management, but I
22 have 12:30. If we can adjourn and break for lunch

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1 and meet back here at 1:30, I think we'll still stay
2 to schedule.

3 Thank you much.

4 (Whereupon, at 12:34 p.m., the meeting
5 was recessed for lunch, to reconvene at 1:30 p.m.)
6
7
8
9
10

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (1:37 p.m.)

3 ACTING CHAIR LASKEY: Okay. Welcome back
4 again. Thank you for your promptness. Hopefully
5 this will get us through the remainder of the day on
6 schedule. And I'd like to resume this afternoon and
7 open by having our lead reviewer, Dr. Maisel, give
8 his review and/or query the sponsor.

9 So Bill.

10 DR. MAISEL: Good afternoon. I don't
11 think there's any debate that AEDs effectively
12 defibrillate the heart and can restore the rhythm
13 back to normal, and there have been some very
14 impressive results that have been cited and discussed
15 this morning regarding public access defibrillation:
16 American Airlines, Chicago Airport, casinos, the
17 public access defibrillation trial. I think public
18 access defibrillation is a good thing, but I don't
19 think that's what we're debating today.

20 I think you could make the argument that
21 with prescriptions public access defibrillation could
22 go on as it is now with AEDs wherever they needed to

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1 be.

2 So what I'd like to try to focus my
3 remarks on are the specific implications of removing
4 the prescription from this device and the first topic
5 I'd like to try to cover is the intended patient
6 population, and it has been stated by both the
7 sponsor and the FDA that there is no change in the
8 intended patient population. I'm not sure that I
9 completely agree with that statement.

10 Something is happening when a patient
11 goes in to see a physician and because not every one
12 of those patients walks out with an AED, and so I'd
13 like to ask the sponsor if they could be a little bit
14 more specific in both their presentation and in the
15 packet they presented some anecdotal comments that
16 physicians made or that patients made stating what
17 their physicians said regarding the reasons for
18 refusing to give them a prescription or dissuading
19 them from getting a prescription.

20 So I wonder if you have any data from
21 physicians or from patients reporting about their
22 physicians, about the reasons why physicians turn

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1 down patients for an AED.

2 DR. SNYDER: We do have some data, if I
3 can have Slide G-33 up, please.

4 This is information gleaned from our
5 telephone fulfillment center. Now, this is the point
6 of contact for a customer who has either gained
7 information from a Web site, a print advertisement,
8 seen a spot that we've run on television, has
9 interest in a home defibrillator. This is the number
10 they call to get information from Philips.

11 First, I want to draw to your attention
12 the fact that in this three-month period or -- excuse
13 me -- four-month period we had contacts from a little
14 over 5,850 people interested in a home defibrillator.

15 Now, of those, based on the information
16 and materials provided by Philips through the phone
17 contact, 90 percent of those did decide that this was
18 not the purchase for them and declined to pursue the
19 purchase further.

20 So the first point I want to make is this
21 has not been a hard sell, and in fact, Philips has
22 successfully dissuaded 90 percent of our potential

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1 customers.

2 But of those that have decided to
3 proceed, the 9.6 percent -- that's 619 individuals --
4 these are people who have researched the issue, made
5 the decision that they are willing to put down a
6 credit card in order to secure a purchase. We then
7 instruct them in the need to get a prescription from
8 their physician and assist them in making that
9 appointment so that they can talk to their physician
10 about a prescription.

11 Next slide, please.

12 Of those people that go to their
13 physician to get a prescription, 71 percent were
14 refused a prescription. Twenty-nine percent did
15 receive a prescription from their physicians.

16 Now, we've done a further breakdown of
17 this data. It has not been submitted to the FDA. We
18 did categorize the reasons given for refusal of
19 prescription. With the permission of the Secretary,
20 I'd be happy to share that data.

21 MS. WOOD: That would be fine.

22 DR. SNYDER: Next slide, please.

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1 This is a breakdown of all the reasons
2 for refusal cited by the physicians when these people
3 who had made a purchase commitment decided to attempt
4 to get a prescription. Now, you'll notice that there
5 are more reasons cited than there were refusals.
6 This is because sometimes multiple reasons were
7 given. So this is categorized as a percentage of all
8 reasons given.

9 The most common reason for not
10 prescribing a defibrillator, 48 percent, was that it
11 doesn't meet or doesn't treat your condition or you
12 don't need it, and I think this is really the point
13 that we're trying to make in our presentations here
14 today, is that what we're trying to address is the
15 population that doesn't have an identified medical
16 issue.

17 The second most common reason for refusal
18 is simply that the physician was not comfortable with
19 prescribing the device or no reason at all is given.

20 The remainders fall in the four percent
21 or less reasons for refusal, and they include things
22 like some physicians offered to implant an ICD

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1 instead. The cost was cited, suggesting to use EMS
2 instead, and so forth.

3 Slide down, please.

4 ACTING CHAIR LASKEY: I'm sorry. These
5 are per patient report or you went to the physicians
6 and got their --

7 DR. SNYDER: No, this is patient reported
8 reason that they were given by their physician for
9 refusing the prescription.

10 DR. MAISEL: Okay. Thank you.

11 I find that very interesting and useful
12 information.

13 Next, I just want to clarify a couple of
14 things about the device description. You did a very
15 thorough job of explaining the device and what it
16 does, and I understand that the device is already
17 approved and, therefore, there's been no new
18 arrhythmia testing, but it would help me to understand
19 a little bit more regarding the algorithm for
20 detecting ventricular fibrillation, exactly what it's
21 doing. You put up that slide with a variety of
22 generic statements, and my main issue is just trying

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1 to understand from a safety standpoint what sort of
2 circumstances might make the device misinterpret a
3 rhythm.

4 DR. SNYDER: Slide up, please.

5 This is a graphic depiction of basically
6 how the algorithm works. I talked about the four
7 different mathematical measures we take of the ECG,
8 and what I've done in this graph is I've plotted
9 three of those. The first is the morphological
10 stability of the complex. Again, how repeatable is
11 the complex, not the heart of our intervals, but the
12 shape of the complex. How repeatable is it from one
13 to another.

14 And as it's scored from the low end here,
15 you can consider this to be a zero. It's a high
16 stability you can consider to be a one.

17 Similarly, the conduction properties, the
18 health of the myocardium, this is basically measured
19 by rapidity of edges in the complexes, sharp
20 transitions in the complexes and so forth, and that's
21 plotted along this axis from lowest conduction, which
22 would be a very sinusoidal in nature, ventricular

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1 tachycardia, for example, up to the very highest
2 conduction values, which would be typical of a normal
3 QRS complex or a rhythm of super ventricular origin.

4 And then on the vertical axis we have the
5 heart rate, which in this graph goes from zero
6 complexes per second asystole up to 600 per minute --
7 excuse me -- not per second. What I've plotted here
8 are the results of analyzing three different rhythms,
9 and this was our validation database and our original
10 development exercise of this algorithm.

11 The red dots represent rhythms for which
12 our over reading physicians -- we sought consensus
13 from three professionals, a cardiologist, an
14 electrophysiologist, and emergency physician. The
15 red dots are the rhythms that they judged would
16 benefit from a shock.

17 The green rhythms that you see down in
18 the lower corner are the rhythms for which no shock
19 should be advised. Those include super ventricular
20 tachycardias, normal sinus rhythm, bradycardias.

21 And what you'll see is characteristic,
22 for example, of normal sinus rhythm, is it has very

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1 high stability, very high conduction, at a modestly
2 low rate. So it falls down in this corner.

3 In order for us to advise a shock, when
4 we plot those three numbers, it has to fall on the
5 other side of the gray surface. For a no shock or
6 for a rhythm requiring shock, it has to be above the
7 surface. If it falls below, that results in a no
8 shock advice.

9 So that you see, ventricular
10 fibrillation, for example, resides in this part of
11 this graph. It has low stability. It has moderate
12 conduction, and it has moderate to high rates. So
13 this is the cloud representing ventricular
14 fibrillation.

15 With tachycardias, you often get higher
16 stability, higher conduction properties, and they
17 reside in this part of the space. Normal sinus
18 rhythms, bradycardias, asystoles, they reside way
19 down here.

20 Now, of course, there are some
21 indeterminate rhythms, rhythms for which for fusion
22 status it's really uncertain from the ECG alone. We

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1 have taken a conservative approach to these
2 arrhythmias, and those are represented by the small
3 number of red dots for which the majority of our over
4 eaters would have preferred the shock, but our
5 algorithm represents a no shock, and this reflects
6 the conservative nature that's responsible for the
7 truly high specificity we've achieved with this
8 arrhythmia system.

9 DR. MAISEL: Is that latter statement
10 then consistent with what I read, that -- and I'm
11 quoting the most common reported concern, I guess,
12 from users -- was that the device did not recommend
13 or deliver a shock for a rhythm that was considered
14 shockable? Can you comment on that statement?

15 DR. SNYDER: Yes. That statement would
16 be in the case of a very fine VF, either had a very
17 low rate of complexes, typically below about 130, or
18 it was a very low amplitude which actually was right
19 on the edge of whether we considered it an asystole
20 or actually a fine VF.

21 So these are patients from which outcome
22 from shock, certainly the arrhythmia could be

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1 terminated, but it actually may be more appropriate
2 and beneficial to do CPR and see if the nature of the
3 arrythmia could be improved.

4 DR. MAISEL: Another question I had
5 regarding the device description was there was a
6 mention of the event review data management software.

7 In other words, I'm trying to understand if a
8 patient does survive their experience, is there a
9 rhythm strip that some medical personnel can review,
10 and if so, how do they obtain that strip?

11 DR. SNYDER: Yes, there is. I'm looking
12 for the proper slide if you give me a moment. There
13 is a number of pieces of information we record within
14 the device. Here we go. Slide up, please.

15 Internal to the device is a memory, and
16 we actually performed three types of data collection.

17 First of all, there's data which is useful in
18 handoff to a second tier responder, and it's
19 available audibly through the voice prompts of the
20 device. And this information is accessed by pressing
21 the I button. There are instructions in the owner's
22 manual so that purchaser knows how to do this for EMS

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1 when they arrived. Certainly EMS organizations will
2 become aware of this as well.

3 It will report the number of shocks that
4 have been delivered to the patient and the minutes of
5 use. So that information is available immediately to
6 second tier response.

7 The device also records information for
8 the purpose you referred to, review through our event
9 review software. It records event data for 15
10 minutes, including internal storage of the
11 electrocardiogram in events, all events. That's
12 shock advisories, shocks delivered, and so forth that
13 occurred during those first 15 minutes of patient
14 use.

15 And then finally there is some more
16 internal data that's recorded, including device
17 manufacturing identification, records of self-test
18 performance and so forth. So we have a complete
19 record of the devices, the diagnostics on a day-to-
20 day basis.

21 DR. MAISEL: I was a little confused. I
22 believe I read that it said the event review data

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1 management software continued to require a
2 prescription. Is that --

3 DR. SNYDER: That's correct. It does.
4 The event review software is really not appropriate
5 for a lay user. I can't envision why a lay user
6 would have need to evaluate the ECG. It's really
7 appropriate for an EMS reviewer, physician review.
8 And it's the same software we use for all of our
9 other defibrillator products. So any system that has
10 event review software has full access to the ECG
11 information that's contained in this device.

12 DR. MAISEL: So I'm a little bit
13 confused. Does the product that we would be giving
14 OTC status to have -- it has the capability to store
15 the ECGs --

16 DR. SNYDER: That's correct.

17 DR. MAISEL: -- but only an appropriate
18 medical person can --

19 DR. SNYDER: Can actually gain access to
20 that information.

21 DR. MAISEL: -- get it out of that
22 device?

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1 DR. SNYDER: Yes.

2 DR. MAISEL: Why is that? Why can't -- I
3 just see that potentially as a barrier to the patient
4 getting appropriate care once they get taken off to
5 the hospital.

6 DR. SNYDER: Can you explain in more
7 detail your concern?

8 DR. MAISEL: A patient has a cardiac
9 arrest. They're resuscitated. EMS comes and they
10 would like to immediately take the patient to the
11 hospital.

12 DR. SNYDER: Yes.

13 DR. MAISEL: There is a delay in trying
14 to retrieve from the device the rhythm strips that
15 will be helpful to the patient's subsequent care.

16 DR. SNYDER: That's certainly a
17 limitation of the product. Unless the hospital had
18 the specific event review software, they would not be
19 able to gain access to that. The information they
20 would have is the length of time the product was
21 attached and how many shocks had been delivered.

22 DR. MAISEL: I see that as a little bit

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1 of a limitation. It's, you know, going back to ICDs
2 in the early 1990s when people got shocked and we
3 didn't know why. Certainly you've demonstrated
4 relatively convincing sensitivity and specificity of
5 the device, but that concerns me a little bit.

6 DR. SNYDER: I will add that this
7 capability is similar to all other AEDs that I'm
8 aware of in that some additional facility is required
9 to extract the data from them. I'm unaware of any
10 AEDs for even public access or EMS response that have
11 built in printers. With that kind of functionality
12 you typically go up to a manual defibrillator.

13 DR. MAISEL: All of those AEDs require a
14 prescription.

15 DR. SNYDER: That's correct.

16 DR. MAISEL: Two main safety issues that
17 I wanted to discuss and mainly trying to get at the
18 point of whether the AED is truly helpful in all
19 cases or whether there are circumstances under which
20 it could actually be harmful.

21 The first is I'd like to discuss the
22 potential delay in notifying EMS, and I'm a little

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1 bit concerned that the only initial notification
2 warning on your device is simply a sticker on the
3 outside of the device, and maybe you can discuss why
4 you chose not to have the very first thing that the
5 device says when you turn it on be, "Notify EMS," or,
6 "Call 911."

7 That seems like a very simple thing to
8 do. Why was that not done.

9 DR. SNYDER: Certainly. I'll address
10 that question first, and then I'd like to ask Lance
11 Becker to come up to add a little more perspective on
12 the history of notification of EMS.

13 But the reason we didn't make the initial
14 voice prompt, "Call EMS," because imagine the
15 scenario. The device is placed in the home according
16 to recommendations adjacent to a phone. The arrest
17 occurs in a remote part of the house. The event is
18 witnessed. You go to retrieve the AED. You then
19 walk back to the patient. You open the device, and
20 then you get the instruction to activate EMS at which
21 point you have to go back to the telephone, dial EMS,
22 discuss the problem with EMS, then go back to the

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1 defibrillator and actually deploy.

2 If we get past the initial labeling, and
3 I want to emphasize that our experience with lay
4 people using AEDs is that they don't fail to activate
5 EMS, and in fact, the studies you heard about this
6 morning were using products that had no labeling
7 about calling EMS.

8 So we've taken that successful EMS
9 notification history and we've now added two more
10 layers of labeling to remind people to call EMS. So
11 we're quite confident in that regard.

12 DR. MAISEL: So are you suggesting that
13 if a user does not immediately notify EMS and they
14 bring the AED to the side of the patient they should
15 not go back and notify EMS? I mean what you just
16 said suggests that you're suggesting something other
17 than the chain of survival.

18 DR. SNYDER: the protocol that has been
19 implemented is if you fail to activate EMS per
20 protocol, take the device to the site of the patient
21 in VF. The protocol that's implemented is to deliver
22 shocks and then issue a reminder.

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1 DR. MAISEL: Okay. I guess I also have
2 an issue with that, I think, for a number of reasons.

3 You've cited many examples of when the device is
4 used or put on a patient and it does not do anything
5 for the patient. There are times when the shocks are
6 delivered, but EMS subsequently comes and delivers
7 additional shocks.

8 I think notification of EMS before use of
9 the device remains a critical component, and the
10 scenario you describe worries me a little bit, and I
11 am concerned that the label alone is not adequate.

12 DR. SNYDER: Yes. I think Dr. Becker has
13 some information he might like to add to my comments.

14 DR. BECKER: The concern that you raised
15 is one that has been sort of peer reviewed, expert
16 reviewed by a number of very large panels, and it is
17 with some difficulty that everyone agrees that you
18 may not be able to come up with something that is
19 perfect in every case.

20 What the American Heart Association
21 determined as they thought about this subject is what
22 do you do -- it's sort of facetiously called the loan

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1 rescuer issue, and the issue is if you are the lone
2 rescuer, do you apply a defibrillator or do you call
3 EMS first.

4 And in fact, the decision was that in the
5 adult, you should apply the defibrillator first and
6 see if that was a shockable rhythm and then go to the
7 telephone, and that is the American Heart Association
8 standard, and that's an international standard as
9 well.

10 So one can imagine why that could be
11 problematic in a very few cases. I think the thing
12 to remember with this device is in approximately 60
13 seconds you will then be prompted to call EMS.

14 So those are the current ways that we do
15 it.

16 DR. MAISEL: The other potential safety
17 issue I wanted to discuss was the timing of CPR, and
18 certainly there is some data, and we can debate the
19 merits of the data that in patients who have been
20 down for longer than four or five minutes, that CPR
21 first rather than immediate defibrillation might be
22 of some benefit. And I certainly recognize the

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1 trouble in making things more complicated than they
2 need to be.

3 Are there instances in your mind when CPR
4 should be administered prior to placing the AED on
5 the patient? For example, in a patient who is found
6 down and either the time is known to be down for
7 longer than four or five minutes or it's not known
8 how long the patient has been down?

9 DR. SNYDER: I'd like to first review
10 what I believe is the study you referred to, and just
11 review the data quickly so that we can consider it,
12 and then again, I'm going to ask Dr. Becker to answer
13 the more general question.

14 Slide up, please.

15 I believe you're referring to the study
16 that was done in Oslo, Norway conducted by Lars Wik,
17 and this study examined 200 VF sudden cardiac arrests
18 over a period of 36 months. Patients were randomized
19 to either immediate defibrillation. There was 96 in
20 this arm or three minutes of CPR prior to
21 defibrillation, and there were 104 patients in this
22 arm.

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1 Now, in the system during the duration of
2 this study, the mean collapse to arrival time -- so
3 that's collapse of patient estimated until ambulance
4 arrives at curbside -- was 12 minutes.

5 Next slide, please.

6 Now, the general hypothesis was that
7 three minutes of CPR performed prior to shocks would
8 result in survival benefit for the overall
9 population, and this hypothesis was not sustained in
10 this study. There was a trend towards that result.

11 If you look, return of spontaneous
12 circulation had a trend towards better results with
13 the CPR first arm, the same for survival to admission
14 and survival to one year or survival for one year
15 following arrest, though none of these differences
16 were significant.

17 Next slide, please.

18 Now, what was interesting in this study
19 was they examined the subset of patients for whom not
20 the down time, but the ambulance response time was
21 greater than five minutes, and in this cohort of
22 patients they discovered that there were significant

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1 improvements in return of spontaneous circulation,
2 survival to hospital admission, and one year
3 survival.

4 But if we add up the numbers that Dr.
5 Becker provided to us this morning, that is,
6 approximately four minutes typically from collapse to
7 activation of EMS, in this case five minutes is the
8 cutoff for ambulance response. That's nine; another
9 two to deploy and deliver defibrillation. We're
10 really talking about a ten or 11 minute down time
11 population in this study.

12 And if we go to the next slide, which
13 represents ambulance response times of less than five
14 minutes, we see that the trend is actually reversed.

15 Again, none of these differences are statistically
16 significant, but observed rates of ROSC was actually
17 higher in shocks where survival was higher and one
18 year survival was also higher, again, not
19 statistically significant, but the trend was in favor
20 of shocks first for, and when we're speaking of down
21 time, approximately ten minutes or less.

22 And certainly with this device we're

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1 hoping to achieve response times much less than that.

2 This is the response that's appropriate to EMS
3 arrival.

4 Dr. Becker, would you like to add further
5 comments?

6 DR. BECKER: This is an issue that a lot
7 of us are very interested in, and I think the point
8 that I would like to make is that what we have to go
9 on today is exactly what the device, in fact,
10 advises.

11 And if I could have the slide up, please.

12 This is the AED treatment algorithm that
13 is currently circulated all over the world, and what
14 it essentially says is that as soon as you have an
15 AED available to you, you attach the AED and you
16 defibrillate if that rhythm is ventricular
17 fibrillation.

18 So I just want to highlight -- slide down
19 -- that our current state of international and
20 national recommendations is when you see ventricular
21 fibrillation, to defibrillate that rhythm.

22 Now, there is a body of data that is

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1 emerging to suggest that there may be a time where it
2 would be better to receive CPR first, and I
3 personally believe that that's probably going to be
4 true, but as of yet, there is not a national
5 organization that has made such a recommendation.
6 There's not an international organization, and there
7 are really fine training organizations that will be
8 examining this, and that may be something that will
9 change in the future.

10 DR. MAISEL: What would be the recourse
11 for -- "recourse" is probably the wrong word -- but a
12 person purchases the device and there are significant
13 changes in the recommendations regarding
14 defibrillation or CPR over the course of the next two
15 or three or five or ten years, and you know, there
16 are hundreds of thousands of devices out there that
17 are not doing the recommended algorithm. How would
18 we respond to that situation?

19 DR. SNYDER: Well, to begin with the
20 device is actually configurable. Again, you use the
21 event review software so that it's not configurable
22 by the lay responder. But the protocol can be

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1 changed. It supports one, two, or three shocks after
2 every interval of CPR, should they be indicated.

3 It also has various CPR compression
4 intervals that can be programmed, anything from a
5 half minute to three minutes at a time. So there is
6 a good deal of flexibility built into the device.

7 Beyond that, if protocols are adopted
8 that the product is not currently capable of
9 supporting, the software can be upgraded in the
10 device, and this would most likely be handled by a
11 male end upgrade for the product.

12 DR. MAISEL: Finally, I wanted to touch
13 on some of the safety issues that have been discussed
14 this morning both by the FDA and Philips. From your
15 submission it appears that there's about 167,000
16 devices that are in service and close to 450,000
17 device service years, and so I think the relatively
18 small number of adverse events that have been
19 reported in the context of that is not that
20 concerning to me.

21 What is of more concern is that there do
22 continue to be a number of recalls related to these

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1 products. I know Philips themselves had a recall
2 related to their AED, and I'd like to have you walk
3 through how a patient notification system would work
4 if a patient needed to be notified or a buyer needed
5 to be notified that their device was under advisory
6 or recall.

7 DR. SNYDER: Certainly. First, I'd like
8 to bring up Slide S-77, please.

9 I would like to review our recall history
10 for the panel's benefit because certainly there have
11 been many recalls of defibrillators.

12 Slide up.

13 The recall history, this product line of
14 defibrillators, the ForeRunner, the FR-2, and the On-
15 Site, is we have had one Philips AED recalled.
16 That's not one recall. It is one recall, but it's
17 one device.

18 The FR-2 has been built with components
19 that might cause -- excuse me? Oh, this was in a
20 device -- excuse me -- that had been built with a
21 component that could lead to an early self-test
22 failure. It was not a device that we understood to

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