

UNITED STATES OF AMERICA
FOOD AND DRUG ADMINISTRATION

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CIRCULATORY SYSTEM DEVICES PANEL
OF THE MEDICAL DEVICES ADVISORY COMMITTEE

+ + + + +

510 (k) DISCUSSION AND RECOMMENDATIONS

+ + + + +

THURSDAY

JULY 29, 2004

+ + + + +

The Advisory Panel meeting convened in the Grand Ballroom of the Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland at 9:00 a.m., Warren K. Laskey, M.D., Acting Chairperson, presiding.

PANEL MEMBERS PRESENT:

WARREN K. LASKEY, M.D., Acting Chairperson, Uniformed Services University of the Health Sciences

MITCHELL KRUCOFF, M.D., Voting Member, Duke

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University Medical Center

PANEL MEMBERS PRESENT (Continued):

WILLIAM H. MAISEL, M.D., M.P.H., Voting Member,
Brigham & Women's Hospital

SHARON-LISE NORMAND, Ph.D., Voting Member, Harvard
School of Public Health

NORMAN S. KATO, M.D., Consultant, Cardiac Care
Medical Group

JOSEPH P. ORNATO, M.D., Consultant, Medical College of
Virginia Hospitals

RICHARD E. RINGEL, M.D., Consultant, Johns Hopkins
Hospital

JOHN C. SOMBERG, M.D., Consultant, American Institute
of Therapeutics

GEORGE W. VETROVEC, M.D., Consultant, Medical College
of Virginia

MICHAEL MORTON, Industry Representative, Cardiac
Surgery, North America Sorin Group

CHRISTINE MOORE, Consumer Representative

GERETTA WOOD, Executive Secretary

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PRESENTERS:

Office of Surveillance and Biometrics Presentation:

BEVERLY GALLAURESI, RN, MPH, Food and Drug
Administration

OSCAR TOVAR, M.D., Food and Drug Administration

Morning Public Session:

MICKEY EISENBERG, M.D., Ph.D., Professor of Medicine,
University of Washington

KELLY HARRIS, Lake Oswego, California

RICHARD A. LAZAR, ESQ., CEO, Early Defibrillation
Law & Policy Center

MATT MCKEE, Cardiac Science, Inc.

ROBERT E. O'CONNOR, M.D., MPH, Professor of Emergency
Medicine, Thomas Jefferson University

FRANK POLL

Sponsor Presentation:

DR. LANCE BECKER, Director, Emergency Resuscitation
Center, University of Chicago

CARL MORGAN, Co-founder, Philips

DR. JEREMY RUSKIN, Founder and Director, Cardiac
Arrhythmia Service and Clinical Electrophysiology

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Laboratory, Massachusetts General Hospital

DAVID SNYDER, Director of Research, Philips

U.S. Food and Drug Administration Presentation:

OSCAR TOVAR, M.D., Lead Reviewer, FDA

Afternoon Public Session:

JOHN GREGOIRE, Plano, Texas

MARY NEWMAN, National Center for Early Defibrillation

GRAHAM NICHOL, M.D., Chair, American Heart
Association AED
Task Force

MICHAEL D. WILLINGHAM, Vice President, Regulatory
Affairs Medtronic Emergency Response Systems

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P R O C E E D I N G S

(9:04 a.m.)

1
2
3 ACTING CHAIR LASKEY: Well, good morning. The
4 Circulatory Systems Devices Panel is meeting today
5 to discuss the pre-market notification for the
6 Philips Medical HeartStart Home, K040904.

7 Ms. Wood, if you can read the conflict of
8 interest statement, please.

9 MS. WOOD: Before I read the conflict of
10 interest, I'd just like to clarify something on the
11 agenda. There will not be a vote today since this is
12 a 510(k) device. The vote was inadvertently left at
13 the bottom of the agenda. So please disregard that.

14 The following announcement addresses
15 conflict of interest issues associated with this
16 meeting and is made a part of the record to preclude
17 even the appearance of an impropriety. To determine
18 if any conflict existed, the agency reviewed the
19 submitted agenda and all financial interests reported
20 by the committee participants.

21 The conflict of interest statutes
22 prohibit special government employees from

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1 participating in matters that could affect their or
2 their employer's financial interest. However, the
3 agency has determined that participation of certain
4 members and consultants the need for whose services
5 outweighs the potential conflict of interest involved
6 is in the best interest of the government.

7 Therefore, waivers have been granted for
8 Drs. Mitchell Krucoff and Joseph Ornato for their
9 interest in firms that could potentially be affected
10 by the panel's recommendations.

11 Dr. Krucoff's waiver involves consulting
12 with a competitor on an unrelated matter for which he
13 receives an annual fee of less than \$10,001.

14 Dr. Ornato's waiver involves consulting
15 with a competitor on an unrelated matter for which he
16 receives an annual fee of less than \$10,001.

17 The waivers allow these individuals to
18 participate fully in today's deliberations. Copies
19 of these waivers may be obtained from the agency's
20 Freedom of Information Office, Room 12A-15 of the
21 Parklawn Building.

22 We would like to note for the record that

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1 the agency took into consideration other matters
2 regarding Drs. Mitchell Krucoff, William Maisel,
3 Joseph Ornato, Richard Ringel and John Somberg.
4 These panelists reported past or current interests
5 involving firms at issue, but in matters that are
6 unrelated to today's agenda.

7 The agency has determined, therefore,
8 that these individuals may participate fully in the
9 panel's deliberations.

10 The agency also would like to note that
11 Dr. Warren Laskey has consented to serve as Chair for
12 the duration of this meeting.

13 In the event that the discussions involve
14 any other products or firms not already on the agenda
15 for which an FDA participant has a financial
16 interest. The participant should excuse him or
17 herself from such involvement, and the exclusion will
18 be noted for the record.

19 With respect to all other participants,
20 we ask in the interest of fairness that all persons
21 making statements or presentations disclose any
22 current or previous financial involvement with any

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1 firm whose products they may wish to comment upon.

2 ACTING CHAIR LASKEY: Thanks, Geretta.

3 If I can have the panel members introduce
4 themselves beginning with Dr. Zuckerman.

5 DR. ZUCKERMAN: Bram Zuckerman, Director,
6 FDA Division of Cardiovascular Devices.

7 DR. KATO: Norman Kato, cardiovascular
8 surgery, private practice, Encino, California.

9 DR. ORNATO: Joe Ornato, cardiologist and
10 emergency physician, Chairman of Emergency Medicine,
11 Virginia Commonwealth University Medical Center,
12 Richmond, Virginia.

13 DR. RINGEL: Richard Ringel, Division of
14 Pediatric Cardiology, the Johns Hopkins School of
15 Medicine.

16 ACTING CHAIR LASKEY: Warren Laskey,
17 interventional cardiologist at Uniform Services
18 University here in Bethesda.

19 MS. WOOD: Geretta Wood, Executive
20 Secretary.

21 DR. NORMAND: Sharon-Lise Normand,
22 Professor of Health Care Policy and Biostatistics,

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1 Harvard Medical School and Harvard School of Public
2 Health.

3 DR. SOMBERG: John Somberg, Rush
4 University, Chicago.

5 DR. KRUCOFF: Mitch Krucoff, cardiology,
6 Duke University Medical Center and Director of the
7 Cardiovascular Devices Unit at the Duke Clinical
8 Research Institute, North Carolina.

9 DR. MAISEL: William Maisel,
10 electrophysiologist at Brigham & Women's Hospital in
11 Boston.

12 MS. MOORE: Christine Moore, consumer
13 member.

14 MR. MORTON: Michael Morton. I'm the
15 industry representative and an employee of Sorin
16 Group.

17 ACTING CHAIR LASKEY: Geretta, if you
18 could please read the voting status statement.

19 MS. WOOD: Pursuant to the authority
20 granted under the Medical Devices Advisory Committee
21 charter, dated October 27, 1990 and as amended August
22 18th, 1999, I appoint the following individuals as

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1 voting members of the Circulatory System Devices
2 Panel for this meeting on July 29th, 2004:

3 Warren Laskey, M.D.

4 Norman S. Kato, M.D.

5 John C. Somberg, M.D.

6 George W. Vetovec, M.D.

7 Joseph P. Ornato, M.D.

8 Richard E. Ringel, M.D.

9 For the record, these individuals are
10 special government employees and are consultants to
11 this panel under the Medical Devices Advisory
12 Committee. They have undergone the customary
13 conflict of interest review and have reviewed the
14 material to be considered at this meeting.

15 This is signed by Daniel G. Schultz,
16 M.D., Director, Center for Devices and Radiological
17 Health, and dated July 23rd, 2004.

18 ACTING CHAIR LASKEY: Thanks, Geretta.

19 Before we proceed with the open public
20 session portion today, I just wanted to introduce Dr.
21 Oscar Tovar who will give us a short presentation on
22 adverse event reports on the AED.

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1 Dr. Tovar.

2 DR. TOVAR: Hi. I would like to
3 apologize because Ms. Beverly Gallauresi who worked
4 with me wasn't included in the agenda, but she is the
5 first presenter.

6 MS. GALLAURESI: Good morning. I'll
7 overlook that little oversight. I won't take it
8 personally.

9 Good morning. My name is Beverly
10 Gallauresi. I'm a nurse analyst in the Division of
11 Post Market Surveillance, Office of Surveillance and
12 Biometrics in the Center for Devices and Radiological
13 Health.

14 I'll present a brief overview of the
15 medical device reporting system and an abbreviated
16 summary of adverse event and product problem reports
17 associated with automatic external defibrillators.

18 The medical devices reporting, or MDR,
19 system is a nationwide passive surveillance system
20 which includes both mandatory and voluntary
21 reporting. Since 1984, manufacturers and importers
22 have been required to submit reports to the FDA of

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1 device related deaths or serious injuries, as well as
2 events involving device malfunction, that may cause
3 or contribute to a death or serious injury.

4 The Safe Medical Devices Act of 1990
5 introduced mandatory reporting of device related
6 deaths and serious injuries by user facilities, most
7 notably hospitals and nursing homes. Voluntary
8 medical device adverse event in product problem
9 reports are most often submitted by health care
10 practitioners, consumers, patients or family members
11 and are received through FDA's MedWatch program.

12 In general, approximately 95 percent of
13 medical device reports received by FDA are from
14 manufacturers, one percent from importers, and the
15 remainder equally split between voluntary and user
16 facility reports.

17 Under the medical device reporting
18 regulation, an adverse event is an event whereby a
19 medical device has or may have caused or contributed
20 to a death or serious injury. This includes events
21 associated with device problems or failures, as well
22 as those events involving use error.

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1 The manufacturer and user device
2 experience, or MOD, is a database that includes all
3 voluntary AED adverse event reports received from
4 December 1993 to the present and mandatory adverse
5 event reports from August of 1996 to the present.

6 Now we'll describe the search methodology
7 we used to obtain the data set of automatic external
8 defibrillator device reports.

9 All medical devices approved or cleared
10 for marketing have a unique three-letter identified
11 called a product code. We searched the MOD adverse
12 event database by product code for AED. As I
13 previously stated, the MOD database includes
14 voluntary AED adverse event reports from December
15 1993 to the present, and mandatory adverse event
16 reports from August 1996 to the present.

17 However, for this analysis we included
18 only mandatory manufacture reports from August 1996
19 through December 2003.

20 Medical device adverse event reports
21 contain information about adverse event or product
22 problems, including where and how the event occurred,

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1 who was involved, and consequences associated with
2 the reported event. Reports submitted by
3 manufacturers contain their evaluations of the
4 adverse event, including coded conclusions drawn from
5 investigations.

6 These numbers represent adverse event
7 reports associated with AEDs submitted by all
8 manufacturers for the eight-year period from August
9 1996 to December 2003. As you can see, the FDA has
10 received 7,644 manufacturer adverse event and produce
11 problem reports associated with AEDs. The number of
12 death reports, 590; injury, ten; and malfunction,
13 7,044.

14 These reports are reviewed in detail to
15 assess signals of actual or potential device related
16 problems.

17 The MDR system, while providing signals
18 of actual and potential device related problems, has
19 some limitations. Under reporting of adverse events
20 to hospitals, manufacturers, and the FDA by health
21 care practitioners is a well known and recognized
22 phenomenon. Thus, events reported to the FDA

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1 represent a subset of the total occurrence of events.

2 In addition, manufacturers are not
3 required to submit denominator information, such as
4 the number of devices manufactured, distributed, and
5 implanted. Thus, due to under reporting and lack of
6 denominator data, accurate incidence rates are unable
7 to be determined based on these data.

8 Furthermore, reports received may not be
9 representative and reflect a variety of reporting
10 biases. Thus, for example, reporting may vary by
11 manufacturer and by the presence or absence of
12 publicity. Because adverse event reports vary in
13 completeness and details, causality often remains
14 uncertain.

15 Dr. Tovar will now discuss in more detail
16 reported problems associated with AEDs based on
17 review of mandatory manufacturer adverse event
18 reports that have been submitted to the FDA.

19 DR. TOVAR: Thank you, Beverly, and
20 again, please accept my apologies.

21 I am Oscar Tovar. I am a medical officer
22 in the Office of Device Evaluation and in the Office

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1 of Surveillance and Biometrics.

2 This morning I am going to present a
3 descriptive analysis from adverse event reports on
4 automatic external defibrillators from 1996 to 2003.

5 The benefits of early defibrillation in public
6 places have been shown in numerous studies as the PAT
7 trial (phonetic), the Chicago area airport, and the
8 Las Vegas casinos.

9 Along with this, there is a steady
10 increase in the deployment of automatic external
11 defibrillators. The estimated AED growth rate for
12 the United States was 8.2 percent for 2000 and 2001;
13 11.5 percent for 2002; and 22 percent for 2003. It
14 is estimated to be about 20 percent per year in the
15 next five years. This data was obtained from Cross
16 and Sullivan.

17 These are the AEDs shipped in the United
18 States for years since 1999 to 2003 and the forecast
19 for the next six years. The plot shows a progressive
20 increase in the number of AEDs shipped.

21 The success of early defibrillation
22 implies that the AED works in the first attempt and

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1 consistently in the following attempts, if necessary.
2 The AEDs, as any other device, are subject to
3 failure, but an AED failure to deliver a
4 defibrillation shock decreases significantly the
5 probability of survival of a patient in ventricular
6 defibrillation. This association of device failure
7 and survival highlights the importance of the
8 awareness of these failures for wherever. There is
9 scarce information about adverse events associated
10 with AED use.

11 The goals of this study were, one, to
12 assess adverse event reports, particularly death,
13 associated with AED failure from 1996 to 2003; and to
14 determine AED component failure or factors that
15 resulted in failed defibrillation associated with
16 death.

17 For this purpose, Beverly and I review
18 medical device reports submitted by AED manufacturers
19 to the FDA for AED related adverse events. The MDRs
20 were received from August 19, 1996 to December 31st,
21 2003. We analyzed the MDRs using the manufacturer
22 and user facility device experience or MOD database

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1 from the FDA.

2 Ms. Gallauresi mentioned before that the
3 conclusions and the determination of the component
4 failure reported by the manufacturers were grouped in
5 categories and were used to assess the association of
6 device and component failure with the patient death.

7 I have arbitrarily separated data from
8 1996 to 2003 in two groups of four years each. The
9 early years, that's the way I call it, the first four
10 years, from 1996 to 1999, and the recent years, from
11 2000 to 2003 because AED availability and technology
12 was somehow different.

13 From 1996 to 1999, we have 191 deaths
14 associated to an AED failure. Of course, these are
15 the deaths that were reported.

16 We have also 1,579 malfunctions and only
17 six injuries and the category that classify things
18 that could have fit into these previous categories as
19 other.

20 From 2000 to 2003, 399 deaths were
21 reported related to an AED failure; 5,465
22 malfunctions; and four injuries.

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1 This view is intended to show the
2 difference between the early years of AEDs, of AED
3 deployment, and the four more recent years of AED
4 deployment. The malfunctions have increased almost
5 three and a half times and death more than doubled.

6 But we have to have an account,
7 increasing numbers of AEDs. The ratio of death to
8 malfunction is about 12 percent for 1996 to 1999 and
9 seven percent for 2000 to 2003.

10 Now I am going to present the different
11 categories per year. The report of malfunctions
12 increased from 105 in 1996 to 1,917 in 2003. It is
13 easy to associate this increase with increase of AED
14 deployed. Maybe better device self-agnostic. With
15 this I was to say that with self-diagnostic, want to
16 imply the device detects the malfunction before use
17 by a patient. You're in daily, weekly or monthly
18 self-diagnostics. That means that it's not during
19 the use of the patient -- on the patient, but during
20 the self-diagnostic.

21 There were very few injuries per year.
22 The maximums were three injuries per each year, and

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1 as you can see, there are very few per every single
2 year during this period.

3 From 1996 to 2000, there were below 70
4 deaths per year, but in 2001, there was an increase
5 over 100 deaths per year and have remained about 100
6 deaths per year associated with the increase probably
7 in the AED numbers of probability reporting. There
8 are several possibilities.

9 Twenty-six manufacturers reported during
10 this period. The results are reported as percentages
11 because in some instances there were multiple
12 conclusions per report. This is a retrospective
13 and -- I'll say it again -- descriptive analysis
14 because the absence of an accurate denominator, even
15 if we know the number of AEDs that have been
16 employed, it is extremely difficult to determine the
17 number of devices used during this period.

18 That's why it is important that we take
19 this data with caution, and I'm going to mention this
20 again later in the presentation.

21 The following slides will show the report
22 of results of the failure analysis in the two periods

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1 of time. These were the most frequent conclusions.

2 No conclusion with 32.3 percent. No
3 device failure with 26.7 percent. Device failure
4 cause or was related to event in 22.4 percent.
5 Unknown if the device contributed to event in 12.2
6 percent. And user error caused or contributed to
7 event with only 4.4 percent, and device maintenance
8 contributed to event in two percent.

9 There is a little confusion, what is
10 every single category. For this I thought that the
11 best way to explain it was with real examples. I had
12 edited the reports in an effort to remove any
13 identifiers or note that it is not literal, and what
14 I am going to read are event descriptions.

15 For example, an example of no conclusion
16 can be drawn and also device failure occur and was
17 related to event. This was the report. Reporter
18 alleged that while attending to the defibrillator, a
19 patient who had been in a car accident and was in
20 full cardiac arrest, the device delivered two shocks
21 but then did not deliver more shocks. The patient
22 subsequently expired. The report indicated the

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1 patient outcome was not a result of the reported
2 malfunction.

3 An example of device failure, this one.
4 Device failure directly caused event. The reporter
5 alleged that when attempting to defibrillate the
6 patient believed to be in ventricular defibrillation,
7 the defibrillator did not deliver a shock. The
8 defibrillator displayed an error message, and the
9 defibrillator could not be switched on.

10 An example of device failure occurred and
11 was related to event. The reporter alleged that
12 medics were attempting to defibrillate a patient, but
13 the device would not discharge. The medics attempted
14 to shock the patient a total of four to five times,
15 but the device continued to not discharge. The
16 medics then obtained another device and defibrillated
17 the patient. The patient subsequently expired.

18 And the last example is an example of
19 user error caused event and device perform according
20 to specifications and order. The Complainant alleged
21 that while attempting to defibrillate a patient with
22 paddles, the user charged the device with the paddles

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1 and the paddle container and the device appropriately
2 displayed an error message and failed to discharge.

3 Second, third, fourth and fifth devices
4 were used in an attempt to continue treating the
5 patient with the same result. Each device had a set
6 of paddles previously attached. The user did not
7 remove the paddles from the container on any of the
8 devices prior to charging the energy. That's the way
9 you read this report.

10 Now I'm going to show the results from
11 manufacturers' conclusions from 2000-2003. The no
12 conclusion has increased to 60 percent. The no
13 device failure here is 12.1 percent. The device
14 failure caused or was related to event in 9.6
15 percent, and the remaining categories add to three
16 percent.

17 This is just for final comparison between
18 the two periods. The major difference is where in
19 our conclusion and in none if device contributed to
20 event; the non-conclusion slice, as I said before,
21 has increased from 32.3 percent to almost 60 percent.

22 On none if device contributed to event decreased

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1 from 27 to 15 percent.

2 As I said before, what I presented were
3 the conclusions about the events, and now I am going
4 to present what were the components of the device
5 that failed during those attempts. These are the
6 results of the failure analysis in terms of the
7 component or the factor that failed in the case of an
8 AED failure.

9 Electrical component was the most
10 frequent result reporting with 42 percent. The
11 electrical component included, for example, diodes,
12 relays, circuit boards, switchers, capacitors, et
13 cetera. There are something like 21 components
14 reported in the category of electrical component.

15 Device performed according to
16 specifications was reporting 32 percent. Device
17 operating outside of specifications in 4.4 percent,
18 and mechanical problems in almost two percent.

19 From 2000 to 2003, electrical component
20 was 36.5 percent. Other was 30 percent. Device
21 performed according to specifications, 21 percent.
22 The defibrillator subassembly is a new category here

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1 and includes, for example, pads, cables, et cetera,
2 and the remaining categories add to five percent
3 altogether.

4 Electrical component decreased from 42 to
5 36 percent. Device performed according to
6 specification decreased from 32 to 21.1 percent.

7 We have to keep in mind again that there
8 is an increase in AED's availability.

9 The AED recalls for this period are shown
10 here per year, and as you can see, the recalls per
11 year were between zero in 1998 to six in 2000 and
12 2003.

13 These results suggest that the number of
14 reported deaths associated with AED failure is
15 actually more frequent than injuries. The number of
16 reported AED failure is increasing along with
17 increase in AED reporting or deployment.

18 There is a relative decrease in reported
19 electrical component failure. There is a relative
20 decrease in reported device operating outside the
21 specification, which includes use area, and
22 increasing number of reported deaths over time

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1 associated with AEDs may have several contributing
2 factors, including increased device availability.

3 Thank you for your attention.

4 ACTING CHAIR LASKEY: Thank you very
5 much, folks.

6 Are there any questions for the
7 presenters from the panel, questions, comments?
8 Several. Good.

9 Dr. Maisel.

10 DR. MAISEL: Oscar, just so I want to
11 make sure I understand what you presented, it looked
12 like there were about 7,600 events and about at least
13 in the early portion of your data 25 percent or so
14 were identified as being caused by the device. Does
15 that mean the total number of device related events
16 was 7,600 divided by four or around 1,800 or 1,900
17 that we can conclude were due to the device?

18 DR. TOVAR: No. It's not that you can
19 divide it by four because that's why I presented per
20 year. There is a progressive increase per year. So
21 the devices or the malfunctions reported, including
22 death, are increasing per year. So injuries,

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1 malfunctions, injuries not too much, but malfunctions
2 and death were increasing per year.

3 DR. MAISEL: Right. What I'm trying to
4 get at is you have reported 7,600 events, and I am
5 trying to understand. I understand that many of
6 those events might be reported, but not due to device
7 malfunction.

8 DR. TOVAR: That's correct.

9 DR. MAISEL: And it appeared that about
10 25 percent were due to device malfunction or that was
11 the manufacturer's conclusion.

12 DR. TOVAR: Yeah, if I understand your
13 question well, I said during the presentation that
14 some of the report or some of the malfunctions were
15 caught during the device diagnostics. For example,
16 it was not during the use, not during the use on a
17 patient. It was, as I say, during a daily
18 diagnostics, weekly diagnostics, yearly/monthly
19 diagnostics. But it was not all the malfunctions
20 were -- actually there are not too many during an
21 actual use.

22 ACTING CHAIR LASKEY: Mitch.

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1 DR. KRUCOFF: Thank you both for just
2 sort of giving us the perspective. I wonder if you
3 could help me understand, given the level of illness
4 that patients have in order to deploy this device in
5 all the other vicissitudes of putting an MDR type of
6 data set together, can you help us understand how you
7 would decide or try and understand whether a patient
8 who is fibrillating would or would not have survived
9 if the device had functioned well, i.e., how do you
10 conclude that the device's malfunction is associated
11 with a death event when essentially the sudden death
12 is the presentation?

13 How the device causes a problem versus
14 how it just fails to turn around a problem?

15 DR. TOVAR: Right. I think we both can
16 answer this question, but Beverly is always ready to
17 jump.

18 MS. GALLAURESI: That's kind of the
19 unknown. Sometimes it's very obvious when the device
20 completely fails and doesn't work. I mean obviously
21 the patient is in fibrillation and so then you don't
22 know if the patient could have been resuscitated or

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1 not.

2 I mean, is it answering your question or
3 am I misunderstanding your question?

4 DR. KRUCOFF: Well, somewhere in there
5 you're coming at least in some events it looks like
6 to a conclusion that the device malfunction was
7 somehow --

8 MS. GALLAURESI: May have caused or
9 contributed.

10 DR. KRUCOFF: Right.

11 MS. GALLAURESI: And then it's the
12 manufacturer that evaluates the device and they
13 report their conclusion codes, and then we have to
14 take that information as the manufacturer reports it.
15 We can't really assess.

16 With these reports you can't really have
17 cause and effect. We can tell when a device fails,
18 and then a patient wasn't resuscitated. That's the
19 information that we have. So it's the great unknown.

20 I don't know if perhaps a patient never
21 would have been saved.

22 DR. KRUCOFF: Right. Even if it had

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1 worked --

2 MS. GALLAURESI: Even if it had worked.

3 DR. KRUCOFF: -- would they have been
4 successfully defibrillated.

5 MS. GALLAURESI: Yes.

6 DR. KRUCOFF: That's what I find would be
7 very -- so there are no criteria per se to understand
8 that because I can't imagine what it would be.

9 MS. GALLAURESI: Have to look above.

10 DR. TOVAR: I would like to add to this
11 that, yes, the manufacturer reported a death that was
12 associated with the use of the device. It doesn't
13 matter the situation. However, sometimes it's not
14 related. That's why I brought up an example in the
15 car crash. It looks like the victim was really
16 injured, and it could have had several, multiple
17 causes to lead to the cardiac arrest of this patient.
18 The AED was used, but the patient died. The
19 manufacturer reported this event, but probably the
20 cause of the death was not the ventricular
21 defibrillation or cardiac arrest.

22 DR. KRUCOFF: Oscar, all I was trying to

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1 understand in your two pie charts over seven years,
2 as the device failure caused or was related to event
3 drops from 22.4 percent to 9.6 percent. I guess what
4 I was trying to understand is is that a difference in
5 reporting, a difference in interpretation. Are the
6 devices doing better or just what? How do you
7 interpret that change in percentage over seven years?

8 DR. TOVAR: Right, right. Probably we'll
9 leave it at that unless you have a --

10 DR. KRUCOFF: No, no. Thank you.

11 DR. TOVAR: Okay.

12 DR. SOMBERG: In the device caused the
13 death outcome, do you have any direct data where the
14 device fired and caused fibrillation or is most of
15 the data the example you gave, that the device being
16 placed on the patient did not successfully work by
17 having a save?

18 DR. TOVAR: Yeah, that's a very good
19 question, and that's what I was trying to remember,
20 that I was going to comment on the previous question.

21 These devices when they say directly
22 cause is when they did not fire, when they did not

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1 shock. At least I have seen many of these individual
2 reports; in any single occasion I saw something that
3 the device caused by the shock. It caused death
4 because it didn't fire.

5 DR. SOMBERG: I see, and is it also
6 correct to state that from my understanding the
7 engineering behind these is that there's a default
8 mode and that the device has question of the
9 arrhythmia due to motion, due to other intervening
10 confounders? It goes to default and does not fire as
11 a safety component?

12 DR. TOVAR: Yes. If the device diagnoses
13 a non-shockable rhythm, it won't fire even if the
14 patient has been in cardiac arrest, and if the
15 patient has been during a long time in ventricular
16 defibrillation, for example, it has a great or high
17 probability to grow into a system with --

18 DR. SOMBERG: We're not finding for
19 asystole. We're not -- but if there's motion or
20 other artifact --

21 DR. TOVAR: For those things, that will
22 depend, yes.

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1 DR. SOMBERG: And there's a question. It
2 doesn't fire to say given the benefit of the doubt
3 the algorithm is not to fire. So the device may have
4 actually worked and the vicissitudes were that there
5 was artifact and it could not identify the proper
6 rhythm.

7 DR. TOVAR: Yeah, that's correct.

8 ACTING CHAIR LASKEY: Well, thank you
9 both for this exhaustive effort, and I guess just to
10 quickly sum up, you're doing the best you can with
11 extremely limited data set. I wouldn't say that
12 there's a lack of a reliable denominator. There is
13 no denominator. It's not that it's unreliable.

14 And I think if we wanted to fill in the
15 other three cells in a two-by-two table, we can.
16 You're just giving us one cell.

17 So what can we do with this? I think
18 it's a blip and it's something important to note, but
19 it just underscores the importance of getting
20 accurate statistics if we're going to make use of
21 them.

22 But we certainly appreciate and applaud

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1 your effort, and I guess on behalf of the panel we
2 would just ask the agency to continue to seek out
3 ways to improve the data collection so that we can
4 get more accurate handles on these things.

5 DR. TOVAR: Thank you.

6 ACTING CHAIR LASKEY: Thank you much.

7 We have a busy, busy morning, and I'd
8 like to commence with the open public hearing, and
9 before we proceed with the roster of speakers, I have
10 one brief statement to read, which is that both the
11 Food and Drug Administration and the public believe
12 in a transparent process for information gathering
13 and decision making.

14 To insure such transparency at the open
15 public hearing session of the Advisory Committee
16 meeting, FDA believes that it is important to
17 understand the context of an individual's
18 presentation.

19 Are you timing me on this? Is that
20 the --

21 (Laughter.)

22 ACTING CHAIR LASKEY: For this reason,

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1 FDA encourages you, the open public hearing speaker,
2 at the beginning of your written or oral statement to
3 advise the committee of any financial relationship
4 that you may have with the sponsor, its product and,
5 if know, its direct competitors.

6 For example, this financial information
7 may include the sponsor's payment of your travel,
8 lodging, or other expenses in connection with your
9 attendance at the meeting.

10 Likewise, FDA encourages you at the
11 beginning of your statement to advise the committee
12 if you do not have any such financial relationships.

13 If you choose not to address this issue of financial
14 relationships at the beginning of your statement, it
15 will not preclude you from speaking.

16 With that, I would like to being the open
17 public hearing session this morning. Speakers, as
18 previously forewarned, will be limited to we're now
19 at five minutes for their presentations, and we have
20 the little electronic timer up here just to keep
21 everybody honest. As I say, we have a lengthy
22 schedule.

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1 The first speaker of the morning is Dr.
2 Mickey Eisenberg. Dr. Eisenberg.

3 DR. EISENBERG: Thank you.

4 My name is Mickey Eisenberg. I have
5 studied out of hospital cardiac arrest for almost 30
6 years as a clinician and researcher at the University
7 of Washington. I'm also the Medical Director of the
8 EMS Program for King County, Washington.

9 MS. WOOD: Pull the mic up just a bit,
10 sir. Thank you.

11 DR. EISENBERG: As to financial
12 disclosure, I am here on my own coin. I have receive
13 no salary support or honoraria from defibrillator
14 manufacturers. Two defibrillator companies have
15 contributed to a University of Washington research
16 fund which I have used in the past to support the
17 salary of a research assistant to study out of
18 hospital cardiac arrest.

19 Let me start with a few facts. Eighty
20 percent of cardiac arrests occur in the home.
21 Defibrillation is the only effective therapy for
22 ventricular fibrillation, or VF. VF usually occurs

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1 with little or no warning. Defibrillation, if
2 delivered quickly enough, leads to a very high
3 survival rate. When delivered in two or three
4 minutes from collapse, 75 percent of patients
5 survive. When delivered in ten minutes, survival
6 rate falls to ten percent or less.

7 And I might point out that that's the
8 situation in most communities throughout America.

9 AEDs are effective, safe. Their
10 operation can be readily mastered by lay persons.
11 We've trained several hundred seniors in the use of
12 AEDs using only a ten-minute video.

13 Patients resuscitated from VF generally
14 make good recoveries, and the shorter the time from
15 collapse to defibrillation, the better the
16 neurologics outcome.

17 You will undoubtedly hear in the coming
18 few hours about the efficacy, safety, and labeling of
19 AEDs, and rather than talk about these issues, I
20 would prefer instead to address the issue of
21 dissemination.

22 I believe widespread dissemination of

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1 AEDs, especially in the homes of higher risk
2 patients, offers the means to improve the current
3 grim mortality statistics. The question is how best
4 to achieve this. Do we use the current medical
5 approach or do we use a consumer approach?

6 In the medical approach, which is what we
7 have now, physicians control dissemination. The
8 device is deemed potentially dangerous. Thus,
9 prescriptions are required. Reimbursement by
10 insurance companies may or may not occur. Cost
11 effectiveness studies demanded by insurance companies
12 and HCFA are near impossible to do because of the
13 ever shifting nature of indications for ICDs.

14 Manufacturer costs, sale priced to the
15 patients remain high because of modest distribution
16 and lack of competition. The net effect is limited
17 dissemination in people's homes.

18 Contrast this approach, the medical
19 approach, to the consumer approach. Because the
20 device is considered safe and training is simple,
21 it's my hope that this committee will recommend over-
22 the-counter status. Economies of scale will lower

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1 the cost. Competition will increase, and the net
2 effect will be a lower price.

3 Like any consumer choice, the consumer
4 decides whether there is adequate value for his or
5 her money. I suspect many older adults will consider
6 \$700 for a home AED as good an investment as optional
7 side airbags, carbon monoxide monitors in their home,
8 home security systems, and any other personal safety
9 device.

10 Clearly, this argument is a
11 simplification of a very complex subject.
12 Nevertheless, the existing prescription based medical
13 approach is leading to only a trickle of AEDs in the
14 homes. A consumer approach with over-the-counter
15 status is, I believe, the best means to achieve
16 widespread dissemination in people's homes, and that
17 can only result in more lives saved.

18 Thanks very much.

19 ACTING CHAIR LASKEY: Thank you, sir.

20 The next speaker on our roster is Kelly
21 Harris. Ms. Harris. Is there a Harris in the group?

22 Yes.

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1 MS. HARRIS: Good morning. I'm Kelly
2 Harris. I'm a sudden cardiac arrest survivor.

3 I was flown here by Philips who made the
4 defibrillator that saved me a year a half ago.

5 I don't really have anything prepared,
6 but what I want to do is just put another face to a
7 survivor because I know a lot of people think that -
8 - excuse me. I'm very nervous, too -- I know a lot
9 of people think that sudden cardiac arrest only
10 happens to maybe senior people or someone who is
11 unfit or overweight, and as you can see, I'm quite
12 the opposite of that.

13 This happened to me when I was only 27
14 years old. When I went to Philips about six or seven
15 months ago to meet their team up in Seattle, they
16 offered me my own home defibrillator for free, which
17 I thought was great. It was an amazing offer.

18 And as I got to talk to them I said,
19 "Well, I'm going to be living alone soon. I have my
20 own implantable defibrillator. So I don't really
21 need it for myself, but I want it to go to my family
22 because, you know, whatever condition I may have

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1 might be hereditary, and I would feel much safer to
2 have it around them."

3 And immediately I was told that that
4 might not be possible, and that even for myself to
5 get it, I would need a prescription from my
6 cardiologist, and so that was surprising because I
7 thought, well, I have already had my cardiac arrest.
8 What more proof do you need that I need one?

9 So anyway, we went ahead and contacted my
10 cardiologist, and he said that, first of all, it
11 wasn't his top priority. So right there that was a
12 lag in time for me to get one, but he said, again, he
13 was happy to do it. He would just want to do more
14 research first.

15 So from the time I contacted him to the
16 time my sister and her family got the defibrillator I
17 would say it was about six or seven weeks. And so
18 that's a long time since sudden cardiac arrest is
19 sudden, and it can happen at any time. And in that
20 seven weeks, someone could have died in that time.

21 So anyway, it ended up happening, and
22 they have it. It's around my family, which is all

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1 that I wanted, and I don't know. Basically I'm just
2 here to say that I believe it's like having maybe a
3 fire extinguisher in your house. You don't need one
4 after your house burns down. You pretty much need
5 one before that.

6 The same with this. It's going to be too
7 late when someone has a cardiac arrest. That's not
8 the time to go ahead and prescribe them or their
9 family a defibrillator. It should be three in one
10 who wants one. It can't hurt anybody because it only
11 allows a shock if there's a shockable rhythm. So it
12 reads the heart rhythm.

13 I couldn't put it on anyone conscious or
14 unconscious that doesn't have a chaotic heart rhythm.

15 So regardless if you push the button, it's not going
16 to do anything. It can't hurt anybody. So if that's
17 the concern with liability, that doesn't exist.

18 It also is helpful because it will walk
19 you through the steps of CPR as well, and so it just
20 speaks very clear English. As long as you understand
21 English and can push a button, you'll be fine.

22 And last year I was flown to New York to

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1 do a video news release with Brandy Chastain, who is
2 their spokesperson, and once that was complete, we
3 actually attended a Girls Talker Camp, and Brandy was
4 there to show all of the girls how to use the AED.
5 She went through it one time and then had a young
6 lady do it who was probably about, I'd say, 13 years
7 old run through it, and she did it correctly the
8 first time on the dummy.

9 So it's very easy. It's not just for
10 adults to use or for medical personnel. Children can
11 use it as well.

12 So I guess that's all I have to say, and
13 I just wanted you to know that this can happen to
14 anybody. It could be your child, your sister, niece,
15 nephew, grandchild.

16 So all right. That's it. Thank you.

17 ACTING CHAIR LASKEY: Kelly, thanks for
18 your time. You're becoming an excellent public
19 speaker. It's nice to know our soccer team has great
20 maturity as well.

21 All right. The next speaker is Dr.
22 O'Connor.

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1 DR. O'CONNOR: Good morning. Thank you
2 for permitting us this opportunity to speak.

3 My name is Robert O'Connor. I'm the
4 President-elect of the National Association of EMS
5 Physicians.

6 The association is an organization of EMS
7 medical directors, as well as other pre-hospital care
8 professionals who are committed to excellence in pre-
9 hospital care.

10 Regarding financial disclosures, I'm here
11 on my own funding. In the past I've received
12 indirect research support from AED manufacturers to
13 support the salary of a research assistant.

14 Sudden cardiac death is one of the major
15 public health problems. It has claimed as many as
16 350,000 lives per year. Many sufferers of cardiac
17 arrest can be successfully resuscitated. This
18 requires integration of 911 access, bystander CPR,
19 prompt defibrillation, and pre-hospital advanced life
20 support. It must be integrated. It must be
21 accomplished in a very timely fashion.

22 Since AEDs have been developed, it has

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1 made early defibrillation feasible, first, by EMS
2 responders, fire personnel, then by nontraditional
3 police, security guards, et cetera, and finally by
4 the lay public, as has been recently demonstrated.

5 Access to AEDs must not result in
6 prolonged delays in activation. So we encourage the
7 integration of a 911 response with the use of an AED.

8 Making AEDs available to non-traditional
9 responders or minimally trained bystanders is an
10 effective strategy for achieving early defibrillation
11 in many communities. Regardless of the deployment
12 strategy, we must insure that these AED programs are
13 integrated into the local EMS system and included in
14 their quality assurance programs.

15 Integration of AED programs into these
16 systems is essential to insure the minimal delays
17 take place during resuscitation.

18 So in summary, we would like to speak in
19 favor of the removal of the prescription requirement
20 for AEDs, with the understanding that either through
21 labeling or intrinsic properties of the device
22 itself, that it specify training and CPR as well as

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1 AED operation to anyone who is potentially going to
2 use the device; that the device be located in an
3 immediately recognizable and accessible location,
4 recognizing that if this is in the home, the occupant
5 of the home may be the person who suffers cardiac
6 arrest and there may be a bystander not familiar with
7 where they keep things in the house.

8 And then finally, that the requirement
9 for integration with existing 911 systems, namely,
10 through first and foremost 911 activation, be
11 contained within the device as well.

12 Thank you.

13 ACTING CHAIR LASKEY: Thanks much.

14 I understand there's a different speaker
15 this morning from Cardiac Science other than Kenneth
16 Olson. So can the representative from Cardiac
17 Science -- thank you.

18 MR. McKEAN: Good morning. My name is
19 Matt McKean (phonetic), and I am the Director of
20 Regulatory Affairs for Cardiac Science, speaking on
21 behalf of Cardiac Science and Ken Olson.

22 Of course, as an employee of Cardiac

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1 Science, they paid for my travel and my salary.

2 My comments here today are I didn't know
3 if I was going to be before or after. So I'll adopt
4 this accordingly.

5 Based on the results of the PAD study and
6 the clinical evidence that is now in place to support
7 expanding the deployment of AEDs into the public
8 domain, and since the majority of the SCA events
9 occur in the home, granting easier access to AEDs
10 will put more AEDs in homes and improve the survival
11 rate of SCA victims, as has been discussed thus far.

12 Should the panel recommend over-the-
13 counter for AEDs and FDA adopts this decision,
14 Cardiac Science is calling for FDA to implement a
15 least burdensome approach for all AED manufacturers
16 to use to obtain rapid 510(k) clearance of qualified
17 devices. This least burdensome approach could come
18 in two forms or perhaps others, but two that come to
19 mind are issuing a guidance document within 30 days
20 to stakeholders including industry and FDA reviewers
21 that allows simple modification of labeling to remove
22 the on the order of physician or prescription

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1 requirement language from the IFU as a simple
2 notification submission to FDA.

3 An alternative approach would be for the
4 use of a 30-day special 510(k) vehicle currently in
5 place to modify the labeling and present that to FDA.

6 Also, regarding classification of the
7 device, currently classified as a Class III, FDA
8 should consider down classifying the AED to a Class 2
9 for the following reasons. AEDs are cleared under
10 the 510(k) regulatory framework and do not require
11 PMA application. Clinical studies have been
12 conducted and published to support the safety and
13 efficacy of AEDs when used within labeling.

14 And, second, in the event of AEDs become
15 over-the-counter approved, the integrity of the
16 regulatory classification scheme for Class 3 devices
17 would be compromised or, i.e., contraindicated.

18 So those are my two comments that I'd
19 like to present both to the panel and to FDA.

20 ACTING CHAIR LASKEY: Thank you.

21 Next up is Richard Lazar.

22 MR. LAZAR: Good morning. My name is

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1 Richard Lazar. I'm the CEO of the early
2 defibrillation Law and Policy Center, which should
3 tell you I'm a recovering lawyer.

4 I am here on my own dime and on behalf of
5 EDLPC. I am not here at the request of or on the
6 dime of any of the manufacturers. In the interest of
7 disclosure, I have in the past done consulting work
8 for two of the major manufacturers and occasionally
9 I'm invited to speak at conferences sponsored by
10 manufacturers.

11 I have provided the panel with written
12 submission which goes into some detail in terms of my
13 views of the current prescription model and how it
14 operates in the real world of public access
15 defibrillation, and I won't reiterate those comments
16 here. It does go into the whole issue of supervision
17 under the direction of a practitioner and adequate
18 indications for use.

19 My comments this morning are directed
20 really and admittedly at a high level on the issue of
21 public health policy, and here's what I think we know
22 in that regard.

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1 We know that SCA strikes somewhere
2 between 250,000 and 450,000 people annually in the
3 United States. We know that most of those events
4 occur in public places or the home. We know that the
5 frequency of sudden cardiac arrest in particular
6 venues is unpredictable and perhaps unknowable. We
7 know that most SCA events are caused by ventricular
8 fibrillation.

9 We know that currently the survival rates
10 for sudden cardiac arrest are somewhere on the order
11 of five percent on an annualized basis -- I'm sorry -
12 - on a nationalized basis, and what that means in
13 real terms is somewhere between 240,000 and 430,000
14 people die from this condition, and only about 12,500
15 to 22,500 survive.

16 We know that rapid defibrillation with
17 AEDs is a safe and effective therapy capable of
18 successfully treating VF induced SCA. We know that
19 based on the current design and usability
20 characteristics of AEDs that the devices are being
21 promptly and properly used by both trained and
22 untrained users in a variety of venues. We know

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1 those things.

2 The conclusion that I draw from those
3 facts is that widespread deployment of AEDs us a
4 public health solution that will, indeed save
5 thousands of lives because AED coverage areas in
6 terms of geography is limited, that is, how long it
7 takes someone to retrieve and use the device.

8 We know that really the solution is to
9 have AEDs deployed throughout places of daily life.
10 We know those things to be true. At least I believe
11 them to be true.

12 With regard to the prescription model,
13 which is really the issue before the panel this
14 morning, the prescription requirement currently in
15 place today adds an unnecessary layer to the
16 purchasing process for those that want to buy and
17 deploy AEDs, and it creates a perception that AEDs
18 are difficult to use and are not designed for use by
19 lay people, when in fact the data suggests otherwise.

20 The perceived benefits of the
21 prescription model which we derive from sort of the
22 drug prescription relationship between a physician

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1 and a patient doesn't transfer well to the public
2 access defibrillation environment, and reasons are
3 described in my written submission, but basically a
4 drug prescription model is a one on one relationship
5 whereas an AED prescription model really involves the
6 doctor and three potential persons, the buyer, the
7 user, and the patient with regard to the AED.

8 So the notion of a consultative or
9 instructive interaction between a physician and a
10 patient doesn't occur in the public access model nor,
11 frankly, could it based on how the system works, and
12 the notion of shared information between a physician
13 and a patient about risks and benefits in those sorts
14 of things can't take place.

15 So, again, my judgment the prescription
16 model simply doesn't transfer well to public access
17 defibrillation.

18 Finally, from a public health
19 perspective, the question I pose to myself is what
20 would change if over-the-counter status were granted
21 for AEDs? It would be easier for people and
22 organizations and corporations to buy and deploy

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1 AEDs. It would create a perception in the mind of
2 potential purchasers that AEDs are, in fact, easy to
3 use and intended for use by lay people

4 From a risk standpoint, which is
5 certainly an FDA mandate, would more people die from
6 sudden cardiac arrest? The answer, of course is no.

7 Most people are dying already.

8 Would more people survive who suffer
9 sudden cardiac arrest? And I think the answer from
10 the data we have today is absolutely yes.

11 So unlike drug interactions and issues
12 relating to the taking of drugs, the issue with
13 sudden cardiac arrest is very binary from a public
14 health perspective. People either live or people
15 die, and the only variable that we can impact here
16 is the promptness with which defibrillation occurs,
17 and that means to continue this effort we have
18 already undertaken over the last decade, for the
19 first time in the health care system industry,
20 continuing to put these therapeutic medical devices
21 in the hands of lay people.

22 And by the way, just a final note not

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1 related to anything else, this is a policy change
2 that wouldn't cost the government any money. People
3 who buy and deploy AEDs pay for them themselves.
4 Whether the insurance industry ultimately does will
5 remain to be seen, but by and large this is not a
6 government funded effort.

7 So that's the conclusion of my comments.

8 I'm happy to take any questions the panel might
9 have.

10 ACTING CHAIR LASKEY: Thank you.

11 MR. LAZAR: Thank you.

12 ACTING CHAIR LASKEY: And our last
13 scheduled speaker is Dr. Gordon from the Red Cross.

14 MS. WOOD: Actually Dr. Gordon submitted
15 a statement to be read into the record.

16 This is the American Red Cross position
17 statement regarding over-the-counter automated
18 external defibrillators.

19 "Sudden cardiac arrest can happen any
20 time and anywhere, and it claims the lives of more
21 than 680 Americans each day. The American Red Cross
22 believes that this is a tragedy that can and should

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1 be prevented. We believe the introduction of an
2 over-the-counter AED would be a positive step toward
3 insuring that properly trained citizens are better
4 able to respond to an unexpected cardiac emergency
5 event.

6 "The Red Cross continues to champion
7 community access to defibrillation as part of an
8 ongoing commitment to save more lives. As a
9 supporter of public access to defibrillation since
10 1998, the organizations vision is to have at least
11 one person in every household trained in life saving
12 first aid, CPR, and AED use.

13 "Because the Red Cross reaches over five
14 million people annually with our first aid, CPR, and
15 AED programs, we know that the availability of a
16 properly trained person and an AED is key to
17 providing the best care to a cardiac arrest victim
18 until emergency medical personnel arrive.

19 "The Red Cross currently provides
20 defibrillation information in all CPR courses and
21 encourages the public to make defibrillation a part
22 of their emergency preparedness plans at home, at

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1 school, at work, and at other public places. The
2 inclusion of defibrillation in preparedness plans and
3 greater access to AEDs can enhance preparedness
4 efforts, help reduce the public's vulnerability and
5 enable citizens to respond to cardiac emergencies.

6 "The American Red Cross mission is to
7 help people prevent, prepare for, and respond to
8 emergencies. We believe that removing barriers to
9 public access to AEDs and training more people could
10 result in more of the American public responding to
11 an unexpected cardiac event. If the removal of this
12 barrier results in even a five percent decrease in
13 the number of lives lost each year, this positive
14 step would result in approximately 25,000 lives saved
15 annually.

16 "Please join the American Red Cross in
17 helping citizens save more lives."

18 ACTING CHAIR LASKEY: Thanks Geretta.

19 Is there anyone else who wishes to
20 address the panel today on the topic?

21 If not, then -- yes, sir.

22 MR. POLLEOTHICO: Good morning. My name

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1 is Frank Polleothico (phonetic). I'm a registered
2 nurse. I'm the executive director of the AED
3 Instructor Foundation. We are a 501(c)(3) nonprofit
4 corporation funded manufactured AEDs and also funded
5 by programs that we conduct.

6 I'm here to speak on behalf of the
7 recommendation to remove prescription, and we fully
8 support that. However, I want to emphasize the fact
9 that AEDs, despite all of the wonderful things we've
10 heard this morning, and I fully believe, do not save
11 lives. AED programs save lives, and AEDs that are
12 not instituted, AED programs that are not implemented
13 and are not part of an on-site emergency preparedness
14 plan, that involve training and leadership and
15 guidance and some oversight, not needlessly
16 bureaucratic, but within the context of an on-site
17 program, be it in a home or a small business, are not
18 going to work.

19 There were 15 million people trained in
20 CPR in this country. Yet paramedics and EMTs report
21 that less than five percent of the time that they
22 respond to a cardiac arrest emergency is somebody

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1 doing CPR. We must not just give people AEDs. We
2 must do it in the context of them being prepared to
3 use them.

4 The growing number of horror stories of
5 AEDs being on site and not utilized scares me. I
6 just heard of another one last night. I probably
7 hear about two a week.

8 So clearly AEDs are marvelous. I have
9 personally used them. I've used them successfully,
10 and I've used them where the patient didn't survive,
11 and I know the benefit they provide. In my
12 experience as an emergency nurse and as a paramedic,
13 as the former Director of EMS for the City of New
14 York, I can only speak to the missing link that AEDs
15 help to fill in the wonderful system of emergency
16 medical services that has been developed in this
17 country in the last 30 years.

18 But AEDs must be operated in context, and
19 while I think the prescription does nothing to help
20 that, and as I agree with all of the speakers so far,
21 I won't even reiterate that; the prescription does
22 nothing to help the AED program issue.

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1 However, guidance and control,
2 involvement directly from the EMS system is essential
3 or AEDs will not fulfill the promise of reducing the
4 tens of thousands of needless premature deaths that
5 occur in this country every year.

6 I thank you.

7 ACTING CHAIR LASKEY: Thank you.

8 All right. Last call. Does anybody else
9 wish to come forth this morning?

10 If not, then I will close the open public
11 hearing portion and would like to proceed with the
12 sponsor's presentation, and if I could just have
13 Geretta.

14 MS. WOOD: I would just like to remind
15 the speakers to introduce yourself and state your
16 relationship to the company and any other conflict of
17 interest you might have.

18 MR. MORGAN: Can we have about 60 seconds
19 to set up a demonstration?

20 MS. WOOD: Sure.

21 MR. MORGAN: All right. Good morning.
22 I'm Carl Morgan, one of the founders of HeartScreen,

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1 which is now a part of Philips Medical Systems. I'm
2 an employee of that organization.

3 As you've heard, we are here today
4 because we propose to remove the prescription
5 requirement for the Philips HeartStart home
6 defibrillator. The prescription requirement reads as
7 follows on our device: "caution. Federal law
8 restricts this device to sale by or on the order of a
9 physician."

10 Our organization was formed 12 years ago
11 to prevent hundreds of thousands of unnecessary
12 deaths due to sudden cardiac arrest. We believe that
13 our focus during that entire 12 years has been
14 towards providing small, easy to use, automatic
15 external defibrillators specifically designed for
16 people that do not have defibrillation in their job
17 description, that is, AEDs that can be used by
18 virtually anyone to help save a life in a moment of
19 need.

20 A lot has gone on in this 12 years, but I
21 think of note this morning is that for the last five
22 years our organization has been in discussion with

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1 FDA on removing the prescription requirement from
2 defibrillators.

3 In November 2002, we launched the
4 HeartStart Home Defibrillator, which we believe is an
5 idea design for prescription removal. We filed our
6 510(k) in 2004, and we're here today to present.

7 During our discussions with FDA, we found
8 that the law requires that medical device labeling
9 must bear adequate directions for use. FDA
10 regulations further define that to mean directions
11 under which the layman can use a device safely and
12 for the purposes for which it's intended.

13 In addition, certain devices, including
14 historic defibrillators, must bear this prescription
15 caution, and this comes under the conditions if a
16 device is not safe, except under the supervision of a
17 practitioner licensed by law to direct the use of
18 such a device, and because of that perceived lack of
19 safety, adequate directions for use cannot be
20 prepared.

21 This description suggests a basis for
22 removing the prescription requirement for the

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1 HeartStart Home Defibrillator. That is, today we
2 hope to demonstrate for you that the technology has
3 an established history of safe use.

4 Further, we hope to demonstrate for you
5 that the Heart Start Home Defibrillator can be used
6 safely and for its intended purpose based upon its
7 labeling alone.

8 Your presenters today include David
9 Snyder, our Director of Research at Philips Medical
10 Systems in Seattle; Dr. Lance Becker, a noted
11 resuscitation researcher, Professor of Medicine and
12 Director of the Emergency Resuscitation Center at the
13 University of Chicago.

14 Dr. Becker will present the results of
15 some of our studies and provide some perspective on
16 the need for early defibrillation.

17 Dr. Jeremy Ruskin, a noted researcher in
18 the management of cardiac arrhythmias. Dr. Ruskin is
19 the founder and Director of the Cardiac Arrhythmia
20 Service and Clinical Electrophysiology Laboratory at
21 Massachusetts General Hospital. Dr. Ruskin will
22 provide today some clinical perspective on the

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1 management of sudden death by providing early
2 defibrillation capability.

3 I'd now like to introduce David Snyder,
4 our Director of Research at Philips Medical Systems
5 in Seattle.

6 DR. SNYDER: Thank you, Mr. Morgan.

7 Good morning, members of the panel, Food
8 and Drug Administration, the public. It is, indeed,
9 a pleasure to be speaking to you today.

10 I will be speaking to you twice. First
11 I'll be introducing you to the product, and then
12 later I'll be standing before the podium to present
13 some study results to you.

14 With that I'd like to proceed to an
15 introduction to the product. As you've seen a
16 picture, this is the Philips HeartStart Home
17 Defibrillator. It did receive clearance from the
18 Food and Drug Administration in November of 2002
19 specifically for use in the home by lay responders.

20 The indications for use of this product
21 are for application to an unresponsive or not
22 breathing victim or not breathing normally victim,

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1 and I want to draw particular attention to the second
2 indication, which is "if in doubt, apply pads."
3 These indications were designed to prevent the
4 necessity for adequate assessment skills on the part
5 of the responder in case of a sudden cardiac arrest.

6 It is not essential for proper use of this product
7 for a person to be able to properly assess whether a
8 patient is in cardiac arrest. Again, if in doubt,
9 apply the device.

10 The safety and effectiveness of the
11 technologies employed in this product have been
12 established over a long history of AED products, and
13 I'll give you some more background on that in a few
14 minutes.

15 But at this point, I would like to do a
16 demonstration for you. The operation of the device
17 is very simple. Activate it by pulling the handle.
18 Place the pads per voice instructions, and press the
19 shock button.

20 I do want to say you just got an
21 inadvertent demonstration of one of the product's
22 features. The beeping was because we have practice

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1 pads installed in this device. After a certain
2 amount of time with practice pads, which cannot
3 deliver therapy, the device will start alerting you
4 telling you that it's not ready for use. So it was
5 not happy being not ready for use.

6 Okay. This is the HeartStart Home
7 Defibrillator in its case. The first thing I want to
8 draw your attention to is it does have a first aid
9 reminder to activate EMS. We recognize that rapid
10 defibrillation is only one element in the important
11 chain of survival in order to assure survival from
12 sudden cardiac arrest. So "call 911" is right on the
13 front.

14 We also recommend placement in a visible
15 place adjacent to a telephone so that can be done
16 properly.

17 There's also a place as you put the
18 device in service to add your own address
19 information. One of the comments that was made this
20 morning is correct. If you have an arrest in your
21 home, it may not be one of the family members that is
22 called upon to respond to the emergency and use the

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1 device. It may be a visitor to your home, and they
2 not even know your address. So that information is
3 right on the front with the EMS reminder card.

4 When you open the device, you're
5 presented with a pair of scissors for cutting away
6 clothing, a quick reference card that can be used,
7 and the device itself. What I'm going to do now is
8 walk through a mock cardiac arrest scenario with our
9 manikin here so that you can understand and see how
10 the voice prompts interact with the user.

11 So you begin, and again, these are
12 practice pads. It's a safe device. It can't deliver
13 therapy. You begin by activating the device.

14 (The following is a transcript of the
15 recording played by the defibrillator while being
16 demonstrated.)

17 DEFIBRILLATOR: Begin by removing all
18 clothing from the patient's chest. Cut clothing if
19 needed. When patient's chest is there, remove
20 protective cover and take out white adhesive pads.
21 Look carefully at the pictures on the white adhesive
22 pads. Peel one pad from the yellow plastic liner.

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1 Place pad exactly as shown in the picture. Press
2 firmly to patient's bare skin.

3 When the first pad is in place, look
4 carefully at the picture on the second pad. Peel the
5 second pad from the yellow plastic line. Place pad
6 exactly as shown in the picture. Press firmly to --
7 no one should touch the patient.

8 Analyzing.

9 No one should touch the patient.

10 Analyzing.

11 Shock advised. Stay clear of patient.

12 Press the flashing orange button now. Shock
13 delivered. No one should touch the patient.

14 Analyzing.

15 Shock not advised. Be sure emergency
16 medical services have been called. It is safe to
17 touch the patient. Check airway. Check breathing.
18 Check circulation. If needed, begin CPR. For help
19 with CPR, press the flashing blue button.

20 Pinch nose, tilt head, and give two full
21 breaths. Breathe. Breathe. Place the heel of one
22 hand in the center of the chest between the nipples.

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1 Place your other hand on top of the first. Push the
2 chest down firmly two inches. Keep time with the
3 beat.

4 Pinch nose, tilt head, and give to full
5 breaths. Breathe. Breathe. Continue with
6 compressions.

7 Pinch nose, tilt head --

8 (End of defibrillator audio
9 demonstration.)

10 DR. SNYDER: And that's really all there
11 is to it.

12 I would like to draw your attention to a
13 few aspects of the scenario you just saw. First is
14 that there was a second level of EMS reminder. The
15 first level again is labeling right on the exterior
16 of the device to activate EMS. Should for any reason
17 that not happen, there is a second vocal reminder
18 after first shocks are delivered. Make sure
19 emergency medical services have been activated.

20 The second thing I want to mention is
21 that once you complete your initial sequence of CPR,
22 you are instructed to stop CPR, at which time a

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1 reanalysis of the heart is performed. If shocks are
2 indicated, you're given the same guidance on
3 delivering shocks. If not, you proceed directly to
4 the opportunity to get CPR coaching again. If you're
5 firm in your CPR skills, you can elect not to get the
6 voice prompts and just proceed without the prompts.

7 These CPR prompts are intended to
8 reinforce. They're not intended to teach CPR. We
9 found that was impractical to do, but we also found
10 that even people who have had regular CPR training
11 don't remember the protocols well. They don't
12 remember placement of hands. They don't remember
13 depth of compression. They don't remember how many
14 compressions, how many ventilations. So the voice
15 coaching is really designed to reinforce those
16 skills.

17 Another thing you may have noticed was
18 the pacing of the prompts was very methodical. It
19 was not rapid. We also found in user testing, which
20 we'll be talking a little bit later about, that if
21 you got ahead of certain responders, not everybody
22 responds at the same rate, but if you got ahead of

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1 people and issued instruction before they had
2 completed the previous task, they tended to
3 completely fail. That is, if we went too fast, we
4 could get a little bit faster for shock, but a
5 certain percentage of people couldn't do it at all.
6 So the pacing is very methodical to insure that the
7 vast majority of people are able to complete these
8 tasks successfully.

9 Now, should you be secure in your skills,
10 you know what you're doing. You move quickly. The
11 prompts will actually catch up with you. The device
12 will detect where you are and the stage of applying
13 these pads and delivering a shock and jump forward to
14 catch up with you.

15 And I want to give you another
16 demonstration right now so that you can see how that
17 works. What I'd like you to pay attention to this
18 time, you heard a lot of very detailed prompts. Now,
19 this time we're going to go much more quickly, and
20 you'll see that all of those detailed prompts do not
21 appear in this scenario because I'm completing tasks.

22 I'm also going to apply the device to

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1 myself. This is now a live defibrillator, and if it
2 detects V up (phonetic), it will deliver a shock.
3 I'm doing this to demonstrate my confidence in the
4 specificity of this product, and I'm going to apply
5 it, lead two. It's not a good defibrillation vector,
6 but it is a representative vector for the ECG that's
7 observed by a defibrillator

8 DEFIBRILLATOR: Begin by removing all
9 clothing from the patient's chest. Cut the -- place
10 pad exactly as shown in the picture. Press pads
11 firmly to patient's bare skin. No one should touch
12 the patient.

13 DR. SNYDER: Okay. I can press this
14 button as many times --

15 DEFIBRILLATOR: Analyzing.

16 DR. SNYDER: -- as I want. It's not
17 going to deliver a shock.

18 DEFIBRILLATOR: No one should touch the
19 patient

20 Shock not advised.

21 DR. SNYDER: I'll press the button again.
22 No shocks.

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1 DEFIBRILLATOR: -- emergency medical
2 services --

3 DR. SNYDER: It simply will not do it.

4 DEFIBRILLATOR: -- have been called. It
5 is safe to touch the patient.

6 DR. SNYDER: So that's a quick run-
7 through of how the product works. You can see that
8 for people not secure in their skills it gives them
9 very detailed instructions. I'll talk about how we
10 derived those instructions a little bit later in the
11 presentation.

12 If you're secure in your skills from your
13 AED training, you can proceed very rapidly.

14 So with that introduction, I'd like to
15 now mention a concept which one of the introductory
16 speakers this morning actually talked about, and that
17 is the notion of a defibrillator as a piece of safety
18 equipment as opposed to a piece of medical equipment
19 prescribed for a particular patient at risk. And
20 this product was specifically designed as a piece of
21 safety equipment.

22 In fact, the labeling in our pre-sales

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1 materials on the outside of the retail box and in the
2 owner's manual contains the statement in the first
3 bullet, which is: "if you have concerns about your
4 health or an existing medical condition, talk to your
5 doctor. A defibrillator is not a replacement for
6 seeking medical care."

7 Again, this device is designed as safety
8 equipment. It's to address this problem of the large
9 cohort of patients for whom symptoms have simply not
10 presented, and they are not a part of the medical
11 system at elevated risk for sudden cardiac arrest.

12 This is a product designed because we
13 don't know who might need it or when. It's equipment
14 that's intended to be used perhaps once in a
15 lifetime. Best case is it will never be used, but
16 perhaps once or twice in a lifetime, and because of
17 this use model, we have identified some
18 characteristics that are important to this kind of
19 product.

20 First of all, it must be safe for any
21 user. The second is it absolutely has to be ready to
22 use when needed. Mostly it's going to sit on a shelf

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1 and gather dust, but the device has to be able to
2 assure its readiness when the emergency occurs.

3 And finally, it has to be very easy to
4 use in the moment. We're not talking about EMTs that
5 do this several times a year. These are people,
6 again, who may do this once in a lifetime.

7 Now, we're going to be presenting you
8 some data on the reliability and safety history of
9 these products, a point I need to establish right at
10 the beginning, is that the HeartStart Home
11 Defibrillator, which is shown in the upper right of
12 this slide, has core technologies that are actually
13 common to all of the defibrillators that Philips
14 Medical Systems has produced.

15 The ForeRunner defibrillator was
16 introduced in 1996. That was followed by the FR-2 in
17 2000, and the HeartStart Home Defibrillator in 2002.

18 The ECG analysis system you just saw
19 demonstrated is common to all of these. There has
20 been no change in what we call the life threatening
21 arrhythmia detector across this base. So any results
22 derived from uses of the earlier devices are also

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1 applicable to the HeartStart Home.

2 You also heard mention in Dr. Tovar's
3 presentation -- I think it was actually the Q&A --
4 about ECG validity measures, the ability to detect
5 artifact within the ECG. That is, signals that are
6 introduced mechanically or electrically that are not
7 of cardiac origin, and this is a key aspect of safety
8 in these products. It's essential that the device
9 understand whether it's truly analyzing cardiac
10 signal or artifacts, and we do have an ECG validity
11 system that, again, is common across all three of
12 these products and has been very effective, and with
13 the advent of the HeartStart Home, we have actually
14 reinforced this capability with a second way to
15 determine whether artifact is present.

16 Now, this is not a feature that's common
17 to all defibrillators. Some have similar
18 capabilities and some have no capability in this
19 regard.

20 The therapy that's delivered by this
21 device is a 150 Joule impedance compensating biphasic
22 waveform. Again, it's common across the entire

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1 product line.

2 For the FR-2, we introduced pediatric
3 attenuation capability or pediatric treatment
4 capability, the ability to deliver 50 Joules for a
5 pediatric patient, and this technology has also been
6 taken forward to the HeartStart Home Defibrillator.

7 And finally, key pieces of the user
8 interface, the core interface, that is, pieces that
9 measure things like pad connection, adequacy of pad
10 connection, various pieces of safety prompting and
11 the general protocol management technologies are
12 common across all three of these products.

13 Now, there is a distinct difference
14 between the earlier products and the HeartStart Home
15 in that the earlier products in the bottom left hand
16 of the slide had ECG displays as well as manual
17 override capability should a trained medical
18 professional have a disagreement with the advisory
19 system.

20 These were deemed inappropriate for a lay
21 market because of no training in ECG interpretation,
22 and they were removed specifically because of the lay

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1 use model, and that feature has actually been
2 replaced by enhanced prompting on proper pads
3 placement which I also demonstrated for you. This
4 was an area that we found that lay responders had a
5 great deal of difficulty with.

6 And we have also added the CPR coaching,
7 again, to reinforce skills that have already been
8 obtained.

9 So the sensitivity and specificity of the
10 ECG analysis system is due to a fairly sophisticated
11 design. We actually take multiple looks at the ECG.
12 the first is rapidity of the signal conduction.
13 It's really a mathematical measure of the electrical
14 health of the myocardium. We also look at the
15 amplitude of the ECG; a measure that we call
16 stability, which is the repeatability of the
17 morphology of the ECG complexes.

18 Normal sinus rhythms and organized
19 rhythms are highly repeatable. VF is very
20 unrepeatable, and it's a strong predictor. We also
21 look at heart rate. Now, the important point of this
22 slide is that no single one of these indicators is

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1 capable of making the machine advise a shock. It
2 actually takes the concurrence of all four of these
3 measures before the machine will advise a shock.

4 I'd like to demonstrate the sensitivity
5 and specificity of this algorithm by presenting a few
6 studies that have been published. The first bullet
7 was the post market study that Philips undertook with
8 the introduction of the biphasic wave form into the
9 marketplace. This was done with our first
10 generation, AED, the ForeRunner, and we reported on
11 the first 100 consecutive applications to VF
12 patients. This involved a total cohort of 286 out of
13 hospital patients. That is, 186 were in nontreatable
14 rhythms.

15 And in this study, the authors reported
16 100 percent sensitivity to treatable rhythms and 100
17 percent specificity to rhythms that should not
18 receive a shock.

19 The second study I would like to draw
20 your attention to was published by American Airlines
21 in the New England Journal of Medicine. They
22 reported on, again, our first generation AED, the

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1 ForeRunner, which they had equipped their airplane
2 fleet with and flight attendants to use. They
3 reported on the first 200 consecutive uses of this
4 product, 15 VF patients in all. These were
5 applications both in flight and in terminal. In some
6 cases the device was retrieved from the airplane to
7 treat a sudden cardiac arrest in terminal.

8 In particular, I want to draw your
9 attention to the specificity number here. Again,
10 it's 100 percent specificity to these 185
11 applications in untreatable rhythms, 100 percent
12 sensitivity to the VF patients.

13 This device was often used as a cardiac
14 monitor in flight. If there was a physician in
15 attendance that wanted to look at the cardiac rhythm,
16 the airline did apply the device as a monitor so that
17 the physician could watch the ECG screen.

18 Now, the authors didn't specifically
19 report on the amount of time spent in doing cardiac
20 monitoring, but our shock advisory system, our
21 arrhythmia detector, is active throughout monitoring.

22 That is, we are continuously looking. So by a very

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1 conservative estimate we're guessing that at least
2 tens of thousands of analyses were performed on these
3 patients in nonlethal arrhythmias without a single
4 false positive advisory.

5 Now, I do want to tell you that we know
6 of one inappropriate shock that has been delivered by
7 these devices. It was a case of successful
8 defibrillation. The patient presented in a course
9 VF. It was recognized. The device was charged. VF
10 was terminated, and the resulting rhythm following
11 shock was actually low amplitude atrial fibrillation
12 with no ventricular activity. It was truly
13 indistinguishable from ECG alone from a very fine VF.

14 The device did analyze that, recommend and deliver a
15 shock based on this atrial fibrillation with no
16 ventricular activity, but there was no negative
17 outcome. The patient survived neurologically intact.

18 Now, I want to present you with some use
19 estimates, and I'm going to put a big caveat on this.

20 In fact, I'm going to jump to the bottom bullet
21 first. These projections are based on a non-random
22 sampling based on ForeRunner and some FR-2 AEDs. As

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1 devices are returned to us for service, they have an
2 internal memory that we're able to examine to see how
3 many times the device has been used, how many shocks
4 have been delivered, and so forth, and from these we
5 have been able to extrapolate out to our installed
6 base of over 150,000 AEDs since 1996, and actually
7 this is over 170,000 today.

8 And what the data tells us is that
9 probably greater than one million total applications
10 to patients have been performed with this line of
11 defibrillators, and of those, approximately 200,000
12 patients required shocks, and approximately 800,000
13 patients did not require shocks.

14 So when you consider that one
15 inappropriate known shock, it has to be considered in
16 the context of approximately a million patient
17 applications.

18 I also want to report that we have seen
19 six confirmed AED emergency use failures across this
20 installed basis and over a million applications.
21 Four of those had no patient impact. One, the
22 patient impact was indeterminate, and in one case

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1 there was possible patient impact. This was actually
2 an event that occurred subsequent to our filing in
3 the 510(k) for this product, and it has been filed as
4 an MDR.

5 During all of this experience since 1996,
6 we have had no complaints about the effectiveness of
7 the biphasic therapy.

8 Now, you heard a lot about MDRs, medical
9 device reports, this morning. So we have summarized
10 the top three causes of MDRs from this line of
11 products, and I want to reinforce the fact that in
12 spite of the large number, 7,000 MDRs, over 7,000
13 MDRs, over the time period that these products have
14 been on the market, Forst & Sullivan 2003 estimated
15 that Philips Medical Systems has about in excess of
16 40 percent of the U.S. AED market, and in spite of
17 that 40 percent market share, we are responsible for
18 fewer than one percent of the filed MDRs during that
19 period.

20 This is a summary of our first top three
21 causes of MDRs. The first is a failure of the voice
22 prompting system due to a speaker failure. Basically

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1 one of the wires to the speaker can break, in which
2 the device does not present voice prompts.

3 There was no patient involvement in any
4 of these cases, and we filed 35 MDRs on this
5 particular failure.

6 The next most frequent cause has been
7 poor patient pads connection. We have filed 11 MDRs
8 on this subject. Patient impact in these cases has
9 been indeterminate, and we suspect pads damaged as
10 the root cause of this problem, although we've been
11 unable to confirm because pads are one of the first
12 things that's discarded after execution of a code,
13 and we have been unsuccessful by and large at
14 retrieving these pads following failure.

15 But, again, you must put the 11 failures
16 in the context of an estimated one million patient
17 applications.

18 And the third most frequent cause of MDRs
19 has to do with algorithm sensitivity. Patient impact
20 in this case was indeterminate. These were basically
21 very long down time, low amplitude, low rate VF,
22 right on the borderline of being classified as an

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1 asystole. So patient impact is truly indeterminate
2 in this case. The ECGs simply did not meet the rate
3 criteria of our algorithm. It was not a product
4 malfunction

5 Now, this slide illustrates steps we have
6 taken in the HeartStart Home Defibrillator, which you
7 are considering today. We use our MDRs as a learning
8 experience, ways to improve our products and to
9 address issues that we see through the MDR reporting
10 system.

11 So I've taken these same three top issues
12 from the ForeRunner in FR-2 experience and show you
13 the actions that we have taken in the design of the
14 HeartStart Home Defibrillator.

15 The first problem is no voice prompts.
16 Now, that's mitigated in the ForeRunner and the FR-2
17 because there are instructions written on a screen.
18 Because there is no screen here, we have been able to
19 develop a speaker self-test. So as part of the self-
20 test, which you heard a little bit about this
21 morning; you'll hear more in the remainder of the
22 presentation, once a week we turn the device on, and

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1 it's able to determine whether the speaker is
2 functional or not.

3 With regard to the second issue, the poor
4 patient pads connection, sometimes this is due to
5 skin condition of the patient, but it may also be
6 attributable to pads. So in the HeartStart Home
7 Defibrillator, we've enclosed the pads in a rigid
8 plastic container, but more importantly, we now have
9 a pad self-test. Every 24 hours the device powers
10 on. It checks for electrical continuity and presence
11 of the pads, but it is also able to do an electrical
12 determination of the condition of the electrogel, the
13 adhesive aspect of the pads, to determine if any
14 drying has happened.

15 And if the pads get to a state, before
16 they get to a state actually, where they wouldn't be
17 usable for defibrillation, we can alert the owner of
18 the product that the pads are drying out. They need
19 to be replaced. They call customer service and get
20 information on how to replace the cartridge.

21 I want to move on now to reliability. We
22 have made a great effort to improve the reliability

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1 of these products because basic design and
2 fundamental product reliability is really essential
3 to safe use and lack of failures, and for context,
4 we've presented data on first year, all causes
5 failure rates for three different products.

6 The first is code master manual
7 defibrillator, which those of you in EMS and
8 hospitals may be familiar with. It was introduced in
9 1991, and during the first year of service of that
10 product we experienced a seven percent all causes
11 failure rate.

12 Now, these aren't emergency use failures.
13 These are failures from all causes.

14 With the introduction of the ForeRunner
15 AED in 1996, we were able to improve that first year
16 all causes failure rate by nearly an order of
17 magnitude to 1.3 percent of devices shipped, and with
18 the advent of the HS-1 -- and I want to mention what
19 the HS-1 is for just a moment -- we're considering
20 the HeartStart Home Defibrillator.

21 It also has a sister product which is
22 identical. AED is the same product, but the labeling

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1 and accessories provided with it are really adapted
2 to a commercial market to a corporate market.

3 So from a standpoint of the use of the
4 product, reliability of the product, the functioning
5 of the product, they're identical. So for some of
6 this data, we've put statistics from both of these
7 products together and they're identified as the HS-1.

8 So over that entire installed base, the
9 first year annualized failure rate of the HS-1 class
10 of products was again reduced by an order of
11 magnitude to .04 percent all causes failure. That's
12 one failure out of 2,500 devices shipped in the first
13 year.

14 I want to go into some more detail now
15 about the self-test. This is a diagram that shows
16 you the testing that we do. It's done on daily,
17 weekly, and monthly basis.

18 On a daily basis we power up the device.
19 It checks for the readiness and condition of the
20 pads to make sure the electrogel is suitable for use.
21 It also checks the functioning of the two computers
22 that are included in the device. It checks all of

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1 the circuitry, references. You no longer have to
2 calibrate this device. It has internal references,
3 and it checks for functionality of the therapy
4 circuitry.

5 On a weekly basis we do all of those
6 tests. Plus we add a full calibration of the ECG
7 front end and a test of the audio system to make sure
8 that the speaker is functional.

9 On a monthly basis, again, we do all of
10 those. Plus we add a full high voltage charge of the
11 defibrillator capacitor and discharge of 150 Joules
12 into an internal load that's contained in the device.
13 You do not have to attach an external load.

14 So on a monthly basis, absolutely
15 everything in this box is tested, and we have a very
16 comprehensive test that's performed on a daily basis.

17 Now, I mentioned our design process of
18 learning from simulated use, and up here I've
19 identified some problems. The way we do this is we
20 take our best cut at what's a good product. What's
21 going to interact well with the user?

22 And then we go out and we seek

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1 volunteers, and we have primarily sought untrained
2 volunteers in environments such as shopping malls and
3 senior citizens centers. And we'll provide them with
4 this product and a manikin and ask them if they could
5 try to save the manikin, and we watch how they
6 interact with the device. We see where people
7 succeed well. We see where they have difficulties,
8 and where they have difficulties, we take the device
9 design back. We come up with new ideas. We
10 implement them. Then we go back out and we do it
11 over again, and we continue with this iterative
12 process until we've satisfied ourselves that all of
13 the common issues are addressed.

14 Five of them are listed here. I'm only
15 going to discuss two of them because they're of key
16 importance. The first is that lay responders don't
17 understand electricity or defibrillation, and a lot
18 of the examples they see on television are not very
19 appropriate for actual use. And we found that if
20 people aren't given explicit instructions, they will
21 do things that are really nonsensical from a
22 defibrillation standpoint.

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1 A common mistake is to put pads on top of
2 clothing. As you saw in the demonstration, what
3 we've done is two things. We've added emergency
4 scissors, and we've added an explicit voice
5 instruction to begin by removing all clothing from
6 the patient's chest, cut clothing if needed.

7 Now, the scissors and the cut clothing as
8 needed is another cue that time is of the essence
9 here. You don't have to unbutton the shirt.
10 Destroying clothing is fine. We give you permission
11 to do it, and we give you the tool to do it with.

12 The second problem we identified that I
13 want to highlight is poor pad positioning. There's a
14 lot of research being published even today. There
15 were two more just this month published.

16 On the problem of properly positioning
17 the defibrillation pads not only among lay users, but
18 among medical professionals, it's a very challenging
19 things for people that don't understand what needs to
20 be done.

21 Because of that, we've added explicit
22 graphics on the pad. You saw those when I was

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1 holding the pads up. They show proper placement.
2 But we also found beyond that, to get people to pay
3 attention to the graphics, we had to add a voice
4 prompt that said look carefully at the picture and
5 place it exactly as shown.

6 By taking these kind of steps, we've been
7 able to achieve a very high success rate in the
8 ability of lay responders to apply this product to a
9 patient and successfully deliver defibrillation
10 shock, and you'll see some study data on that in just
11 a few minutes.

12 Just a little bit more about the product
13 that's being considered. Most of what you're going
14 to see and hear about today is the device itself,
15 what you saw on the table, what you saw me holding
16 and demonstrating. There's actually much more to the
17 total product than just that box.

18 In particular, I want to draw attention
19 to the purchase aspect of the ownership life cycle
20 for this product. We have specific information on
21 the problem of sudden cardiac arrest, what a
22 defibrillator does, et cetera, et cetera. It's

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1 contained in the product packaging itself. It's also
2 available in pre-sales materials.

3 We maintain a product Web site that also
4 has resources and links to resuscitation
5 organizations and frequently asked questions.

6 We also have the customer service
7 available that can provide product information,
8 training resources, and in particular, if you
9 purchase the product we offer grief counseling
10 following use, and we also offer throughout this life
11 cycle access to physicians should you have a question
12 you would like to address to a physician.

13 Another aspect of the product that may
14 not be obvious has to do with set-up and maintenance,
15 and that is there are voice prompts in this device
16 that were not demonstrated that help you actually set
17 the device up. When you install the battery, it
18 tells you it's not ready for use. Install the pads
19 cartridge. If you remove the cartridge, it will tell
20 you to reinsert it. It wants to be ready for use,
21 and it's very unhappy if it's not ready for use, and
22 it will start giving you instructions and warnings to

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1 make sure that it is ready for use.

2 This also is important in case of any
3 failure that may be detected by the self-test.
4 Again, the device will start chirping, and that blue
5 information button that I used for CPR information
6 will start flashing. If you press the button, it
7 will give you information on what needs to be
8 corrected. You can contact Philips customer service
9 and get help in correcting the issue.

10 So that wraps up my introduction to the
11 HeartStart Home Defibrillator. Again, it was
12 designed specifically as safety equipment, really a
13 paradigm shift in the way we're using these products.

14 The technology is using the device that
15 has a history of safety and readiness, and it was
16 specifically designed for ease of use in the hands of
17 the lay responder.

18 With that I'd like to introduce Dr. Lance
19 Becker, Professor of Medicine, University of Chicago.

20 DR. BECKER: Thank you very much.

21 My name is Lance Becker. I'd like to
22 thank the panel and the public for coming. This is

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1 quite a honor to be here.

2 I'd like to disclose that I'm a paid
3 consultant to Philips this morning. In addition, I
4 have no equity or stock in that company nor any of
5 the other manufacturers.

6 I have been a consultant to several of
7 the other defibrillator manufacturers over the years.

8 I have intellectual property, some patents in
9 resuscitation that involve cooling induction, and I
10 compete for grants for the University of Chicago.

11 In my real life, I'm an emergency
12 medicine doctor on the South Side of Chicago, and I
13 have studied cardiac resuscitation for many years.
14 It's my pleasure to do a clinical overview of the
15 problem of cardiac arrest and our therapies, although
16 had I known that Dr. Eisenberg was going to be here
17 beforehand, since he's the world's expert on that, he
18 could have probably done it for me.

19 I will then go over some of our safety
20 and usability data in our simulated study.

21 In the United States, we have about two
22 million people a year that die. Those are the number

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1 of deaths each year in our country, and most experts
2 estimate that about half of those deaths, about a
3 million deaths a year occur from some form of
4 cardiovascular disease.

5 You've heard a lot of different numbers
6 on how many sudden cardiac arrests there are, and
7 most experts agree that it's somewhere in the
8 vicinity of a quarter of a million deaths per year
9 from cardiac arrest.

10 Now, while there's some dispute on what
11 the actual numbers are, no one disputes that this is
12 not a major public health concern, and I think none
13 of us in the room would have to go too far before we
14 could think of an individual who we know who has died
15 from sudden cardiac arrest.

16 Now, I want to make two points about the
17 epidemiology of this disease. The first is that
18 because 80 percent of these occur in the home and 50
19 percent of these are witnessed in the home, the point
20 I want to make is we do not right now have a national
21 idea, a strategy for how to deal with home cardiac
22 arrest, other than call for the EMS system, and we

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1 know that the survival rate in the home is far worse
2 than the survival rate in public places.

3 So lacking a home strategy, I just want
4 to suggest how important the potential of a home
5 device may actually be.

6 The second point that I want to make is
7 that according to the American Heart Association and
8 many other investigators, the majority of victims of
9 sudden cardiac arrest have no prior symptoms. That
10 is to say they are not high risk patients who have
11 been identified as having had a mild myocardial infarction
12 or anything.

13 They are individuals who are first
14 getting their wake-up call to cardiac disease when
15 they suddenly collapse and die. And it's for this
16 reason and for that segment of our population that
17 the notion of moving from a prescription to a public
18 access to public availability is so important.

19 Now, a few words about how we treat
20 cardiac arrest. This is from the American Heart
21 Association, and it says that the way that we try to
22 save victims of cardiac arrest is that we want them

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1 to receive early access, early CPR, early
2 defibrillation, and then early advanced care.

3 And note that the American Heart
4 Association suggests a goal of receiving
5 defibrillation in less than five minutes, and I'd
6 like to spend just a few more minutes on why time is
7 so very critical during cardiac arrest.

8 You can see here in the shaded area the
9 mortality curve that we see with each passing minute
10 of cardiac arrest, and you can see on this axis is
11 the probability of survival. Minutes go across the
12 bottom, and with each passing moment somewhere
13 between seven, ten percent of the potential
14 individuals who could be rescued are lost.

15 If we just start to think, well, how long
16 does it take to defibrillate someone, we learn some
17 very important information. We know that in most
18 arrests, it takes somewhere around four minutes
19 before the collapse is recognized and EMS is called
20 and an ambulance is dispatched.

21 Well, time unfortunately does not stop
22 for that. It then takes a certain amount of time for

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1 the ambulance to get to the address. In very good
2 systems, six minutes is considered a very good
3 response for the EMS system.

4 Time continues to pass. It takes a
5 certain amount of time to get to the patient, to
6 apply the pads, and so in very good locations,
7 significant numbers of our current survivors are
8 defibrillated at approximately 12 minutes after their
9 collapse, and what we know is that that is a very
10 prolonged time, and it's not surprising that most
11 studies have survival rates in the vicinity of five
12 percent or less.

13 Now, the notion has been for many years
14 that we want to move victims of cardiac arrest up
15 that curve so that defibrillation can be done at a
16 much earlier point, and you can see that in theory as
17 you move up that curve, you'll have much higher rates
18 of survival.

19 And what I want to do now is share with
20 you some of the data that lets us know that that is,
21 indeed, true, that one can, indeed, move up that
22 curve.

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